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Proposal for Certification Tests and Standards for Closed-Circuit Breathing Apparatus

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
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UNIT OF MEASURE ABBREVIATIONS USED IN THIS REPORT

breaths/min	breaths per minute	mL/min	milliliter(s) per minute
hr	hour(s)	mm H_2O	millimeter(s) of water pressure
kg	kilogram(s)	mm Hg	millimeter(s) of mercury
L	liter(s)	ppm	parts per million
L/min	liter(s) per minute	s	second
lb	pound(s)	°C	degree(s) Celsius
min	minute(s)	%	percent

PROPOSAL FOR CERTIFICATION TESTS AND STANDARDS FOR CLOSED-CIRCUIT BREATHING APPARATUS

By Nicholas Kyriazi[1]

ABSTRACT

Significant portions of the present Federal regulations for certification of closed-circuit breathing apparatus (42 CFR 84) are not quantitative. The human-subject testing portion of the regulations specifies activities rather than metabolic work rates; however, heavy human subjects have higher oxygen consumption, CO_2 production, and ventilation rates than lighter human subjects performing the same activities. This means that apparatus certified using different human subjects have effectively passed different tests. In addition, apparatus performance is monitored only during selected intervals of testing, and always during rest, rather than during the entire performance period. Further, testing is arbitrarily terminated at specific rated durations, leaving unknown the performance during the remaining duration. Duration itself is misleading to users who believe that the apparatus will last a certain time no matter how much they weigh or how hard they work. The actual duration obtained from an apparatus, however, is highly variable, being inversely proportional to the work rate at which it is used.

In this report, recommendations are made to (1) replace the present regulations for certification of closed-circuit breathing apparatus with quantitative tests specifying metabolic work rate rather than activity, (2) continuously monitor relevant physiological stressors, (3) continue testing until exhaustion of the oxygen source, and (4) classify closed-circuit breathing apparatus by quantity of usable oxygen, i.e., capacity, rather than by duration. Physiology-based stressor levels are suggested as well.

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INTRODUCTION

The present regulations in the United States for certification of closed-circuit breathing apparatus (CCBA) (Title 42 of the Code of Federal Regulations, Part 84) were derived from the original U.S. Bureau of Mines' (USBM) Schedule 13, "Procedure for Establishing a List of Permissible Self-Contained Oxygen Breathing Apparatus," of March 5, 1919. The human-subject tests in Schedule 13 are composed of various activities associated with mine rescue, such as walking at 3 miles per hour, carrying a sack of bricks weighing 50 lb over an overcast, and sawing wood. In both Schedule 13 and the present 42 CFR 84, administered by the Respirator Branch of the National Institute for Occupational Safety and Health (NIOSH), Morgantown, WV, these and other activities, performed for specific time periods, are combined to make tests of 3, 5, 10, 15, 30, and 45 min, and 1, 2, 3, and 4 hr. A manufacturer applying for certification must request a specific rated duration for its apparatus so that a time-specific test can be chosen. This is a reasonable way to *qualitatively* evaluate mine rescue apparatus, but it is not *quantitative* and can be misleading to the user.

Specifying activities rather than work rates results in different work rates being imposed by different human subjects, varying with weight and physical condition. Using different human subjects for different apparatus certifications means that different approved breathing apparatus have effectively passed different tests. This is unfair to both the manufacturers and the users.

Quantitative performance testing of CCBA ideally requires specifying the oxygen consumption rate, CO_2 production rate, ventilation rate, and respiratory frequency. This not only provides manufacturers with a complete description of the expected work rate, but also assures users that all approved apparatus have passed the same test. This can be done using a breathing and metabolic simulator (BMS), with control over all of the aforementioned metabolic parameters, or with a human subject, with control over only one parameter at a time, usually oxygen consumption rate.

In addition to specifying work rates instead of activities, continuous monitoring of the physiological stressors—inhaled oxygen and CO_2 concentrations, breathing pressures, and inhaled wet- and dry-bulb temperatures—is recommended. Further, it is recommended that there be no regulation of components of apparatus, such as specifying activation pressures for demand and relief valves, flow rates for regulators, etc. The overall performance of the apparatus, which encompasses the performance of individual components, is the primary concern.

Additional deficiencies of the present regulations are as follows:

(1) 42 CFR 84.94 specifies gas flow requirements for CCBA. Paragraph (c) states that the demand valve for CCBA is required to supply 30 L of oxygen per minute "in the fully open position." The test is performed activating the valve manually (such as with a pencil or finger) to check the flow. In actual use, however, demand valves are activated either by low breathing bag volume or low breathing bag pressure. One approved device delivers 90 L/min when activated manually but requires large negative breathing pressures to elicit even 30 L/min. However, breathing pressures during human-subject testing are not presently regulated. Users of this device in an actual emergency complained that they "couldn't get enough air" [MSHA 1984] and either breathed around the mouthpiece, slowed down, or removed the mouthpiece entirely.

(2) Testing is ended at the rated duration requested by the manufacturer at the time of the submittal. However, the apparatus is not usually fully expended at the exact time of test termination. This leaves its remaining performance unknown. It is reasonable to expect that a user will not necessarily remove an apparatus exactly at, or before, its rated duration, and that some users will use the apparatus at a work rate higher than that at which it was tested, thus experiencing its postrated-duration performance within the time period of its rated duration. Several approved apparatus, if used to the full capacity of their stored breathing gases, will expose the wearer to greater than 10% CO_2 (due to an oxygen supply much greater than the CO_2 absorbent capacity) or lower than 10% oxygen (due to a very large breathing bag, which is difficult to sufficiently purge of nitrogen).

(3) If donned in a certain way, some CCBA may expose the user to hypoxic conditions. If sufficient nitrogen is exhaled into the breathing circuit of a compressed-oxygen apparatus such that the demand valve is not activated after a full inhalation, and if the user's oxygen consumption rate is higher than the constant flow rate, the oxygen concentration may fall to subambient levels before the demand valve can be activated.

(4) Because apparatus are certified for specific durations, users may expect that the apparatus will last that long regardless of who is wearing it or what activity is being performed. However, an apparatus used by a heavy person performing hard work will not last its rated duration and may give the user a false sense of security, which could be dangerous in an emergency.

Following are recommendations for tests, methods, and performance criteria for CCBA.

PROPOSAL FOR CERTIFICATION TESTS AND STANDARDS FOR CCBA

PREFACE

A user of CCBA should be assured that an approved device will be safe throughout its use and that all approved devices have passed the same test. This can be accomplished through quantitative certification tests and continuous monitoring of physiological stressors until the stored-gas supply is expended. In order to fully evaluate an apparatus, there are three major areas of required scrutiny: capacity, performance, and wearability. Three tests are recommended:

(1) A constant work rate test at a work rate representative of the intended use, which will be referred to as the "capacity" test.
(2) A composite test with both high and low work rates, intended to draw into use all of the components of the apparatus such as the demand and relief valves, which will be referred to as the "performance" test.
(3) A human-subject test that includes numerous physical activities and body orientations, intended to evaluate the apparatus' impact on the wearer, which will be referred to as the "wearability" test.

The capacity test will determine the quantity of usable oxygen delivered to the user. The quantity of usable oxygen will be used to classify the apparatus. This test will be at a constant oxygen consumption rate to be agreed upon by the manufacturer and NIOSH as representative of the intended use. The duration attained at that work rate will be noted for the benefit of the consumer, but will always be linked to the work rate at which it was obtained. The manufacturer may choose to have an apparatus tested at several constant work rates to show a range of usable oxygen quantities varying with work rate.

DEFINITIONS

CCBA - A closed-circuit breathing apparatus is self-contained and has both a CO_2-absorbent component and a compliant breath-storage component (breathing bag).

STPD - Standard temperature and pressure, dry. All volumes in this document are specified at these conditions, which are 0 °C, 760 mm Hg, and containing no water vapor. (An example illustrating the importance of specifying conditions is that 1 L measured at body temperature and ambient pressure, saturated, (BTPS) at Johannesburg, Republic of South Africa, where the ambient pressure is 627 mm Hg, becomes 0.83 L BTPS in Norfolk, VA, and 0.67 L measured at STPD).

VO_2 - Volume rate of oxygen consumed in L/min
VCO_2 - Volume rate of CO_2 produced in L/min
V_e - Volume rate of gas exhaled in L/min
RF - Respiratory frequency in breaths/min

CLASSIFICATION OF APPARATUS

CCBA shall be classified by quantity of oxygen usable by the subject rather than by duration, which varies inversely with use rate. The quantity of usable oxygen shall be determined by the capacity test, described in the "Test Descriptions" section, at a constant work rate agreed upon by the manufacturer and NIOSH; the apparatus shall be classified by the quantity of oxygen used by a human subject or a BMS, described in the "BMS Versus Human-Subject Testing" section, with the quantity rounded off to the nearest lower increment of 5 L. If more than one work rate is used, the quantity of usable oxygen at each shall be noted.

REQUIRED COMPONENTS

(1) Remaining service-life indicator (entry apparatus only).
(2) 25% service-life warning device (entry apparatus only).

TEST DESCRIPTIONS

The capacity and performance tests may be performed on either a BMS or a calibrated human subject. The wearability test shall be performed on a human subject. A BMS permits the selection of not only the oxygen consumption rate but also the CO_2 production rate, the ventilation rate, and the respiratory frequency. Use of a human subject does not permit this extent of control. The wide variation between human subjects in the metabolic parameters other than the oxygen consumption rate may present a problem. For example, two human subjects working at the same oxygen consumption rate will probably have different CO_2 production rates, ventilation rates, and respiratory frequencies. At the least, the other parameters should be measured and noted for human-subject testing.

The capacity test and the performance test shall be performed on three apparatus each. The wearability test need be performed on only one apparatus.

All of the tests shall be continuously monitored (as described in the "Testing Procedures" section).

The capacity and performance tests shall be considered concluded either when the stored-gas supply is expended or when a physiological stressor level has exceeded the recommended limit (as described in the "Testing Procedures" section). If a stressor level is exceeded in any test for more than 1 min, the apparatus fails and is rejected.

Capacity Test

The likely oxygen use rate of an apparatus depends on its purpose—mine rescue, escape, fire service, toxic chemical

cleanup, etc. The capacity test work rate should approximate the average oxygen use rate for the apparatus' intended use in order to give the consumer a general idea of its likely duration for that use. A constant work rate, rather than varying work rates, is used in order to more easily discern the characteristics of the apparatus over its entire service life. The apparatus shall be tested at a work rate agreed upon by its manufacturer and NIOSH (light, moderate, heavy, or high) until the breathing gas supply is expended. The quantity of oxygen used at that time (duration × oxygen use rate) shall determine its classification.

Recommended work-rate parameters are shown in table 1.

Table 1.—Work-rate parameters: capacity test
(all volumes at STPD)

Work rate	VO_2, L/min	VCO_2, L/min	V_e, L/min	RF, breaths/min
Light	1.00	0.80	22.0	17.0
Moderate[1]	1.35	1.15	30.0	18.0
Heavy	2.00	1.80	44.0	20.0
High	2.50	2.50	55.0	22.0

[1]The moderate work rate is the average level at which the 50th-percentile miner (87 kg) performs during the 1-hr man test 4 in the present regulations [Kamon et al. 1975].

Performance Test

This test will ensure that, in cases of high or low metabolic work rate, the apparatus will not catastrophically fail in some way. (It must be assumed that any type of apparatus may be used at both high and low work rates.) The high work rates used in the test will likely activate a demand valve, if present, and stress the CO_2-absorbent canister; the low work rate will likely activate a relief valve, if present. Continuous monitoring will enable evaluation of these components in use. It is recognized that the apparatus may sacrifice some efficiency when used at very high or low work rates; therefore, its quantity of usable oxygen is not rated during this test. The test shall consist of repeating the following three-work-rate cycle until the breathing gas supply is expended: 3.0 L/min for 5 min, 2.0 L/min for 15 min, and 0.5 L/min (or less for human subject at rest) for 10 min. This cycle requires 50 L of oxygen. If the apparatus contains significantly less than this, as determined by the capacity test, the alternating times shall be reduced proportionally so that one cycle of work rates is completed. The performance test shall be started by the exhalation of two large breaths into the apparatus before donning it. This will determine the susceptibility of the apparatus to hypoxia.

The work-rate parameters are shown in table 2.

Table 2.—Work-rate parameters: performance test
(all volumes at STPD)

Work rate	VO_2, L/min	VCO_2, L/min	V_e, L/min	RF, breaths/min
Very high	3.00	3.20	65.0	25.0
Heavy	2.00	1.80	44.0	20.0
Low	0.50	0.40	20.0	12.0

Wearability Test

This test will ensure that the apparatus will not be physically harmful to, or hinder, the user significantly in any anticipated activity. At least the following activities shall be performed, in any order, for sufficient duration to ensure compatibility with the human form: stooped walking, crawling, lying on each side and on back, climbing a laddermill and steps, crawling on stomach, bending over to touch toes, turning head from side to side and up and down, and handling anticipated equipment. Continuous monitoring will be employed to assess the orientation sensitivity of the apparatus.

The user shall be able to easily control the functioning of the apparatus through manipulation of readily distinguishable control mechanisms, if applicable.

Quantitative Leak Test

With a pressure of −300 mm H_2O applied to the breathing circuit of the CCBA, the leak rate into the breathing circuit shall not exceed 87 mL/min. (See "Testing Procedures" section for derivation and performance details.)

Gas Permeability

The manufacturer shall provide evidence that the submitted apparatus does not permit dangerous levels of any gases with which it is claimed to be compatible, or likely to be encountered in intended use, to permeate the breathing circuit for the longest duration possible in use, or on repeated uses if reusable. (The present regulations at 42 CFR 84.88 require only that the breathing bag material withstand permeation by gasoline.)

High- and Low-Temperature Tests

The manufacturer shall recommend temperature limits within which the apparatus must be stored and used. The CCBA shall pass all performance tests at these limits. The low and high recommended storage temperatures shall be maintained for 24 hr, after which the apparatus shall pass the capacity and performance tests at the corresponding low or high recommended use temperatures.

Shock and Vibration Test

The CCBA will be subjected to shock and vibration appropriate to its intended use conditions as recommended by acknowledged industry representatives or the appropriate government agency, after which it must pass the capacity, performance, and wearability tests.

For mine escape apparatus stored on machinery, a shock and vibration test as described by Stengel et al. [1982] is recommended. For mine escape apparatus that may be belt-worn, the present Ro-Tap test is appropriate.

Hypoxia Scenario Test

Under certain circumstances, it is possible in some CCBA to create a situation in which oxygen levels fall too low to sustain human life. For example, on a compressed-oxygen CCBA with a demand valve, if enough nitrogen is contained in the breathing circuit to prevent activation of the demand valve at the end of a full inspiration, and the oxygen-use rate is higher than the constant flow, oxygen levels may fall to subambient levels before the demand valve is activated. The potential for this situation to occur will be ascertained during the first minutes of the performance test. Exhaling into the apparatus twice before donning it and the immediately following 3.0 L/min oxygen consumption rate in the performance test together define the hypoxia scenario test.

TESTING PROCEDURES

Continuous Monitoring

The capacity, performance, and wearability tests shall be continuously monitored, whether using a BMS or a human subject. The stressors monitored shall be, at least, average inhaled levels of CO_2 and oxygen, minimum inhaled CO_2 level, end-of-inhalation wet- and dry-bulb temperatures, and peak breathing pressures. These stressors shall be monitored at the mouth/ apparatus interface with instruments that are capable of breath- by-breath response. The temperature probes shall be located in the center of the air stream. The pressure tap shall be perpendicular to the air flow. Each stressor will be discussed separately.

Monitored Stressors and Recommended Limits

Recommended stressor limits are based on physiological research performed at the Noll Laboratory for Human Performance Research at The Pennsylvania State University and funded by the former USBM. The contract final reports describing this research [Kamon et al. 1984a,b; Hodgson 1993] are available for consultation at the NIOSH Pittsburgh Research Laboratory.

CO_2 and Oxygen Concentrations

The peaks of instantaneous gas concentrations (high oxygen, low CO_2) continuously monitored at the mouth during use are not the actual concentrations inhaled by the user since they do not take into account apparatus dead space. Dead space is the apparatus' internal breathing circuit volume containing exhaled air that is directly inhaled, uncleansed of CO_2, during inhalation. The low values of CO_2, for example, reveal only the best performance of the CO_2 scrubber. Average inhaled concentrations of both gases can be calculated electronically by multiplying instantaneous gas concentration values by the simultaneously occurring inhalation flow rates, summing these values over the entire inhalation, and then dividing that volume by the total inspired gas volume [Bernard 1977].

The physiological research conducted at The Pennsylvania State University showed no disabling physical effects in active men breathing 5% CO_2 for long periods of time [Kamon et al. 1984a]. However, in some test subjects, the decision-making process was slightly impaired after breathing 4% CO_2 for 1 hr. We therefore recommend that, during use testing, the average inhaled levels of CO_2 remain below 4% and oxygen levels remain above 16% [Dinman 1978].

Breathing Pressures

During any use test, the peak pressures shall not exceed 200 mm H_20 for exhalation and -300 mm H_2O for inhalation. It was found in physiological research [Hodgson 1993] that 80% of test subjects ($n = 10$) could generate these pressures for approximately 4 min. The population of users who could not generate these pressures would be limited to work rates that kept breathing pressures below these levels. This is considered an acceptable tradeoff for gains in reducing the size and weight of apparatus.

Classification of apparatus as positive-pressure will be at a particular level of work: light, moderate, heavy, or high. During the capacity test chosen by the manufacturer, inhalation pressures must stay above ambient pressure at all times.

It is recommended that the peak pressures generated during the tests be listed in the approval documentation and available to the consumer.

Temperature

It has been found that human thermal sensitivity is related to the wet-bulb temperature. In research at The Pennsylvania State University [Kamon et al. 1984b], researchers showed that wet-bulb temperature of the inspired air is a better descriptor of heat stress to the tissues of the mouth than either dry-bulb temperature, relative humidity, or both of these combined. For the same inhaled dry-bulb air temperature, the thermal load of humid air is higher than that of dry air. The maximum thermal load tolerated by a human being can be specified by an infinite number of combinations of dry-bulb temperatures and relative humidities, or by one wet-bulb temperature. The highest tolerable wet-bulb temperature of inhaled air has been found to be approximately 50° C [Kamon et al. 1984b]; this is recommended to be the limit for all respiratory protective devices.

Until recently, breath-by-breath measurement of wet-bulb temperature was not possible due to the slow response time of humidity-measuring instruments. However, the Pittsburgh Research Laboratory has developed a fast-response, wet-bulb thermocouple with a response time of <1 s [Kyriazi 1988].

It is recommended that the highest inhalation temperature generated during the tests be listed in the approval documentation and available to the consumer.

BMS Versus Human-Subject Testing

A BMS is a machine that simulates both the breathing and metabolic functions of a human being. The former USBM developed four such simulators since the early 1970s [Kyriazi 1986]. Such a machine was desired for the ability to quantify and control input metabolic levels. A human subject on a treadmill can also be used by varying the speed and/or grade until a desired oxygen consumption rate is achieved. However, the CO_2-production rate, ventilation rate, and respiratory frequency will likely vary among human subjects even at the same oxygen consumption rate. This is a major advantage of the BMS over human subjects, in addition to the better repeatability and constancy.

Quantitative Leak Test

Assumptions

(1) CO is the gas most likely to be encountered underground that is dangerous in the lowest concentrations, with a threshold limit value of 35 ppm.

(2) The highest likely ambient concentration of CO is 10%.

(3) The highest expected realistic oxygen consumption rate is 3.0 L/min with a corresponding V_e of 80 L/min and peak inhalation flows of approximately 250 L/min. The in-leakage is examined at these conditions.

(4) The highest negative pressure permitted during the proposed tests is -300 mm H_2O. This is assumed to occur during the inhalation peak flows of 250 L/min.

Reasoning

An 87 mL/min in-leakage of 10% CO during an instantaneous inhalation flow rate of 250 L/min results in an inhaled CO concentration of 35 ppm, occurring at the highest-permitted negative pressure of -300 mm H_2O.

Test Setup

Required components are a rotary vane pump powered through a voltage regulator, a mass flow meter calibrated for air or nitrogen, a pressure transducer, and flexible connecting tubing.

Connect the inlet port of the rotary vane pump to the outlet port of the mass flow meter. Connect the inlet port of the mass flow meter to a "T" connector branching to the pressure transducer and to the mouthpiece of the breathing apparatus to be tested.

Test Procedure

(1) Connect the apparatus to the test setup.

(2) Turn on the voltage regulator controlling the rotary-vane pump. (Note: The flow rate will be high and the pressure will remain near ambient until the breathing bag is evacuated of air. After the bag has collapsed, the pressure will sharply drop.)

(3) Adjust the voltage regulator controlling the pump until the pressure, as read on the pressure transducer, stabilizes at -300 mm H_2O.

(4) Read the flow rate on the mass flow meter once a stable number is obtained. This is the apparatus leak rate. A leak rate of no more than 87 mL/min is permitted. (Note: If the leak rate continues to slowly fall, this may indicate that backflow through a relief valve is diminishing as its check valve seats itself better with continued pressure.)

SUMMARY

In order to determine if a closed-circuit breathing apparatus is safe to wear and to ascertain its capacity and performance characteristics, it is necessary to subject it to a known input until its gas supply is exhausted and to continuously monitor its output throughout this period. Currently, an apparatus is certified by subjecting it to an unknown and random input, monitoring its output only during rest periods and terminating the test before it is expended, when a user could continue to wear it. This practice is inadequate to determine the apparatus' safety, its capacity, or its performance characteristics. The tests and methods proposed here are an attempt to remedy these present shortcomings.

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