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EVALUATION OF PROPOSED HUMAN SUBJECT CERTIFICATION TESTS FOR SELF-CONTAINED BREATHING APPARATUS

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16. Abstract (Limit: 200 words)

In 1977 the U.S. Bureau of Mines proposed a new series of human subject certification tests for self-contained breathing apparatus (SCBA). The Los Alamos National Laboratory was asked to evaluate these tests. Eight SCBAs, one open-circuit and 7 closed-circuit (4 mine rescues and 3 escapes), were worn by test subjects while performing the proposed tests. The functioning of the apparatus during the majority of these tests was monitored continuously. The major conclusions derived during this study are these: (1) The proposed tests are not too physically demanding. (2) As long as human test subjects are used, there should be a minimum test subject weight. (3) The important apparatus variables to be measured are the breathing resistance, temperature, and CO_2 and O_2 concentrations of the inhaled gas. (4) Continuous monitoring should be employed. (5) New pass/fail criteria based on realistic estimates of the physiological requirements of the user, tempered by present and future engineering limitations, are needed. (6) When available, breathing machines should be used for the majority of certification testing. (7) A more realistic ergonomics test than that presently proposed is needed. (8) System gas leak and facepiece leakage tests are also needed.

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FOREWORD

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EVALUATION OF PROPOSED HUMAN SUBJECT CERTIFICATION TESTS FOR SELF-CONTAINED BREATHING APPARATUS*

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ABSTRACT

Current certification testing of self-contained breathing apparatus includes tests with human subjects wearing the apparatus while exercising. During these tests, certain apparatus variables are measured during rest periods. Because of concerns that the present tests may not accurately simulate the stresses to which an apparatus is subjected in the field, the Bureau of Mines proposed new human subject tests. It was also felt that different measurement techniques would supply more reliable data on the apparatus response to these stresses. The Los Alamos National Laboratory was asked by the Bureau to evaluate the proposed tests and monitoring techniques.

The major conclusions derived during this study are these:

(1) The proposed tests are not too physically demanding.
(2) As long as human test subjects are used, a minimum subject weight should be required for certification tests.
(3) Important apparatus variables are the breathing resistance, temperature, and carbon dioxide and oxygen concentrations of the inhaled gas.
(4) Continuous monitoring should be used, rather than monitoring only during rest periods.
(5) New pass/fail criteria based on realistic estimates of the user's physiological requirements, as tempered by present and future engineering limitations, are needed.
(6) When available, breathing machines, rather than human subjects, should be used for most certification testing.
(7) A more realistic ergonomics test than that proposed is needed.
(8) A gas leak test for the system and a facepiece leakage test are also needed.

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I. INTRODUCTION

At present, self-contained breathing apparatus (SCBA), as well as other respiratory protective devices, are tested for certification by the National Institute for Occupational Safety and Health (NIOSH) according to published regulations. Test specifications for breathing apparatus are detailed in Sub Part H of 30 CFR 11 (12). These regulations discuss what the required physical and mechanical characteristics are for devices submitted for testing and also how NIOSH assesses whether the equipment can supply the physiological needs of the user, as determined by actual human testing and by simulated activity using breathing machines.

Bureau of Mines personnel were concerned that some of the human tests were redundant, that subjects were not stressed to realistic levels, and that the monitoring methods were outdated. Work done at Pennsylvania State University to determine the physiological stress imposed on persons wearing breathing apparatus questioned the usefulness of the present tests. Factors studied at Pennsylvania State included short-term high-stress levels compared with more moderate but steady-state physical exercise (4), true metabolic requirements of individual tests (7), and personnel work rates that simulate mining activity (3).

In 1977 the Bureau of Mines proposed a new series of apparatus man tests which would attempt to reduce or eliminate problems and inconsistencies of the existing tests (11). The Los Alamos National Laboratory was asked to evaluate these new tests.

A. Existing NIOSH Certification Tests

The present certification procedures for breathing apparatus include four test series that determine whether the apparatus can supply enough breathing gas and, in the case of closed-circuit apparatus, whether it can remove enough carbon dioxide while the subject is exercising. There are limits on the breathing resistance and temperature of the inspired gas. The four current tests are shown in Table 1. For convenience, these tables describe only tests on apparatus for the following service times: 30 min, 1h, 3h, and 4h. The original tables included additional service times.

Service time (Section 11.85-10, Ref. 12) of open-circuit apparatus is determined by using a breathing machine to drive air from the storage tank into the facepiece and out into the atmosphere. For closed-circuit apparatus (11.85-11, Ref. 12), a subject wears the apparatus during Test 4 in Table 1. The time that the apparatus supplies adequate breathing air during this test becomes the official duration of the apparatus, to the nearest standard duration (11.53, Ref. 12).

Carbon dioxide concentrations (11.85-12a, Ref. 12) are determined for an open-circuit apparatus while it is being cycled by a breathing machine, with 5% carbon dioxide, by volume, added into the facepiece with each machine "exhalation." For closed-circuit apparatus, only the parts that contribute to the dead-air space are mounted on a dummy head, and these cycled with the breathing machine as above (Section 11.85-12b, Ref. 12).

TABLE 1 - Current SCBA man tests from 30 CFR 11 H

For brevity, only testing schedules for apparatus of 30 min or longer duration are listed. Official tables also include values for 3, 5, 10, 15, and 45 min.

Test 1

Task	Apparatus Duration 30 min	1 h
1. Sample	2	2
2. Walk 3 mph	8	18
3. Sample	2	2
4. Walk 3 mph	8	18
5. Sample	2	2
6. Walk 3 mph	6	16
7. Sample	2	2

For 2-, 3-, and 4-h-duration devices, repeat 1-h exercise.

Test 2

(Apparatus rated for 2 or more h duration is tested for 2-h maximum)

Task	Apparatus Duration 30 min	1 h	2 h
1. Sample	2	2	2
2. Walk 3 mph	3	6	10
3. Carry 50 lb over overcast	2 times in 4 min	4 times in 8 min	5 times in 10 min
4. Walk 3 mph	3	3	5
5. Climb[a]	1	1	1
6. Walk 3 mph	-	3	5
7. Climb[a]	-	1	1
8. Sample	2	2	2
9. Walk 3 mph	2	5	11
10. Climb[a]	1	1	1
11. Carry 50 lb over overcast	3 times in 6 min	5 times in 10 min	5 times in 10 min
12. Sample	-	2	2
13. Walk 3 mph	3	3	Repeat above for 1 h
14. Climb[a]	1	1	
15. Walk 3 mph	-	3	
16. Climb[a]	-	1	
17. Carry 45 lb at 3 mph	-	2	
18. Walk 3 mph	-	4	
19. Sample	2	2	

TABLE 1 (cont)

Test 3

Task		Apparatus Duration 30 min	1 h
1.	Sample	2	2
2.	Walk 3 mph	2	3
3.	Run 6 mph	1	1
4.	Pull 45-lb weight to 5 ft	30 times in 2 min	60 times in 6 min
5.	Lie on side	3	5
6.	Lie on back	2	3
7.	Crawl	2	2
8.	Sample	2	2
9.	Run 6 mph	1	1
10.	Walk 3 mph	2	10
11.	Pull 45-lb weight to 5 ft	60 times in 6 min	60 times in 6 min
12.	Sample	-	2
13.	Walk 3 mph	3	10
14.	Lie on side	-	4
15.	Lie on back	-	1
16.	Sample	2	2

For 2-h apparatus, run Test 3 for 1 h and Test 1 for 1 h. Apparatus rated for more than 2-h duration is tested for 2-h maximum.

Test 4

		30 min	1 h
1.	Sample	2	2
2.	Walk 3 mph	2	2
3.	Climb[a]	1	1
4.	Walk 3 mph	2	2
5.	Pull 45-lb weight to 5 ft	60 times in 5 min	60 times in 5 min
6.	Walk 3 mph	1	3
7.	Carry 50 lb over overcast	1 time in 1 min	4 times in 8 min
8.	Sample	2	2
9.	Walk 3 mph	3	4
10.	Run 6 mph	1	1
11.	Carry 50 lb over overcast	2 times in 3 min	6 times in 9 min
12.	Pull 45-lb weight to 5 ft	60 times in 5 min	36 times in 3 min
13.	Sample	2	2
14.	Walk 3 mph	-	6
15.	Pull 45-lb weight to 5 ft	-	60 times in 5 min
16.	Carry 45 lb at 3 mph	-	3
17.	Sample	-	2

For 3-h apparatus, perform Test 1 for 1 h, Test 4 for 1 h, and Test 1 for 1 h. For 4-h apparatus, perform Test 1 for 1 h, Test 4 for 1 h, and Test 1 for 2 h.

[a]Vertical treadmill inclined 15° from vertical at 1 ft/s, or an equivalent exercise.

Gas concentrations are continuously monitored. During "inhalation," CO_2 concentrations shall not exceed an average of 2.5% for a 30-min apparatus, 2% for a 1-h apparatus, 1.5% for 2 h, and 1% for greater than 2 h. These measurements evaluate only the effect of facepiece dead-air space on the CO_2 concentrations in the inhaled air.

Carbon dioxide is also measured during human Tests 1-4 (Section 11.85-12d, Ref. 12). Sampling is downstream from the scrubber but is done only during the designated rest periods for each test, and CO_2 concentrations shall not exceed 0.5% except in escape apparatus equipped with a mouthpiece, where 1.5% is permitted (13). The subject's condition rapidly returns to normal when exercise stops. Consequently, the time delay between the peak exercise period and the gas sampling time creates some questions as to exactly what is being measured.

Breathing resistance is measured both on a test bench and during the human tests (Sections 11.85-5,-6, and-14, Ref. 12) in Tests 1-4. However, this resistance is also measured during rest and therefore it will fail to record the maxima during the actual maximum stress periods.

The only references to measurement of oxygen content are those taken during Tests 5 and 6. (These tests are not included in Table 1.) In Test 5 (Section 11.85-16, Ref. 12) the subject wears the apparatus while resting. He is allowed to control the breathing gas supply to maximize duration. Oxygen content is measured at 15-min intervals and should not fall below 19.5%.

Special testing for liquid oxygen equipment is described in Test 6 (Section 11.85-17, Ref. 12). Two tests are run, one with the apparatus filled and one with the apparatus one-fourth full. In each test, subjects spend one-fourth of the time in each of four positions: prone, on each side, supine. The oxygen content of the inhaled gas is measured continuously, and should not fall below 19.5%. Note that the present Test 3 includes crawling and lying on the side and back, for a total time of 15 min in a 1-h test, so Test 6 may be unnecessary.

Inhalation temperatures are measured during rest in all human tests (Section 11.85-18, Ref. 12) and they should not exceed the values shown in Table 2. The typical humidity of an open-circuit apparatus is less than 50%, whereas in closed-circuit apparatus humidity is greater than 50%. Maximum permitted values are after correction for deviation from 24°C (75°F). Again, one would expect that these measured values are expected to be lower than the actual numbers experienced by the test subjects during high activity levels.

B. Proposed Certification Tests

The tests proposed by the Bureau of Mines are outlined in Table 3. Test A was substituted for Test 1 to familiarize the subject with the apparatus. After consultation with Bureau personnel, we performed Test A for a maximum of 1 h, regardless of the ultimate duration of the apparatus.

Tests 2 and 3 from 30 CFR 11 include several activities to determine the wearer's ability to perform complex tasks without hindrance by the apparatus. All of these ergonomic-type tests have been combined into the

TABLE 2 - Currently permissible maximum inhalation temperatures for SCBA tests

	Relative humidity			
	<50%		>50%	
Service Time	°F	°C	°F	°C
0.5 h	125	52	110	43
2 h or less	115	46	105	41
3 h	110	43	100	38
4 h	105	41	95	35

Temperatures to be corrected to 75°F (24°C).

TABLE 3 - Proposed human subject tests

Test A to replace Test 1 (to familiarize wearer with equipment)
Maximum test: 1 h

Task	Apparatus Duration 30 min	1 h
1. Walk 3 mph, level	15	15
2. Sit	5	5
3. Walk 3 mph, 5% grade	10	15
4. Sit	-	5
5. Walk 3 mph, level	-	15
6. Sit	-	5

Test B to replace Tests 2 and 3 (tests ability to perform complex tasks)
Maximum test: 1 h

	Apparatus Duration 30 min	1 hr	
1. Climb vertical treadmill 33 ft/min	3	3	(Horizontal treadmill equivalent: 3.5 mph at 10% grade).
2. Pull 44 lb, 5 ft	5	5	
3. Crawl 0.5 mph	3	5	
4. Run 4.4 mph, level	3	3	
5. Carry 44 lb, 3 mph	5	5	
6. Stooped walking, 2.5 mph	5	5	
7. Walk 3 mph, level	6	5	
8. Sit	-	5	
9. Crawl 1 mph	-	3	
10. Lie supine, side, prone	-	3	
11. Walk 3 mph, level	-	15	
12. Sit	-	3	

Test C to replace Test 4 (duration for mine rescue)

	30 min	1 h	3 h	4 h
1. Walk 3 mph, level	5	17	Run Test A 30 min	Run Test A 60 min
2. Run 5 mph, level	5	3	Run Test A 60 min	Run Test C 60 min
3. Walk 3.5 mph, level	5	10	Run Test C 60 min	Run Test C 60 min
4. Walk 4 mph, 5% grade	10	5	Run Test A 30 min	Run Test A 60 min
5. Sit	5	5		
6. Walk 3.5 mph, 5% grade	-	10		
7. Walk 4 mph, 5% grade	-	5		
8. Sit	-	5		

Test D - (for escape only apparatus)

Task[a]	Apparatus Duration (60 min)
1. Walk	2
2. Run	5
3. Walk	3
4. Run	3
5. Walk	3
6. Run	2
7. Walk	4
B. Run	2
9. Walk	5
10. Run	1
11. Walk	10
12. Run	2
13. Walk	4
14. Run	1
15. Walk	10
16. Run	3

[a]Walk: 3.5 mph, level
Run: 5 mph, level

single Test B. Because the overcast and vertical treadmill (ladder mill) usually are unavailable to manufacturers of breathing apparatus, all tasks in Test B were accomplished with an ordinary treadmill, weights, and pulleys, thus eliminating the need for special test apparatus. As with Test A, Test B was limited to a maximum of 1 h.

Because Tests 2 and 4 are about the same difficulty metabolically, and because Test 4 is used in 30 CFR 11 to determine the duration of the apparatus, it was believed that Test 2 added nothing. Test C is proposed to determine the duration of the mine rescue apparatus, replacing both old Tests 2 and 4. It involves walking, running, and sitting, all in a limited space, which would permit continuous monitoring. This test is continued for at least the design duration or until it must be stopped because of failure of the apparatus.

The final new test, Test D, is proposed to determine if an apparatus used only for escape will survive and function during the high-stress activities of a life-threatening emergency. We believe this test should be used to specify the duration of the apparatus also.

To evaluate the proposed tests A-D, eight SCBA were worn by human test subjects while they performed Tests A, B, and C. The escape-type apparatus were also used in Test D. During the tests, the functioning of the apparatus was monitored continuously except during Test B. The following sections describe the apparatus tested, the instrumentation used, and the important test results.

II. EXPERIMENTAL PROCEDURES

A. Breathing Apparatus Tested

Eight different breathing apparatus were used in this project. Of these, all but one were approved by NIOSH.

1. Open Circuit Scott Pressur-Pak IIA; TC-13F-40. This 30-min, pressure-demand (positive pressure in the facepiece during normal inhalation) unit uses compressed air and is one of the most popular SCBA for firefighting and industrial use. Thirty-minute apparatus, whether open- or closed-circuit, are not to be approved for use during underground mine rescue and recovery operations except as auxiliary equipment.

2. Closed Circuit. All of the remaining units are closed-circuit or recirculating respirators, in which oxygen is supplied from a source, and exhaled carbon dioxide is removed by a scrubber. Most of these units supply a continuous flow of oxygen at about 1-1/2 L/min or greater. Additional oxygen is normally added either when the breathing bag is completely collapsed or when the pressure within the breathing system is lowered beyond a certain point.

a. Mine Rescue. All of the mine rescue units have conventional full-face masks. Nose cups are used to reduce fogging owing to the high humidities within the recirculating system and to reduce the mask dead space, which tends to dilute incoming oxygen with CO_2 from previous exhalations.

Rexnord (Biomarine) Bio-Pak 60P;TC-13F-85. This 1-h., compressed-oxygen unit supplies continuous positive pressure to the facepiece through a spring-loaded breathing bag. A continuous flow of 2 L/min is supplied. If the continuous flow is inadequate for the wearer's requirements, the breathing bag will collapse and open a valve supplying additional oxygen. The 1-h duration is considered insufficient for mine rescue purposes, but it is useful for above-ground rescue and firefighting. A sealed chamber contains a salt that acts as a phase-change cooler.

Aerorlox; TC-13F-32. This 3-h device uses liquid oxygen as the breathing gas supply. Although it is not built to maintain positive pressure in the facepiece, the high generation rate of gaseous oxygen tends to minimize the negative pressure in the facepiece. This cryogen cools the breathing gases, which tend to heat up in most rebreathers. The device must be filled immediately before use, however, because the liquid oxygen continuously boils away.

Draeger BG-174A; TC-13F-57. This 4-h device is the most popular for mine rescue purposes. Compressed oxygen supplies a continuous flow of 1-1/2 L/min with additional oxygen on demand. When this apparatus is started, an oxygen purge fills the breathing bag to drive nitrogen and contaminants out of the system.

Mine Safety Appliances (MSA) prototype. This 4-h compressed-oxygen device was developed as part of a research project sponsored by the Bureau of Mines, and it carries no NIOSH approval. Special features include a spring-loaded breathing bag, which maintains a positive pressure within the facepiece during normal breathing. This unit lacks a continuous oxygen flow, only supplying it upon demand. A removable water-cooling pack can be prefrozen and inserted into the unit to cool the inhaled gas.

b. Escape. The following units were all manufacturered as 1-h devices for mine escape purposes. They were designed to be lightweight and small enough to be carried by a miner. All use a mouthpiece and breathing bags that are exposed in use (permissible in escape gear), and they have no warning device for the end of the 1-h service life.

Draeger Oxy SR-60B; TC-13F-87. This unit's chemical oxygen system uses potassium superoxide, which reacts with CO_2 and moisture in exhaled breath, releasing oxygen. A single breathing hose connects the mouthpiece to the breathing bag, but a separate path is provided into and out of the scrubber. Recharging the unit requires returning it to the factory.

CSE AU-9A1; TC-13F-101. This compressed-oxygen device operates as a pendulum: a single breathing tube connects the mouthpiece through the scrubber to the breathing bag. Exhaled air passes through the scrubber twice, once when exhaled, and again when inhaled. All other units use a different path into and out of the scrubber. The compressed-oxygen bottle is nonrefillable.

Ocenco EBA 6.5; TC-13F-104. The Ocenco breathing apparatus, also using compressed oxygen, has two valves in the mouthpiece and two separate breathing hoses. It functions the same as the mine rescue apparatus tested, with a refillable, light-weight, fiberglass-wrapped oxygen bottle and replaceable scrubber. Because of high breathing resistance caused by the demand valve and leaks around the mouthpiece-to-hose connection, evaluation tests were not completed with the EBA 6.5. See Sections III.B.3 and III.C.2 in this document. (Recent information from Ocenco indicates that the leakage problem has been corrected(9)).

B. Measurements Taken

The most important difference in monitoring the apparatus variables in these tests and in the current certification tests is that we monitored continuously rather than sampling only during rest periods as is the current procedure. Continuous monitoring more accurately describes the functioning of the apparatus than the present procedure does, because pulmonary ventilation, oxygen uptake, and CO_2 production decreases significantly when exercise stops (4). Thus, more extreme values of the measured variables should be recorded with continuous monitoring.

The variables normally monitored were temperatures of the gas entering the mask or mouthpiece, exiting the sorbent canister, and of the surface of the sorbent canister; the gas pressure in the facepiece and in the compressed-gas cylinder; the oxygen and CO_2 concentrations in the mask or mouthpiece and in the inhalation tube or breathing bag; and the amount of gas vented from the breathing bag. It was impossible to monitor all variables with all apparatus, and the exceptions are noted.

The only physiological variables measured were the subject's weight, determined before and after a test, and his heart rate during the test. Heart rate was recorded at the end of every task or 5-min period. The heart rate monitor was set to alarm if the rate exceeded 85% of the subject's maximum, as previously determined by a maximal stress test (see Section II-C).

1. Temperatures. All temperatures were measured with 0.005-in. (0.013-cm) Chromel/Alumel thermocouples using a 0°C cold junction reference. The outputs were recorded on a 10-in. wide, three-pen, strip-chart recorder (Linear Instruments Co. Model 595). Calibrations, which could be accomplished at any time before or during a run, utilized a three-dial potentiometer (Rubicon Model 2780).

a. Inhalation. Inhalation temperatures were monitored in the inhalation tube where it attaches to the mask or mouthpiece. The normal temperature range recorded was 21-49°C (70-120°F) with resolution of 0.25°C (0.5°F).

Many of the temperatures and other measured variables varied greatly in short-term peak values. In these cases, the average values were estimated by looking at the chart recordings. Depending on the apparatus design, the inhalation and exhalation temperatures often differed significantly. When two breathing hoses were used, one for inhalation and one for exhalation, and the breathing valves were located between the thermocouple and the subject's mouth, temperature swings were minimal at 0.25-0.5°C. When the thermocouple was between the valves and the mouth, swings up to 3°C were measured. When only one breathing hose was used for both inhalation and exhalation, the temperature changed more than 10°C at times.

These large swings resulted from the differences in temperature between inhaled gas and exhaled breath. Because of the thermocouple time constant, the temperatures of the inhaled gas could not be determined accurately. This constant is defined as the time required for the thermocouple to reach 63% of the temperature of a fluid into which it is suddenly immersed; the estimated time was about 1 s for these thermocouples. During strenuous work, while test subjects are breathing at 30 cycles/min, once every 2 s, the actual temperature and that recorded may differ greatly. This problem is discussed in Section III. A.

b. Sorbent Gas and Canister Surface. The temperatures of the gas exiting the sorbent canister and on the outside surface of the canister were measured where possible. The recorders were usually calibrated to read from 21-77°C (70-170°F) for the sorbent gas temperatures and 21-132°C (70-270°F) for the canister surface temperatures.

2. Pressures.

a. Breathing Resistance. Breathing resistances were monitored by probes inserted either through the facepiece or directly into the mouthpiece or breathing tube where it attached to the mouthpiece. Pressures were measured with a Validyne Model DP-45 pressure transducer and a Model CD-15 carrier demodulator. The output was displayed on a two-pen, 10-in. strip-chart recorder (Linear Instrument Co. Model 485). The transducer was calibrated against an inclined manometer with the recorder set normally to read ±5 in. H_2O (±12.7 cm H_2O). When breathing resistances varied outside this range, either the recorder zero was offset to allow a different pressure range to be monitored but still retain a total span of 10 in., or the recorder span was changed to read ±10 in., 20-in. total.

b. Cylinder Pressure. Gas cylinder pressures were monitored in most tests with devices that used gas cylinders with a Celesco Model PLC 5000-psi strain gage pressure transducer and a Model BCR-50A transducer indicator. The transducer was substituted for the visual pressure indicator. The output, set to read 0-5000 psi, was recorded by the same two-pen recorder as the breathing resistance. Calibration was against a 5000-psi Heise gage. The cylinder of the CSE unit required emptying before the transducer could be connected. As these bottles are not normally refilled, we minimized the refilling by not installing the transducer for all tests, however, they were installed for all D tests.

3. Gas Composition. The oxygen and CO_2 concentrations of the inhalation gas were measured with a mass spectrometer (Perkin-Elmer Model 1100 medical gas analyzer). The CO_2 and oxygen outputs of the analyzer were recorded simultaneously on a strip-chart recorder (Linear Instrument Co., Model 485). Full scale for CO_2 was 0-10% and for oxygen, 0-100%.

Calibration used standard gases: 5.8% CO_2; >99.5% oxygen; and >99.5% nitrogen.

Concentrations were usually sampled at two locations: (1) in the mask, mouthpiece, or mouthpiece hose connection; and (2) wherever there was the least amount of exhaled CO_2. The latter was usually in the breathing bag or between the bag and the inhalation valve. However, owing to their configurations, certain apparatus were sampled elsewhere. In the Draeger BG-174A, the sample point was approximately halfway between the mask and breathing bag, on the mask side of the saliva trap. Sampling in the MSA apparatus was at the far end of the inhalation line, just inside the breathing valves located at the connection to the bag. Location (2) was not measured with the open-circuit Scott because we assumed that all exhaled gas is vented.

The concentrations of oxygen and CO_2 were recorded simultaneously, but only from one location at a time. Because we wanted to know the concentration of oxygen and CO_2 in the inhalation gas, we emphasized analyzing the gas sampled where it contained the minimum exhaled CO_2, at location 2. At the other location, the presence of exhaled gas made data interpretation much more difficult. The CSE apparatus was a pendulum device, in which exhaled breath passes through the sorbent twice, once when it is exhaled before it enters the breathing bag and again when it is inhaled when it leaves the breathing bag. As this second pass should remove even more CO_2 from the inhalation gas, it was felt the minimum concentration in the breathing line during inhalation represented the CO_2 concentration in the inhaled gas better than the concentration in the breathing bag. In actuality, by the end of certain tests, the CO_2 concentration was higher in the breathing line than in the bag. This may be due to desorption of previously sorbed CO_2 when the sorbent material is exhausted, or it may simply be due to sorbent exhaustion.

4. Vented Gas. The amount of gas vented from the breathing bag was measured with a Fleisch pneumotachograph (Instrumentation Associates, Inc., Model 7319, 0-60 L/min). The pressure drop across the Fleisch was measured with a differential pressure transducer (Validyne Model DP-45), using a Model CD-15 carrier demodulator; the pressure was recorded on a Soltec Model 252 integrating strip-chart recorder. This allowed both the instantaneous and total amount of vented gas to be determined. Calibration was performed with a dry gas meter (American Meter Co. Model DTM-325).

5. Subject Variables. Every subject wore a heart rate monitor (Respironics Exersentry) during each test. Heart rates were noted every 5 min or when a task was complete. The monitor was set to alarm if the subject's heart rate exceeded 85 of his maximum, as previously determined during a maximal stress test examination. If the heart rate exceeded this value for more than about 30 s, the test was terminated (see Section II. C). This time was allowed because the monitor would sometimes indicate a heart rate >85% for only a short period and then return to a rate <85%.

The subjects were weighed before and after each test to determine the weight loss incurred during the tests. This weight loss is an indication of the severity of the total test.

C. Test Protocol

Because we wanted the tests to be physically demanding but we did not want to be required to have medical personnel in attendance, the test protocol (Appendix A) limited the selection of subjects to those with minimal risk. The protocol was approved by the Los Alamos National Laboratory Human Use Committee. Major features of the protocol are

- the subjects range in age from 18 to 35 years;
- each was subjected to a maximal exercise stress test (Bruce protocol) given by a licensed cardiologist who could then approve the subject's participation (the subject's maximum heart rate was determined during this testing);
- all subjects were required to complete at least 12 min of the Bruce test corresponding to approximately 12 METS. One MET is the resting metabolic rate, assumed to be 3.5 mL/kg-min oxygen consumption;
- during a test with an SCBA, if the subject's heart rate exceeded 85% of his maximum, the test was to be terminated. This restriction in testing eliminated a requirement that medical personnel be in attendance during testing;
- the minimum subject weight was 160 lbs (73 kg);
- the maximum permissible apparatus weight (see Appendix A, Form 1, Sections 1 and 3b) for an individual subject was determined from the formula

Allowed Apparatus Weight (lbs) = 1.25 (Subject's Weight) - 185.
Thus, a 160-lb individual could test a 15-lb apparatus, but it would require a 180-lb person to test a 40-lb unit.

D. Test Subjects

All test subjects were paid volunteers who met the requirements stated in the Test Protocol. Details concerning each of them are given in Table 4. For the testing of any one apparatus to be considered complete, three different subjects each had to complete one test series with that apparatus, i.e., tests A, B, and either C or D, depending on which type of apparatus was tested. Any test that was terminated early because the apparatus failed to meet the needs of the subject was considered a completed test. These failures were caused by exhaustion of the breathing gas, excessive inhalation temperature (47°C), excess CO_2 concentration (3.4%), or low oxygen concentration (18%). No test subject was required to complete a test series on every apparatus. In fact, only a single subject, No. 10, accomplished this. Although most subjects appeared to do their best, subjects 7, 8, 9, and 10 appeared to be especially highly motivated. Only subject No. 9 had previous mine experience.

TABLE 4 - Results of Bruce maximal stress test

Subject	Age in Years	Weight in Pounds (kg)	Minutes of Test Completed = Approximate METS	Maximum heart rate		
				Predicted BPM	Attained BPM	% of Maximum
1	26	160 (73)	14-1/4	199	200	100
2	27	169 (77)	12-1/2	198	200	100
3	23	173 (79)	13	200	200	100
4	27	175 (80)	16	198	188	95
5	27	190 (86)	15-1/2	198	200	101
6	33	195 (89)	12	190	188	99
7	20	245 (111)	14	200	167	84
8	24	208 (95)	15	201	177	88
9	25	195 (89)	15	200	177	89
10	18	185 (84)	14-1/4	200	177	89

[a]Beats per minute.

III. RESULTS AND DISCUSSION

Table 5 lists all tests that were conducted. Any test that was not continued for the specified duration of the apparatus was considered a completed test. In Table 5, the times and reasons that these completed tests were stopped are noted. Other tests were stopped for a number of different reasons. Although these were not considered completed tests, the reasons but not times for stopping them are also noted.

Our limitation of 85% of heart rate maximum led to many of these latter terminations. Although the data are inconclusive, it appears this problem could have been minimized by selecting test subjects who could complete at least 14 min of the maximal exercise stress test (14 METS).

Note that the purpose of these tests was not to evaluate the apparatus but the tests themselves. That is, apparatus, all currently certified except the MSA prototype, were used only to determine how they would respond to the proposed certification tests. Because these tests are different from the current tests and because we used continuous monitoring, the current pass/fail criteria do not apply. Performing more rigorous tests and monitoring the apparatus continuously will probably reveal measured variables exceeding present NIOSH specifications.

Strip-chart recordings were obtained for most of the variables, producing a large amount of data, most of which are superfluous for evaluating these proposed tests. The important data from only the completed test series, usually the maximum and the times these occurred, are listed in Tables 6 - 10. Data from Test A (familiarization) are omitted. All variables were not measured during all Test B (ergonomics) activities, so data from this test are not included either. The following data are listed in the tables:

- temperature of the inhaled gas (Table 6);
- breathing resistance: maximum and minimum pressures in the mask or breathing tube (Table 7);
- CO_2 concentrations in the mask or mouthpiece (Table 8);
- maximum rate gas vented from the apparatus and the total amount vented during the test (Table 9); and
- physiological variables: weight loss, and heart and respiratory rate (Table 10).

Other factors recorded but omitted from the tables were temperatures of the gas exiting the sorbent canister and of the outside surface of the sorbent canister, gas cylinder pressure, and oxygen concentrations.

A. Inhalation Temperature

Table 6 lists the maximum inhalation temperatures recorded during Test C for the open-circuit and mine rescue or during Test D for escape devices, the times when these temperatures occurred, the ambient room temperature during the test, and the applicable present certification temperatures.

Heat problems have long been noted with closed-circuit apparatus because of the exothermic reaction of the CO_2 scrubber. Open-circuit apparatus like the Scott contain no scrubber and cooling is provided by

TABLE 5 - Evaluation tests conducted

Subj No.	Number of Tests A	B	C	Duration of Completed Test if Less Than Rated Time[a]	Reason for Stopping Test
					Open-Circuit
					Scott Pressure-Pak II
3[b]	1	1	2	B--22 min	B--exhaustion of gas; C--excessive heart rate
4	1	1	1		B and C--excessive heart rate
5	2	-	-		A--excessive heart rate
6[b]	2	2	1	C--20 min	A--incorrect recorded temperature; B--excessive heart rate; C--exhaustion of gas supply
7	1	2	-		B--excessive heart rate
10[b]	1	1	1	B--29 min	B--exhaustion of gas supply
					Closed-Circuit
					Rexnord (Biomarine) BioPak 60P
2	2	-	2		A--poor facepiece fit; C--excessive heart rate in both tests
3[b]	1	1	2		C--poor facepiece fit
6	-	-	1		
7[b]	1	2	1	C--52 min	B--instrumentation malfunction C--exhaustion of gas supply
10[b]	1	1	2		C--incorrect recorded temperature
					Aerorlox
8[b]	1	1	1		
9[b]	1	1	1		
10[b]	1	1	1		
					Draeger BG 174A
8[b]	1	1	2		C--gas compositions incorrect
9[b]	1	1	1	C--111 min	C--high inhalation temperature-47°C
10[b]	1	1	1	C--170 min	C--high inhalation temperature-47°C
					MSA Prototype
8[b]	1	1	1		
9[c]	1	2	1		B and C--excessive heart rate
10[b]	1	1	1		

TABLE 5 (Cont)

Escape Devices

					Draeger Oxy SR60B	
1[b]	1	1	1	1	D--56 min	D--gas supply exhausted
2	1	-	-	-		
8[b]	1	1	1	1	C--52 min D--56 min	C and D--gas supply exhausted
10[b]	1	1	1	1	D--48 min	D--gas supply exhausted
					CSE AU-9A1	
7[b]	2	1	1	1	C--46 min D--24 min	A--O_2 deficient at 7 min C,D--high CO_2-3.4 and 3.6%
9[b]	1	1	1	1	C--34 min D--42 min	C,D--high CO_2-2.4[d] and 4.1%
10[b]	1	1	1	2	C--24 min D--48,57 min	C--high CO_2-2.6%[d] D--high CO_2-3.6 and 4.5%
					Ocenco EBA 6.5	
9	1	-	1	1	D--59 min	D--no temperature record D--high inhalation temperature-49°C
10	1	-	1	2	C--49 min D--12 min	C--high inhalation temperature-48°C D--O_2 deficient

[a]No more than one test was stopped for any subject/test combination.
[b]Completed test series.
[c]Because sufficient sorbent canisters were not available, a Test C could not be completed.
[d]Test stopped prematurely. Test C not required for escape apparatus.

TABLE 6 - Maximum inhalation temperature

Subject	Ambient Temperature (°C)	Current NIOSH Temperature Limits[a] (°C)	Max Recorded Temperature[b] (°C)	Time Maximum Occurred (min)
		Open-Circuit - Test C		
		Scott		
3	--	52	28	0
6	27	55	27	0
10	22	50	22	0
		Mine Rescue - Test C		
		BioPak 60P		
3	25	42	43	56
7	26	43	43	53
10	25	42	41	56
		Aerorlox		
8	24	38	32	145
9	24	38	23	150
10	24	38	24	150
		Draeger BG-174A		
8	25	36	52	175
9	23	34	47	111[c]
10	24	35	47	170[d]
		MSA Prototype		
8	24	35	39	175
9	23	34	35	112
10	24	35	41	175
		Escape - Test D		
		Draeger Oxy SR60B		
1	27	44	53/43	49
8	26	43	56/40	48
10	24	41	49/42	45
		CSE AU-9A1		
7	29	46	49/39	12
9	29	46	51/41	24
10	26	43	48/40	52
		Ocenco		
9	26	43	49	120
10	23	40	46	8

[a]After correction for deviation from 24°C (75°F) ambient temperature.
[b]A single value denotes a 3°C or smaller difference between inhalation and exhalation. Two values are the recorded inhalation/exhalation temperatures at the time of maximum inhalation temperature.
[c]Test stopped by experimenter because of self-imposed temperature limit.
[d]Test stopped by subject because of excessive temperature.

TABLE 7 - Breathing resistance

Subject	Maximum Exhalation Pressure (in. of H_2O)	Minimum Inhalation Pressure (in. of H_2O)	Pressure Difference (in. of H_2O)	Time of Maximum Resistance (min)
		Open Circuit - Test C		
		Scott[a]		
3	3.7	-0.7	4.4	25
6	5.0	0.2	4.8	21
10	3.5	-0.6	4.1	20
		Mine Rescue - Test C		
		BioPak 60P[a]		
3	3.5	-0.8	4.3	55
7	3.8	-0.6	4.4	52
10	3.6	-0.4	4.0	55
		Aerorlox		
8	3.7	-2.0	5.7	145
9	3.6	-1.3	4.9	145
10	3.3	-1.0	4.3	125
		Draeger BG-174A		
8	5.0	-2.5	7.5	174
9	1.7	-1.8	3.5	111
10	3.9	-3.3	7.2	170
		MSA Prototype[a]		
8	3.4	-1.6	5.0	174[b]
9	2.7	0.0	2.7	95
10	3.1	-0.9	4.0	175
		Escape - Test D		
		Draeger Oxy SR608		
1	3.1	-1.2	4.3	13
8	3.8	-2.1	5.9	48
10	2.7	-1.1	3.8	13
		CSE AU-9A1		
7	7.4	-8.6	16.0	24
9	6.0	-6.4	12.0	42
10	4.4	-4.2	8.6	57
		Ocenco		
9	2.8	-3.5	6.2	42
10	3.0	-1.5	4.5	7

[a]Positive-pressure units.
[b]Minimum inhalation pressure, -2.3 at 215 min.

TABLE 8 - CO_2 concentrations

Subject	Maximum Concentration (%)	Maximum Concentration Time (min)	Maximum/Minimum Concentration (%)	Maximum/Minimum Concentration Time (min)
	Inhalation Tube		Facemask	
	Open Circuit - Test C			
	Scott			
3	Not measured: < 0.05%		3.7/0.5	30
6	Not measured: < 0.05%		5.7/0.6	15
10	Not measured: < 0.05%		2.7/0.3	30
	Mine Rescue - Test C			
	BioPak 60P			
3	0.7	55	5.6/1.3	55
7	0.7	52	6.3/0.7	35
10	1.2	55	7.5/0.7	45
	Aerorlox			
8	0.5	145	7.1/0.7	180
9	0.2	180	6.4/0.8	50
10	0.5	145	7.7/0.8	145
	Draeger BG-174A			
8	0.4	235	6.4/1.0	20
9	0.2	25	6.3/0.9	20
10	0.3	26	6.3/0.7	20
	MSA Prototype			
8	0.3	175	6.9/2.2	175
9	None for 115-min duration of test		7.5/0.7	110
10	0.3	175	7.2/1.5	155
	Breathing Bag		Mouthpiece	
	Escape - Test D			
	Draeger Oxy SR60B			
1	Not measured		7.1/0.9	8
8	1.3/1.0	43	8.5/1.2	42
10	1.4/1.1	2	8.5/1.2	42
	CSE AU-9A1			
7	5.5/3.5	24	9.4/3.6	24
9	5.8/3.8	42	9.5/4.1	42
10	5.0/3.5	52	8.6/4.5	57
	Ocenco			
9	2.0	59	7.5/0.9	42
10	0.1	8	6.4/0.4	10

TABLE 9 - Vented gas

Subject	Duration of Test (min)	Maximum Vent Rate L/min	Time (min)	Total Vented During Test (L)
		Mine Rescue - Test C		
		Draeger BG-174A		
8	240	1.3	200	23
9	111	1.1	39	12.3
10	170	1.0	160	13.5
		MSA Prototype		
8	240	0		0
9	115	0.5	95	9.2
10	240	0.7	144	5.1
		Escape - Test D		
		Draeger Oxy SR-60B		
1	56[a]	3.5	13	50
8	56[a]	3.2	10	60
10	48[a]	10.1	26	64
		Ocenco		
9	59	0.16	46	0.5
10	12[b]	0		0

[a]Breathing gas supply exhausted.
[b]Oxygen deficiency.

TABLE 10 - Physiological variables

Subject	Test B Weight Loss (lbs)	Test B Heart Rate Maximum Beats/min	Test B Heart Rate Time (min)	Test B Respiratory Rate Maximum Breaths/min	Test B Respiratory Rate Time (min)	Test C Weight Loss (lbs)	Test C Heart Rate Maximum Beats/min	Test C Heart Rate Time (min)	Test C Respiratory Rate Maximum Breaths/min	Test C Respiratory Rate Time ~~(min)~~	Test D Weight Loss (lbs)	Test D Heart Rate Maximum Beats/min	Test D Heart Rate Time (min)	Test D Respiratory Rate Maximum Breaths/min	Test D Respiratory Rate Time (min)
							Scott Pressure Pak II								
3	----	170	23	----	----	---	170	25	25	10, 20,25		Test Not Run			
6	0.4	165	17	32	16,20	1.0	146	20	30	20		Test Not Run			
10	0.8	130	20	28	20,25	0.8	129	20	25	25		Test Not Run			
							BioPak 60P								
3	1.2	164	16	30	16,21	1.0	169	55	38	55		Test Not Run			
7	2.4	132	3	27	3,21	1.8	129	35	27	45		Test Not Run			
10	2.2	125	13	25	47	1.4	131	35	36	55		Test Not Run			
							Draeger Oxy SR-608								
1	3.8	149	16	30	16,21	1.8	135	35	29	30,35	1.8	174	13	34	7
8	1.8	122	21	35	21	1.8	120	35	32	20	2.2	129	47	36	18
10	1.2	127	3	36	21	1.4	106	35	33	35	2.4	120	42	37	30
							CSE Au-9A1								
7	1.6	149	26	24	31	1.8	138	35	28	35	1.2	159	24	28	24
9	1.2	133	26	25	21,52	1.8	131	33	25	15	1.4	152	18	26	24
10	2.0	111	21	27	16,21	3.2	115	35	24	5,10	3.2	157	58	29	52

the rapid expansion of breathing air from the cylinder. The liquid oxygen Aerorlox unit is cooled by the evaporating cryogen. Of the four rescue units tested, all Aerorlox tests and two BioPak tests stayed within the present NIOSH certification limits. Although both of the 4-h devices exceeded these limits, the MSA probably was cooler because it included a cooling pack. This pack is simply a water-filled container, previously frozen, which can be attached to a portion of the apparatus through which the inhalation gas flows.

Although the temperature and other measured variables were sometimes higher than those measured by NIOSH during certification using current procedures, this does not mean these apparatus are unsafe, should not be certified, or should not be used. The reasons for these differences were that the proposed tests were more strenuous than the current ones, continuous monitoring was used rather than only during rest periods, and the subjects may have been heavier than the NIOSH subjects. Because of these differences, the present pass/fail criteria do not apply to our tests. The present criteria are noted only as a frame of reference and to illustrate that new pass/fail limits need to be established if these proposed tests and testing procedures are adopted.

Subject No. 10, while wearing the Draeger BG-174A, requested that the test be stopped at an inhalation temperature of 47°C. This subject was highly motivated and tested all eight apparatus. However, he stated that he was unable to take a full breath because of the high temperature and during a follow-up interview said that his lungs hurt for about half a day. Because of this, we subsequently limited the temperature at which a test would be stopped to 47°C for a 4-h unit. This is why the test with subject No. 9 using the same apparatus was terminated early. This subject said that the inhalation air was hot but that he could have continued. Subject No. 8, who was first to test this unit, completed the test although the gas temperature reached 52°C. These results show that the tolerance for high temperatures depends on the subject.

With most escape apparatus, large temperature changes were recorded during a respiratory cycle. The lower temperatures listed in Table 6 were measured during exhalation and the higher ones were recorded during inhalation. When we compared the exhalation temperatures with normal body temperature, 37°C, a 1-6°C lag in thermocouple response was indicated. Because the residence time of the air in the lungs was probably insufficient to allow it to reach body temperature, the true lags were probably somewhat less than this. However, we assume that the maximum inhalation gas temperatures are higher than the values recorded.

In all of our testing, we monitored continuously rather than only during rest periods, as is done during current certification testing. The temperature decreases when a subject stops exercising, and, depending on the apparatus and length of time before the temperature is measured, this decrease can be several degrees. Moreover, the temperature probe used by NIOSH for certification may be a little slower to respond than was the thermocouple we used. These factors alone show the need for new pass/fail criteria if these tests and testing procedures are adopted for certification purposes.

The maximum tolerable inhalation gas temperature is a function not only of the length of time that that temperature gas is inhaled but also of the relative humidity of the gas and the ambient temperature in which the device is used. The body must lose heat by dissipating either sensible or latent heat or the core temperature will rise. With the ambient temperature higher than body temperature, sensible heat cannot be dispelled. If relative humidity is also high, cooling by evaporation of perspiration from body surfaces is hindered. When the inhaled gas is also hot and humid, breathing may heat rather than cool the body. While the first two factors are a function of the particular circumstances in which an SCBA would be used, the third is dependent on the apparatus and is potentially correctable.

Because of the advantages of a cooler or drier environment to the wearer, we ask the following question: Should apparatus weight be increased if it would provide cooler or less humid inhaled gas? A pertinent observation is that the MSA unit, with provision for some cooling, operated considerably cooler than did the Draeger BG-174A with no cooling. Although all other construction features of the two units were not identical, we believe that the temperature difference was at least partly due to the cooling pack, and the MSA unit is still within the present weight limitations. With an increased weight allowance, the Draeger temperatures probably could have been lowered and that of the MSA temperatures decreased even more.

B. Breathing Resistance

For purposes of certification, SCBAs are divided into open-circuit and closed-circuit categories. Open-circuit breathing apparatus may be demand-type (facepiece pressure is positive during exhalation and negative during inhalation) or pressure-demand (facepiece pressure is positive during inhalation also). Closed-circuit apparatus were available only in the demand-type during promulgation of these regulations. When the pressure-demand closed-circuit apparatus were offered, an attempt was made to fit its performance into the existing regulations.

Of the apparatus tested, the Scott was the only open-circuit, positive-pressure unit. The following are closed-circuit, negative-pressure (demand) units: Draeger BG-174A; Aerorlox; and the three escape devices, Draeger Oxy SR-60B, CSE, and the Ocenco. Two closed-circuit positive-pressure (pressure-demand) SCBA were tested, the BioPak and MSA prototype.

Below is a list of acceptable breathing resistances as described in 30 CFR 11. Depending on the test, resistances are measured either on a breathing machine or with a constant gas flow.

1. Open Circuit, Positive Pressure: Exhalation (Section 11.85-6, Ref. 12). Static pressure (no flow) shall not exceed 1.5-in. water column. The facepiece pressure at a continuous (exhalation) flow of 85 L/min shall not exceed the static pressure by more than 2 in. (a total of 3.5 in. positive.)

Inhalation: static flow from the apparatus (Section 11.85-8 a-c, Ref. 12) shall be greater than 200 L/min at zero gage pressure in the facepiece. Thus, the maximum pressure differential between exhalation and inhalation is 3.5 in. During tests on a breathing machine (Section 11.85-5a,b, Ref. 12) operated at 24 respirations/min, 40-L/min volume (Section 11.85-3b, Ref. 12), and 120-L/min peak flow, the mask or mouthpiece pressure shall not fall below 1.25 in. less than static.

2. Closed Circuit, Negative Pressure Exhalation (Section 11.85-6e, Ref. 12). While on the breathing machine, the exhalation resistance shall not exceed 2 in.

Inhalation (Section 11.85-5c, Ref. 12). The inhalation resistance shall not differ by more than 4 in. from the exhalation resistance while the apparatus is being operated on the breathing machine. The maximum pressure differential is 4 in.

3. Closed Circuit, Positive Pressure. There are no specific certification requirements for these apparatus. Stein (11) suggested a maximum pressure differential of 3 in.

Both high exhalation and high inhalation pressures are of concern to wearers of breathing apparatus. The wearer senses the difference between exhalation and inhalation pressures during each breath and will be uncomfortable when this difference is large. Table 7 shows the inhalation pressures associated with maximum exhalation pressures. These measurements were taken during Test C for rescue apparatus and during Test D for escape apparatus.

The Scott, BioPak, and MSA prototypes are designed to maintain positive pressure in the facepieces. This positive pressure minimizes the inward leakage of contaminated atmospheres from just outside the facepiece. Certification requires positive pressure to be maintained with the open-circuit devices only if the instantaneous demand for air does not exceed 200 L/min. (Some modern open-circuit devices may be able to sustain positive pressure at higher flow rates, 400 L/min or so.) Closed-circuit devices have relatively low flow from the oxygen bottle, and during a large and rapid inhalation, the breathing bag can collapse completely, resulting in negative pressures in the facepiece. Hence, the terms positive-pressure or pressure-demand refer only to the testing conditions in 30 CFR 11. Raven (10) agreed that during a heavy work load, mask pressure can become negative during inhalation. He states that from a physiological viewpoint, the open-circuit, pressure-demand equipment is inadequate for the ventilatory stresses of high workloads.

The three positive-pressure devices listed in Table 7 do show negative pressure during some of the Test C activities. Note that with the exception of the CSE, the maximum exhalation pressures are similar for the positive- and negative-pressure SCBA under the heavy work loads of tests C and D. However, the negative-pressure units generally show greater inhalation resistances, which translate into larger total pressure swings. As noted in Section III. A, tests with the Draeger BG-174A on subjects 9 and 10 were terminated early. Had subject 9 continued, higher breathing resistances probably would have been recorded. One MSA test, that with subject 9, was also stopped early;

again, we think that higher values would have been noted if the test had continued.

The escape devices were of two types: chemical-oxygen (Draeger Oxy SR-60B) and compressed oxygen (CSE and Ocenco). None of these three units is designed to deliver positive pressure. The Draeger performed the best and exhibited pressures similar to the mine rescue demand units. However, in only one test were the present certification test requirements met. With the Ocenco, the subjects complained that they were receiving insufficient breathing gas and they had to change their breathing rhythm. This problem appeared on the chart records as intermittent inhalation spikes of greater than 10 in. (These were single spikes and were not tabulated in Table 7.) The apparent reason for this difficulty was that an extra deep inhalation was required to open the demand valve. This was the only unit tested that the subjects complained strongly about the breathing resistance. Generally, higher inhalation resistances were noted with the CSE, but there were fewer subject complaints.

C. Gas Composition

1. Carbon Dioxide. The maximum carbon dioxide concentrations measured in both the mask and inlet tube are given in Table 8. In the Scott open-circuit device, CO_2 concentrations in the air entering the mask were the same as in the supply tank, 0.05%, so no CO_2 measurements are necessary. With rescue apparatus, data listed for the "Inhalation Tube" column were measured at that location farthest from the subject's mouth. For the escape apparatus (Draeger Oxy SR-60B, CSE, and Ocenco), sampling was actually in the breathing bag, and "mouthpiece" measurements were taken from the inhalation tube. The maximum values during inhalation are recorded, but when inhalation and exhalation differ more than 0.2%, both concentrations are given: exhalation/inhalation.

The present certification requirements allow a maximum of 0.5% CO_2 during the human subject tests of mine rescue apparatus. (This measures scrubber efficiency.) This requirement is met, except with the Bio-Pak. We do not believe that the measured concentrations with this unit, 0.7% to 1.2%, are dangerous or unreasonable; in fact, they are less than the 1.5% allowed for escape devices of the same 1-h duration.

Of the escape apparatus, the Draeger gases were well within the limit of 1.5%. Even in the one test when the breathing bag was not monitored, the maximum CO_2 concentration in the mouthpiece during inhalation was less than this. Of the two tests run with the Ocenco, only one approached the certified duration of the apparatus. In this case, 1.9% CO_2 was measured. The other test was terminated early at 12 min because of oxygen deficiency (see Section III.C.2.).

The CSE had the highest CO_2 levels of any apparatus tested. This apparatus is a pendulum device in which the same tube is used for both inhalation and exhalation. The exhaled air passes through the sorbent into the breathing bag. When a subject inhales, air from the breathing bag retraces a path through the sorbent. Because of this, the CO_2 concentration might be assumed to be lower in the mouthpiece than in the breathing bag. However, when these tests were stopped because of high concentrations, at least 3.4%, this was untrue. We assume the reason is that previously sorbed CO_2 is being expelled from the top of the sorbent bed during inhalation. This may be the primary cause for higher concentrations in the CSE than in any of the other apparatus, none of which are pendulum devices.

With all breathing apparatus, some of the exhaled breath trapped in the dead space within the mask or inhalation tube is inhaled in the subsequent breath, thereby increasing the effective concentration of CO_2. How serious this problem is depends on the dead space volume, the CO_2 concentration of both the expired breath and of the gas entering the inhalation tube, and the total volume of the following inhalation. To estimate the amount that the CO_2 concentration might increase because of dead space, we assumed a 200-cm^3 dead space volume with 7% CO_2 in the exhaled breath, and a 2-L tidal volume. With these assumptions, if the incoming breathing gas contains no CO_2, then the integrated, inhaled CO_2 concentration would be 0.7%. With the same assumptions, integrated, inhaled CO_2 concentrations of 1.0%, 2.0%, 3.0%, and 4.0% would occur when the gas entering the inhalation line had CO_2 concentrations of 0.3%, 1.4%, 2.6%, and 3.7%, respectively. From these numbers it can be seen that the inhaling of previously exhaled breaths would be considered a problem only if there is concern for inhaled CO_2 concentrations of 1%-2%. If, as seems more reasonable, safe concentrations are near 3%, then dead space is no longer a concern with reasonable apparatus design.

2. Oxygen. Most apparatus supplied adequate oxygen, usually in concentrations of at least 30% within a few minutes after the subject donned it, and remained above this value for the remainder of the test. One CSE unit exhibited an oxygen deficiency at 7 min for no known reason. Some of the Ocenco units leaked in the mouthpiece-inhalation hose connection, which could have allowed ambient air to be sucked into the apparatus. Because the nitrogen remains unchanged in the system, its concentration can increase as oxygen is consumed leading in time to an oxygen deficiency. This apparently caused the low oxygen concentration in the Ocenco test, which was terminated for this reason. Recent information from Ocenco (9) indicates this problem has been corrected.

D. Vented Gas

All units tested were instrumented to measure the amount of gas that was vented to the atmosphere, except for the Scott open-circuit apparatus, which vents all exhaled gas, and the BioPak and CSE, on which the pneumotachograph could not be mounted without modifying the apparatus unacceptably.

Table 9 lists the vented gas data. The Aerorlox data are not included because venting was continuous; 1600 to 2500 L were vented during the 3-h tests at rates varying from 4 to 18 L/min. The venting data from the other units are of interest, primarily for future design purposes, but it should not be necessary to monitor this variable during certification testing. All that should be necessary is to determine that the device will last for the specified duration tests, C for mine rescue and D for escape.

For design purposes it is instructive to compare the data from the two 4-h compressed-oxygen devices, the Draeger BG-174A and the MSA. The Draeger supplies a constant 1.5 L/min of oxygen to the breathing bag, and in the one test which lasted 4 h, vented a total of 23 L. The venting occurred almost entirely during periods when the subject was seated. Even during light workloads, the physiological demands were high enough to consume all the continuous-flow oxygen and to require that additional demand oxygen be added. (Another test was run on subject No. 8, for which the data are not tabulated because of errors in the temperature recording, in which 21 L was vented.)

The MSA unit has no constant oxygen flow. During the two completed 4-h tests, 5.1 and 0 L were vented. In the test stopped at 115 min, 9 L was vented. Constant flow is used to prevent a build-up of nitrogen in the facepiece and a lowering of the oxygen concentrations. Because so little extra gas was vented with the 1.5 L/min constant-flow provision, incorporating this provision, at least in 4-h apparatus, would seem preferable if these tests truly simulate field demand.

E. Physiological Variables

Although the purpose of this testing program was to study the responses of the apparatus under test and whether the subjects could complete the tests, and not the physiological responses of the test subjects, some observations can be made. Heart rate was measured at the end of every 5-min period or task, whichever came first; the subjects were weighed before and after every task to determine weight loss; and the respiratory rate was determined from the breathing resistance records. These data, particularly maximum recorded heart rate, can help compare the relative stresses placed on the subjects during the different tests.

One difficulty in comparing these stresses is that we ran Tests B and D for only 1 h but many C tests lasted 3 or 4 h. Thus, Table 10 lists data for only the 0.5- and 1-h apparatus for Tests B, C, and D. Although we were not required to run the C tests with the escape apparatus, these were performed and the data are included for the Draeger Oxy SR-60B and CSE Au-9A1. The Ocenco data are not included, as the B tests were not run with this device. Owing to the demand valve and leakage problems, we thought that this device was inappropriate for evaluating human subject tests.

The data in Table 10 are the maximum heart and respiratory rates with the occurrence times, and the weight loss in each test. In most cases, the same or higher heart and respiratory rates occurred in Test B than C. These results indicate that certain Test B tasks are more strenuous than the tasks of Test C. A comparison of the same variables recorded during Tests C and D shows that Test D is more stressful than C.

F. Other Apparatus Variables

Other apparatus variables monitored, not pertinent to certification testing but of interest, are the temperatures of the gas leaving the sorbent canister and the canister surface, and the pressure in the compressed-gas cylinder.

1. Sorbent Gas Temperature. This variable was monitored in all closed-circuit apparatus except the Aerorlox, Draeger Oxy SR-60B, and CSE. In these devices it was not possible to monitor gas temperature without modifying the apparatus unacceptably.

Not surprisingly, the Draeger BG-174A that exhibited the highest inhalation temperatures, a three-test average of almost 49°C, also showed the highest average sorbent gas temperature, 119°C. With the other devices, the relative values of inhalation temperature did not correlate with sorbent gas temperatures. That is, the inhalation temperatures for the BioPak, MSA, and Ocenco devices were 42, 40, and 37°C, respectively, while the corresponding sorbent gas temperatures were 51, 76, and 109°C. (The Ocenco datum is from the single test, which lasted for 59 min.)

2. Canister Surface Temperature. These measurements were taken on all apparatus but the Scott. The lowest average maximum temperatures were recorded with the BioPak, 48°C, and the Aerorlox, 47°C. The reason for the low BioPak temperature is the canister shape, wide and thin. This shape spreads the heat over a large area as it traverses the sorbent bed. The Aerorlox is cooled by the vaporizing liquid oxygen. The highest temperatures were recorded with the Draeger BG-174A, an average maximum of 121°C. The other devices exhibited intermediate temperatures: MSA, 58°C; Draeger SR-60B, 77°C; CSE, 89°C; and Ocenco, 93°C.

These temperatures are the averages of the maxima which were recorded for each device, but they are not necessarily the maxima that actually existed. The true maxima will depend on the geometry and heat transfer characteristics of each canister. Because the canister surface reaches no uniform temperature, the thermocouple placement is critical in recording the true maximum. In these tests, the thermocouples were attached on the canister approximately in the center axially, except for the BioPak where it was attached in the center radially.

The only interest in measuring this temperature during certification would be because of the possibility of burning the user or damaging other apparatus parts. Burn possibilities are best determined in the ergonomics test, Test B. The mine rescue devices are packaged so that the heat should not damage other apparatus parts. However, with some escape apparatus like the Ocenco and CSE, the breathing bag can touch the sorbent canister. If this bag is fabricated to withstand temperatures of 100°C or higher, this temperature should pose no problem. However, if canister surface temperature is considered a possible problem, applying a heat-sensitive paint that changes color at a temperature below that at which the bag would be damaged would be better than attaching one or more thermocouples.

3. Gas Cylinder Pressure. This variable was measured on all apparatus but the Aerorlox and Draeger Oxy SR-60B, where compressed gas

is not used. The major certification question is whether a given device will actually last a specified time. This can be determined best by a duration test, using either human or machine. Any breathing gas still present when the test ends can be read easily on the pressure gauge permanently attached to each device.

IV. CONCLUSIONS

A. Work Levels of Proposed Tests

These proposed certification tests are not too physically demanding. Our test subjects, all in good physical condition, were, with a few exceptions, able to complete the tasks, even though higher work rates than presently employed for certification were involved. Two tests were stopped because of excessive temperatures (subjects stopped voluntarily or were told to stop). Other tests were terminated because the subjects' heart rates exceeded 85% of their measured maxima. This latter condition was imposed on us by the Human Test Protocol, under which we were permitted to use human subjects without medical personnel in constant attendance. In most cases, our subjects were willing to continue beyond the 85% limit. Maximum stress restrictions or unavailability of medical personnel may not be problems to others conducting these tests.

Although we do not know whether the average miner could have completed all these tests, we believe certification should be based on requirements for an individual in above-average physical condition, e.g., 80th percentile. Also, the apparatus should meet the requirements of a heavier than average miner. Therefore, a minimum test subject weight should be specified.

B. Continuous Monitoring

Continuous monitoring is a desirable improvement because rapidly changing conditions can be determined, thereby producing more information and reducing the risk to the ultimate user. The breathing resistance, temperature, and CO_2 and oxygen concentrations of the inhaled gas are the important variables, and these should be measured continuously during Tests C and D. For safety, heart rates should also be monitored. Because Test A is not a strenuous one, only CO_2, oxygen, and heart rate need to be monitored. In Test B, heart rate should be monitored continuously and periodic checks of CO_2 and oxygen made.

Our continuous monitoring frequently indicated levels exceeding present 30 CFR 11 limits for temperature, mask pressure, and CO_2. These extreme values are not seen in the present certification tests because the subject is at rest when the measurements are made. We cannot specifically recommend the upper physiological limits for these variables. Physiologists, medical personnel, and individuals who can relate the effects of stressful, life-threatening situations to physiological requirements should suggest safe limits. Comments on practical engineering and cost limitations could also be solicited from breathing apparatus manufacturers. The regulatory agencies and the Bureau of Mines must weigh these factors before proposing new pass/fail limits for these important variables.

Trade-offs between some of these variables are possible, but we cannot determine now, for example, whether the wearer benefits from additional weight if this yields cooler or dryer inhaled gas. Additional weight might also permit greater gas flow, reducing the negative mask pressures seen during the heavy breathing accompanying high work rates. These questions call for additional research.

C. Breathing Machine

Whether an apparatus meets all certification requirements, except ergonomics, would best be determined with a breathing machine as is being proposed in Europe (2). Stresses to which an apparatus is subjected and its response to those stresses depend on the subject using it. Using a machine would allow all apparatus to be stressed to the same level during certification, rather than being dependent on the specific subject available. Because any individual physical type could be simulated, a decision would be needed about certification criteria. For example, should pass/fail criteria apply to the average miner or to the largest miner in the best physical condition who could place the greatest stress on the apparatus? However, before a machine could be used for certification, true simulation of the stresses produced by human subjects would need to be demonstrated.

For open-circuit equipment, a simple breathing pump will suffice, but for rebreathers, a metabolic simulator would be required. Such a device is not standard in the United States, but the Bureau of Mines is currently investigating promising designs. Until such a machine is available, human subjects must still be used.

D. Duration

For the Scott open-circuit apparatus, almost all wearers went the full 30 min. However, anecdotal information from firefighters indicates that the 45 ft^3 of air available in 30-min units can be expected to last for about 20 min during heavy work. Apparently both the present man and breathing machine tests for open-circuit apparatus were inadequate to simulate the true work rates for short duration (0.5-h) apparatus.

Two of the rescue rebreathers, the Aerorlox and Draeger BG-174A, have been used extensively for mine and other emergencies. We are unaware of complaints about inadequate duration in the field with this equipment. Our subjects were able to complete Test C (high temperature was the reason for stopping two Draeger tests), and we conclude that Test C adequately simulates the metabolic demands for long-term rescue activities.

Test D was originally proposed to prove escape devices safe from catastrophic failure (11), a task for which a breathing machine is ideally suited. In this proposal, Test C would determine duration even for escape devices. However, if wearers are expected to work harder during escape emergencies than during rescue, then the duration test for escape apparatus should be more severe. Unfortunately, experience is no guide because the three escape devices tested are new and have not yet proved their duration adequate to the task. Therefore, we recommend that Test D be used to determine the duration of escape apparatus until field experience determines the test's adequacy.

E. Mask Dead Space

Mask dead space is determined now by a breathing machine test, whereas the efficiency of the scrubber is measured using human subjects. To us, this appears backwards. Scrubber efficiency should be a straightforward measurement of the CO_2 as it exits the scrubber. In fact, most of the levels that we measured were little higher than those allowed under 30 CFR 11, except for the CSE unit where the pendulum system is believed to have contributed to the high CO_2. When a metabolic simulator is available, we believe that it should be used to measure scrubber efficiencies. We suggest that the Bureau determine whether higher CO_2 levels than those now permitted would adversely affect the wearer, and if not, whether higher permitted levels would be of some advantage in the design of new apparatus. We believe that dead space was no problem with any of the tested apparatus. Continuous monitoring during Tests C and D and a separate scrubber efficiency test would eliminate the need for a separate dead-space test.

F. Ergonomics Test

We question the use of Test B as an ergonomic evaluation. By ergonomics testing, we mean a determination of the effect that wearing the device has on the wearer's ability to perform his tasks, such as mine rescue. If we compare Test B with the British practical performance test (5), we see that Test B calls for climbing, pulling, crawling, and running. The British, on the other hand, require an apparatus wearer to, for example, build a barrier, negotiate a complex gallery through confined spaces, fit through small openings, carry a stretcher holding a dummy, and climb up and down ladders. We conclude that, difficult as it may be to build and maintain a facility necessary to support the British tests, the usefulness of breathing apparatus can be determined better by the British tests than by ours. In addition, based on heart rate, certain exercises in Test B seem to require the wearer to work harder than those in Test C.

Apparatus manufacturers would find it difficult to duplicate the facility described in the British standard. Draeger markets a system that, although smaller and simpler than the British gallery, does provide smoke and obstacles to traverse. We suggest that the Bureau provide a facility such as that of Draeger or that a test facility be maintained at the Bureau's Bruceton mine. For a suitable fee, it could be made available to potential applicants for SCBA approval so that they might use it, without prejudice, for their developmental activities. Such a facility would ensure that all new designs meet at least some minimum criteria based on actual workplace geometry.

Because no laboratory testing can exactly duplicate actual use, we suggest that some system be developed to permit the use of devices that, having passed all of the laboratory tests, will be used for a limited time in the field before final certification is granted. Use in mine rescue team competition is a possibility. This may reduce early failures and prevent the purchase of new designs before they have actually proven themselves in the field.

G. Gas-Tightness Test

A test for the integrity of the complete SCBA needs to be established. That is, a test should determine whether or not ambient air can enter the system when it is maintained at a negative pressure, possibly -5 in. As an example of the need for such a test, the Ocenco device leaked so badly that an oxygen deficiency was recorded in one test. However, it had passed the current NIOSH gas-tightness test (Section 11.85-19, Ref. 12), in which six persons wore the apparatus in an atmosphere of 1000 ppm of isoamyl acetate for 2 min each and did not smell the gas. If any leak is to be allowed, the maximum permitted size would need to be based on the expected toxic concentrations in the working environment and the maximum permissible inhalant levels in the gas.

H. Fit Factor Test

The test protocols examined in this project included no determination of the respiratory protection (fit factor) provided by each device; in other words, how well the face mask fits. As with system leakage, the minimum fit factor required depends on the ambient concentration and permitted levels of toxic substances in the SCBA. For example, in mines, the primary risk is CO. Typical values for CO after an explosion or mine fire are estimated to be as much as 12% with 1% more typical (2). Although the present TLV and STEL for CO are 0.005% (50 ppm) and 0.044% (440 ppm), respectively (1), exposures of 0.02% (200 ppm) for a few hours undoubtedly would not be debilitating. For long durations, exposure levels of 0.01% (100 ppm) are safe (8). Reducing an exposure of 1% to 0.01% requires a protection factor of 100. If we wish to allow for greater than 1% CO and maintain a safety margin, we should aim for a protection factor of 1000. So that a protection factor of 1000 or more can be measured, methods of quantitative fit testing must be used instead of the NIOSH isoamyl acetate test. We recommend the methods used in Ref. 6, but stressing the subjects to higher levels.

Current full facepieces, available in one face size and operated under negative pressure, have difficulty in providing a protection factor of 1000 to most wearers. Newer designs in multisized facepieces may be able to protect wearers to protection factors of greater than 1000, but present equipment cannot. Positive-pressure SCBA may solve the problems of facepiece fit. No standards exist for positive-pressure closed-circuit SCBA. We suggest that such limits be similar to the requirements for open-circuit equipment: maximum pressure swing of 3.5 in. and the facepiece should not be driven negative with a metabolic simulator that is operating at the same rate as the breathing machine for open-circuit equipment.

When the pressures in the facepieces of positive-pressure apparatus are positive, the fit factor provided can be greater than 10,000 (6). However, Table 7 shows the positive-pressure apparatus (Scott, BioPak, and MSA prototype) were driven to negative pressures during the heavy exercises of Test C. Also, almost all apparatus tests exceeded the present 30 CFR 11 criterion of 3.5-in. maximum pressure swing. Our data were, of course, collected during continuous monitoring and not during rest periods, as required by the present certification tests.

In the recent paper (6) discussing the protection provided by positive-pressure rebreathers, none of the subjects were stressed to a level that would tend to drive the facepieces into the negative-pressure region. We have no data on the protection provided by nominally positive-pressure apparatus when the facepieces are driven negative. Because duration of the negative pressure would be short compared with the total wearing time of the apparatus, positive-pressure devices would be expected generally to provide greater protection than that expected from negative-pressure equipment. Data are needed to prove the effectiveness of positive-pressure apparatus during heavy work.

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APPENDIX A -- TEST PROTOCOL*

FORM 1

USE OF HUMAN SUBJECTS

STATEMENT BY PRINCIPAL INVESTIGATOR OR ACTIVITY DIRECTOR

A. Activity Director: J. F. Stampfer

B. Activity Title: Evaluation of Man Tests of Self-Contained Breathing Apparatus

C. Department: HSE-5 Worker Protection Studies Section

D. Telephone Extension: (505) 667-7342

E. Date Submitted:

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1. Identify the requirements for the subject population. Explain the rationale, if the population includes a special group such as prisoners, children, mentally disabled, or those whose ability to give informed consent may be in question.

   The population delimitations require the subjects to be healthy volunteers, 18-35 years old, a minimum of 160 pounds, and capable of completing at least 12 minutes of the Bruce stress test protocol. This test must be carried out within six months of the subject's participation in this program. The maximum weights of the apparatuses to be carried by the subjects will vary linearly from a maximum of 15 pounds for a 160 pound subject to 40 pounds for subjects of 180 pounds or more. All subjects will be volunteers.

2. Specifically identify those procedures in which a human subject is used which depart from the application of those established and accepted methods necessary to meet his needs, or which increase the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service.

   Procedures to be used in this investigation that increase the ordinary risks of daily life include (see Section 3):

   a. Maximal exercise stress testing (MXT)
   b. Submaximal walking and running on a treadmill using a self-contained breathing apparatus (maximal poundage = 40 pounds).

3. Describe and assess any potential risks -- physical, psychological, social, legal, etc., and assess the likelihood and seriousness of such risks.

*This protocol was developed mainly through the efforts of Dr. Peter B. Raven, Department of Physiology, Texas College of Osteopathic Medicine, Medical Education Building, Fort Worth, TX 76107.

a. Maximal exercise stress testing (MXT) is primary to this investigation and obviously increases the risk of ordinary daily life. Inherent in the use of symptom limited MXT is the possibility of an untoward cardiac event such as arrythmia or ischemia. These changes may proceed to culminate in a "heart attack." In asymptomatic subjects below the age of thirty-five the risk of such an occurrence is negligible (see Section 5), such that both the American Heart Association and American College of Sports Medicine agree that on-site physician coverage during such testing is not a necessity. However, all of the proposed MXT will be performed at the Medical Center in the presence of a cardiologist (Dr. Carolyn Linnebur or Dr. Jon Johnson).

b. Submaximal exercise testing: The submaximal tests (outlined in Appendices A through D) form the major basis of the investigation. The subjects will be required to walk and run on the level and up a grade on a motor driven treadmill while wearing a self-contained breathing apparatus. Interspersed with the walking and running exercises may be stooped walking, ladder climbing, carrying weights, pulling, crawling and resting. The duration of these intermittent tests range from one minute to 15 minutes of work with rest periods of three to five minutes in the seated position. The length of time for any one test ranges from 30 minutes to four hours. Only one test will be performed in one day by a subject. Based on unpublished pilot data, the level of work with the added weight of the apparatus will not exceed 80% of an individual's maximum $\dot{V}O_2$ at heart rates of approximately 85% of the individual's maximum and energy expenditures of 10-12 METS. (These pilot data, collected by our consultant physiologist, Dr. Peter Raven, identified the heart rate of a 194 pound subject, after ten minutes work at 9 METS wearing a 35 pound backpack, as 145 BPM (maximum heart rate, 180 BPM) and that of a 154 pound subject, after ten minutes work at 13.6 METS wearing the same backpack, as 180 BPM (maximum heart rate, 200 BPM)). If the subject's heart rate reaches or exceeds 85% of his maximum as established by the MXT, the session will be halted.

It is intended that the submaximal tests will be performed at the Pajarito School building with a CPR-trained technician in attendance, but with no physiological monitoring, except heart rate, or clinical aid. However, as this workload is clearly submaximal and the subjects have been screened by MXT to maximum for cardio-vascular disease, it is presumed that the actuality of a cardiac event occurring is negligible (see Section 5).

4. If electronic or stressful instrumentation is to be used, provide the name of the manufacturer, the model number and appropriate specifications of the device, as well as how it is to be used on the subjects.

5. Describe procedures, including confidentiality safeguards, for protecting against or minimizing potential risks and an assessment of the likely effectiveness of the procedures (i.e., physician's examination; required attending physician; attending registered technician, etc.).

Confidentiality of subject data will be assured by utilizing experiment numbers and codes. A master code and all subject files will be kept in a locked file and any data entered into a computer data base will be by code and subject number.

The risk outlined in No. 3 for MXT are, in fact, rare instances of the extreme. The reported incidence of cardiac events during MXT for asymptomatic populations aged less than 35 years of age is less than 1 in 100,000. Initial screening for symptoms contraindicating MXT and the close monitoring of the subjects by a licensed cardiologist (Dr. Carolyn Linnebur or Dr. Jon Johnson), reduces the risk to the subject. As this is a clinical testing facility within a medical center, the emergency procedures and equipment for defibrillation, cardioversion and drug therapy are readily available.

This preliminary screening MXT is the primary means by which subjects will be evaluated for increased risk during the submaximal tests. If, in the opinion of the cardiologist, there is a question concerning a subject's ability to complete 10-12 MET work for intermittent periods, then the subject will not be permitted to participate in the investigation.

6. Assess the potential benefits to be gained by the individual subject, as well as benefits which may accrue to society in general as a result of the planned work.

   a. Each individual subject will obtain a thorough clinical evaluation as well as have documentation of their cardiovascular fitness.

   b. The investigation is an evaluation of tests to be used in certifying self-contained breathing apparatuses for use in the field. Hence, society will benefit indirectly in that the feasibility of using these tests will be identified.

7. Analyze the risk/benefit ratio.

   The risk/benefit ratio is difficult to assess. However, we believe the increased risks, outlined in Sections 3 and 5 above, are minimal with respect to the benefits to be obtained: by the subject, a free maximal exercise stress test; and, by society, increased safety of self-contained breathing apparatus.

To assist the Committee further in its analysis of the direct or potential benefit of this activity against the potential risk to the individual, answer the following questions in the spaces provided:

1. What specific information will this activity provide, and what is the significance of that information? (Please answer in language that can be readily understood by persons in disciplines other than yours.)

   This investigation is a feasibility study of whether the suggested tests are appropriate for use as certification tests for self-contained breathing apparatus.

2. Could this information be obtained from other animals or other laboratory models?

_______ YES ___XX___ NO Explain your response.

These respirators are designed for human use during rescue work.

3. Are there alternative ways to acquire this information from human subjects that may avoid the risks identified in Items 2 and 3?

___ YES _XX___ NO. If "YES" response, explain why the alternatives are not being used.

4. Is participation in the activity completely voluntary? __XX__ YES ___ NO. If "NO" response, explain.

5. May any subject withdraw from the activity at any time without penalty?

__XX__ YES _____ NO
If "NO", explain.

This "yes" is qualified by the payment scheduled provided in Item 6.

6. Is any kind of incentive offered to the subject? __XX__ YES _____ NO
If "YES" response, explain the type and amount.

The following table lists the scheduled of payments (dollars) for completion of the indicated series of tests with an apparatus of given duration. The individual tests are shown in Appendices A through D.

Approximate Total Req'd Time	Duration Of Test	Payment on Completion of Test: A	B	C	D	Total
1.5 Hours	30 Min.	$20	$25	$ 30	$50	$125
2 Hours	1 Hour	$30	$40	$ 55	$95	$220
5 Hours	4 Hours	$60	$95	$155	Not run	$310

Note: All tests must be run in order, A-B-C-D, for any particular device tested.

If any test is not completed, payment will be made at the rate of $5.00 per hour.

SIGNATURE of SUBMISSION ______________________
Principal Investigator or Activity Director

SIGNATURE of APPROVAL ______________________
Group Leader

Attached are copies of the Informed Consent Form 2 and the "Lay Summary" which will be presented to the subject. The "Lay Summary" covers the six basic elements, identified below, required for informed consent.

Informed consent must include the following six basic elements:

1. A fair explanation of the procedures to be followed, and their purposes, including an identification of those which are experimental.

2. A description of any attendant discomforts and risks reasonably to be expected.

3. A description of any benefits reasonably to be expected.

4. A disclosure of any appropriate alternative procedures that might be advantageous for the subject.

5. An offer to answer any inquiries concerning the procedures.

6. An instruction that the person is free to withdraw his consent and to discontinue participation in the project or activity at any time without prejudice to the subject.

Summary

Evaluation of Man-Respirator Certification Tests

for

Self-Contained Breathing Apparatus

Activity Director: J. F. Stampfer

The need for a new type of man testing of self-contained breathing apparatus for certification has been identified by the government as essential for the safety of the actual user.

The object of these studies is to observe whether the suggested performance tests challenge the apparatus sufficiently when being worn by a human. This type of testing is different than the usual bench-type testing. The performance tests ask you to wear self-contained breathing apparatus like a backpack weighing approximatley 35 pounds or less. It consists of a face mask, breathing tubes and a pack containing your oxygen supply. The system used to provide oxygen and absorb the carbon dioxide you produce during your breathing results in the breathing air usually being wetter and, consequently, appearing warmer than normal. Although this is discomforting, it should not be harmful to you. However, if you cannot continue with the test because of the discomfort, do not hesitate to stop working. The work you will be asked to perform consists of walking, running, crawling, pulling, stooped walking, ladder climbing, carrying weights and sitting, and are set at levels ranging from rest to approximately 80% of your capacity. While the length of time for each test should vary between 30 minutes and four hours, individual tasks do not exceed 15 minutes. You will perform only one test per day but are requested to perform at least three or four tests total.

Prior to this performance testing, you will receive free a thorough medical screening exam including a resting electrocardiogram and a maximal exercise stress test. This screening will be performed by Dr. Carolyn Linnebur or Dr. Jon Johnson, consultant cardiologists to the Los Alamos National Laboratory. This test must have been conducted within six months of your participation. The results of this will be used to see if you are acceptable for the investigation. Also, the results of these tests will be provided to you on request.

During the course of the tests you are free to terminate and withdraw from the study at any time. Furthermore, the investigators may conclude the tests at any time at their discretion; e.g., if any subjective or physiological discomfort is observed or if your heart rate reaches or exceeds 85% of your maximum as determined by the MXT. You must be free of drugs and alcohol prior to and during each test and, furthermore, you must refrain from caffeine drinks (Coke, Dr. Pepper, coffee and tea) and smoking at least twelve hours before the stress test and three hours before the work tests.

As in any activity, some risk is involved. In this case, the major risk is of a cardiac event during the maximal stress testing. However, the probability of such an event occurring under these conditions is reported to be less than 1 in 100,000. During the testing of the self-contained breathing apparatus, there will be no medical personnel in attendance except for a CPR-trained technician, but the risks are reduced because you should not be stressed to your maximum as you were during your initial maximal stress test.

The benefits which will accrue from this program are twofold. First, you as an individual will receive a free maximal exercise stress test. You also may be paid for your participation. Second, society will benefit because this program should result in safer self-contained breathing apparatuses.

We will compensate you, if you are not a Los Alamos National Laboratory employee participating during your normal work hours, according to the following schedule:

Approximate Total Req'd Time	Duration of Test	Payment on Completion of Test				
		A	B	C	D	Total
1.5 Hours	30 Min.	$20	$25	$ 30	$50	$125
2 Hours	1 Hour	$30	$40	$ 55	$95	$220
5 Hours	4 Hours	$60	$95	$155	Not run	$310

Note: All tests must be run in order, A-B-C-D, for any particular device tested.

If any test is not completed, payment will be at the rate of $5.00 per hour

We will make every effort to prevent physical injury that could result from this investigation. The work, responsibility, or tasks performed under this agreement by the consultant herein and any injuries arising therefrom are covered by operations conducted under Contract W-7405-ENG-36 and New Mexico Workman's Compensation.

I have read and understand the description of the study, including the detailed explanation of each procedure. I have been given opportunity to ask questions and discuss the study and its potential risks and benefits. I understand that requests for additional information will be welcome. I also understand that I may withdraw from the project at any time without penalty and I hereby give my consent to the study.

By signing this form, the test subject hereby agrees that the exclusive remedy for damages arising from injuries due to participating in this program is exclusively limited to coverage under New Mexico Standard Workman's Compensation Liability and that this limitation is binding on all parties claiming an interest by and through the subject.

Date

Patient/Subject Signature

Witness to Patient/Subject Consent and Explanation Signature

FORM 2

USE OF HUMAN SUBJECTS

INFORMED CONSENT

NAME OF SUBJECT: ____________________

1. I hereby give consent to ____________________ to perform or supervise the following investigational procedure or treatment:

   Maximal exercise stress testing and submaximal work evaluation of self-contained breathing apparatus.

2. I have (seen, heard) a clear explanation and understand the nature and purpose of the procedure or treatment; possible appropriate alternative procedures that would be advantageous to me; and the attendant discomforts or risks involved and the possibility of complications which might arise. I have (seen, heard) a clear explanation and understand the benefits to be expected. I understand that the procedure or treatment to be performed is investigational and that I may withdraw my consent for my status. With my understanding of this, having received this information and satisfactory answers to the questions I have asked, I voluntarily consent to the procedure or treatment designated in Paragraph 1, above.

____
DATE

SIGNED: ____________________
Witness

SIGNED: ____________________
Subject

or

SIGNED: ____________________
Witness

FORM 3

USE OF HUMAN SUBJECTS

COMMITTEE ACTION

1. Activity Title: Evaluation of Man Tests of Self-Contained Breathing Apparatus.

2. Activity Director: J. F. Stampfer

3. Group: H-5 Section: Worker Protection Studies

4. Telephone Extension: 7342

5. Date Submitted: ____________________

__________ The statement submitted for the activity conforms to the University Policy on the Protection of Human Subjects and the activity is approved.

__________ The statement submitted for the activity does not conform to the University Policy on the Protection of Human Subjects and the activity is disapproved for reasons stated on the attached sheet(s).

____________________ Signature for the Committee

____________________ Date

APPENDIX A

Test A

Activity	Length of Time Given Activity is Performed[a] (Minutes)					
	Designated Service Time of Apparatus to be Tested					
	30 Min	45 Min	60 Min	120 Min	180 Min	240 Min
Walk, 3 mph, level	15	15	15	Use 60 min test 2 times	Use 60 min test 3 times	Use 60 min test 4 times
Sit	5	5	5			
Walk, 3 mph, 5% grade	10	15	15			
Sit		5	5			
Walk, 3 mph, level		5	15			
Sit		5				

[a]The complete test for a given apparatus is described by reading down the column under the designated service time for that apparatus.

APPENDIX B

Test B

Activity	Length of Time Given Activity is Performed[a] (Minutes) Designated Service Time of Apparatus to be Tested 30 Min	45 Min	60 Min	120 Min[b]	180 Min[b]	240 Min[b]
Ladder Climb; 33 ft/min	3	3	3	TA-60 min. TB-60 min	TA-60 min TB-60 min TA-60 min	TA-60 min TA-60 min TB-60 min TA-60 min
Pulley, 44 lb/5 ft, 10/min	5	5	5			
Crawl through tunnel, 1/2 mph	3	3	5			
Run, 4.4 mph, level	3	3	3			
Carry 44 lb., 3 mph, level	5	5	5			
Stooped Walking, 2.5 mph, level	5	5	5			
Walk, 3 mph, level	5	5	5			
Sit		5	5			
Crawl, 1 mph, level		3	3			
Lie on back, side, front		3	3			
Walk, 3 mph, level		5	15			
Sit			2			

[a]The complete test for a given apparatus is described by reading down the column under the designated service time for that apparatus.

[b]TA refers to Test A
TB refers to Test B

APPENDIX C

Test C

Activity	Length of Time Given Activity is Performed[a] (Minutes) — Designated Service Time of Apparatus to be Tested: 30 Min	45 Min	60 Min	120 Min[b]	180 Min[b]	240 Min[b]
Walk, 3 mph, level	5	5	17		TA-30 min	TA-60 min
				TA-30 min	TA-60 min	TC-60 min
Run, 4.2 mph, level	5	5	3	TC-60 min	TC-60 min	TC-60 min
				TA-30 min	TA-30 min	TA-60 min
Walk, 3.5 mph, level	5	10	10			
Walk, 4 mph, 5% grade	10	5	5			
Sit	5	5	5			
Walk, 3.5 mph, 5% grade		10	10			
Walk, 4 mph, 5% grade		5	5			
Sit			5			

[a]The complete test for a given apparatus is described by reading down the column under the designated service time for that apparatus.

[b]TA refers to Test A
TB refers to Test B
TC refers to Test C

APPENDIX D

Test D

Activity[b]	Length of Time Given Activity is Performed[a] (Minutes) — Designated Service Time of Apparatus to be Tested: 30 min	45 min	60 min
Walk	2	2	2
Run	5	5	5
Walk	3	3	3
Run	3	3	3
Walk	3	3	3
Run	2	2	2
Walk	4	4	4
Run	2	2	2
Walk	5	5	5
Run	1	1	1
Walk		10	10
Run		2	2
Walk		2	4
Run		1	1
Walk			10
Run			3

[a]The complete test for a given apparatus is described by reading down the column under the designated service time for that apparatus.

[b]Walk; 3.5 mph, level
Run; 5 mph, level

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