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October 22, 1987

National Institute for Occupational Safety & Health
944 Chestnut Ridge Road
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Attention: Mr. John B. Moran, Director
Division of Safety Research

Subject: 42 CFR Part 84 Revision of Tests and Requirements for Certification, Respiratory Protective Devices

Dear Mr. Moran:

Clifton Precision supports the NIOSH position to develop a Revision of Tests & Requirments for Certification of Permissibility of Respiratory Protective Devices. We believe the state of the art is within the practicality range to provide a positive-pressure, semi-closed circuit self-contained breathing apparatus, especially when using a pressure-demand regulator. The positive-pressure will be a definite safety feature to eliminate any inward leakage of contaminated atmosphere from outside the mask and/or helmet.

The following comments address those paragraphs which Clifton believes may require additional review and/or modification; those paragraphs not commented upon are understood and acceptable to Clifton as currently written.

Subpart A - General Provision

84.1 Purpose. Clifton recommends that the purpose of the prescribed procedures and requirements be expanded to include firefighter and industrial respiratory protection.

84.2 Certified Respirators.

(a) Add statement that NIOSH, may, at its discretion undertake its own testing, and/or evaluating of applicant's respirator.

84.3 Definition. Expand definition of respirator, workplace, and simulated workplace to include more than "individual engaged or representation of miner or mining work sites, such as firefighting and industrial environment.

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Subpart B - Application Procedure

84.11 Contents for NIOSH Certification.

(d) Delete "which are made on regular production tooling", will eliminate tooling costs prior to NIOSH approval. If improvements are to be made in state of the art, companies with large engineering model shops and tool rooms can fabricate equipment with all specifications that will be incorporated in the regulator production processing without some of the up-front tooling for small production runs.

(e) Need to improve definition of "a sample of the packaging materials" - is this for the applicant's user maintenance, informational and instructional materials only or for the completed packaged SCBA?

(f) Engineering drawings: define level of drawings, etc., TOP, MAJOR, or ASSEMBLY.

(g) Include the use of computer printout of part numbers instead of engineering parts list.

(h) Most engineering drawings have a standard format which spells out "material in proprietary".

(i) The proposed NIOSH fee is open ended. The Government requires good cost estimating and, therefore, the proposed test program at NIOSH for additional costs to cover verification testing, etc. should have a maximum limit or, at least, bracket costs for man-testing and/or SCBA duration approvals.

Subpart C - Quality Assurance

Clifton is in receipt of the NIOSH letter dated September 15, 1987, to all respirator manufacturers with a recommended submittal package in an effort to reduce paperwork for the manufacturer and NIOSH. This includes an agreement that the manufacturer will submit additional documentation within 24 hours if required.

84.20 Quality Assurance.

(f) An audit of certified products needs a number to define how many may be tested per year.

84.21 Most quality assurance groups need a little more definition of "fails to comply with an applicable requirement contained in Subpart C". Standard manufacturing processes allow for some rework or repair during assembly, usually before the lot is submitted for Quality Assurance.

84.22 Notification.

(b) The total number of respirators produced, and/or approximately shipped should be for group or time units were fabricated with defective parts or inspection failure.

84.23/84.24 Clifton believes the "Comply with an applicable requirement" contained in this subpart should be limited to 84.21 (a).

Subpart D - Respirator Testing by Applicant

(a) In order to assure equal testing between different manufacturers, Clifton believes a required number of units should be tested with a NIOSH pre-approved test procedure.

(c) If NIOSH, at their discretion, undertakes their own testing, how are the units to be obtained and who pays for the test program? It seems this requirement should be the same for all manufacturers or at least the same type of respirator.

(f) The review within 90 days and the simulated workplace testing should be normally completed in six months in order to eliminate approval delays.

84.31 Guidelines for Simulated Workplace Testing.

(a) NIOSH needs to provide a method of evaluation of

workplace protection factor in order for each manufacturer to simulate the same test conditions.

(b) Work conditions that represent places and conditions in which it is anticipated the respirator could be used vary from mining to fire-fighting to industrial contamination. Therefore, one test simulation may not cover all workplaces.

(d) Here again, the NIOSH time frame of 90 days could mean that a new test program would require one calendar year to complete.

84.34 Respirator test results and protocol. It would seem that some manufacturer's procedure and test protocol would cause proprietary information problems.

Subpart E - NIOSH Certification Label

(b) 9. The fully charged weight of the SCBA is acceptable; however, the fully discharged weight permanently and legibly marked on all SCBA will vary with closed-circuit units because of trapped moisture within the CO_2 scrubber.

(b) In addition to MSHA limitations, Clifton believes an additional requirement for 100% oxygen closed circuit SCBA should state that 100% oxygen is dangerous in environments of open flame or high radiant heat.

84.41 Marking Requirements.

(a) Attached or printed on following location: SCBA, entire label should be on the assembly main moulding plate or support member as many of the SCBA components, such as harness assembly, could be replaced during overhaul and repair.

(b) Most manufacturers use the component serial number to include any type of lot number or control and the date of manufacture.

Subpart F - Maintenance, Informational and Instructional Material

(a) Only the operation, test, and/or inspection manual should be shipped with each respirator. If a maintenance manual is shipped with each unit, unqualified personnel could try to repair their owe units instead of using approved technical people.

Subpart H - Withdrawal of Certification

(i) The determination by NIOSH of a "defective" certified respirator needs additional definition as to new - used - and not defective because of field mishandling.

(j) A definite number of respirators should be spelled out for testing during any one period of time.

Subpart J - Fee Determination

For estimating development and manufacturer costs, the Government needs a basic fee per test program similar to 30 CFR, Part II.

Subpart O - Technical Definition

Compressed breathing gas means oxygen or air stored in a compressed state; add "and/or a breathing gas in which the oxygen concentration is greater than 23% by volume."

Subpart P - Classification

84.210 Classification of Certified Respirators.

(ii) Closed-circuit SCBA, add "all classification of SCBA closed-circuit are further classified as either 100% oxygen or mixed gas breathing compressed gas. An alternate classification would be one for: Respirators to be used in open flame, or high radiant heat".

(2)(c) Atmoshpere Supplying Respirators

Closed Circuit SCBA (P or N) (Es or En) (O_2 or mixed gas)

Subpart Q - General Construction and Performance Requirements

84.222 Breathing Tubes.

Shutoff air flow due to kinking: Many respirators have been approved with instruction manuals that specify the user to grab hose (kink) and suck on mask to check face seal.

84.223 Body Harness.

(c) Harness for SCBA shall not when exposed to temperatures of 400 degrees F for 30 minutes. This requirement should be included in paragraph 84.248-17 Flammability Test amd reference ASTM D2863-77.

84.224 Respirator Containers.

(d) The required tests should be listed so that manufacturer can perform them before certification is sought.

84.227 Exhalation Valve Leakage.

(b) The allowed 30 ml per minute is excessive amount of leak for respirators to be used in chemically contaminated environments.

84.233 Positive Pressure Atmosphere Supplying Respirators.

(a) How is the test of a positive pressure regulator to be tested in a negative pressure mode? Also, will negative pressure test give meaningful results?

Subpart S - SCBA

84.240 SCBA Description.

(1) Closed Circuit Apparatus. Sources composed of:

(i) Compressed oxygen

(ii) Breathing gas with oxygen concentration

greater than 23% by volume

(iii) Chemical oxygen or liquid oxygen

84.242 Interchangeability of O_2 and air; use of 100% O_2 in open flames and high heat.

(b) Do not use such apparatus when there is direct exposure to open flames or in high radiant heat. (This limitation applies to 100% oxygen apparatus only.)

84.245 Timers.

(f) Cylinder pressure is reduced to between 20-25% of its rated service time.

(g) Use same tolerance spread as (f). Is 20-25% a typing error? Currently specify 25 ±2%.

(h) Need to define location of noise measured; at users ear level or indicator source.

(i) Seven seconds for timers to indicate the remaining service-life is very short when compared to the 20-25% required for cylinder pressure which would be approximately 17 minutes for two hour SCBA.

84.246 Hand Operated Valve.

(i) Safety Relief Valves.

(1) The relief valve should be required to open at a minimum of 0.5 in.w.c. above full bag pressure to assure complete filling of bags and should be allowed any maximum as long as the unit meets 84 @ 248-5(b)(3). The purpose of this test to assure complete filling of the bags. Because this test is specified in order to ensure complete filling of the bag, it would be better to flow a steady flow into the bag and specify that the relief valve will not vent until the bag contains 5 liters of gas. The bags could be evacuated to -1.0 inch H_2O

column and hose 1.5 lpm exhaled into the bags. The vent valve would not be allowed to vent until 3 minutes 20 seconds after the pressure in the bags reached 0.0 inch H_2O column. Also, it would help if the flow at which the relief valve pressure was tested was stated. Mode 1 failure is not clear. Failed open mode, does that mean the first stage regulator is tampered with in order to supply the facepiece pressure regulator with full cylinder pressure.

84.248-1 Components Exposed to Oxygen.

There is an ASTM specification for oxygen compatibility of materials to fluid and gaseous impact and mechanical impact. It can be used for any mix of gas if properly specified. ASTM G86-84, G74-82 and G63-83 serving as a standard guide for evaluation of materials for such use. NIOSH could specify pressure threshold, etc.

84.248-3 Breathing Bag Test.

ASTM has a test for permeability to gases which we suggest NIOSH specify. Material to meet permeability test per ASTM F739-81 test samples are three, 3.00 x 3.00 x thickness of bag material used.

Test Temperature: 27 ±3 degrees C
Challenge Gas: Gasoline Vapor in Nitrogen, Saturated
Minimum average breakthrough time to be twice the specified life of the apparatus.

84.248-4 Weight Markings.

The fully discharged weight of a closed circuit apparatus will change from time to time because of excessive moisture in the CO_2 scrubber, depending on duration and amount of work completed during the use cycle.

84.248-5 Breathing Resistance Test.

(b) Instead of limiting static pressure, limit the

imposed work of breathing.

(2) NIOSH could impose a maximum work of breathing value, similar to the attached Naval report 2-80, page 47 and figure 4 from page 45. The most important properties of an SCBA are protection and work imposed on user. Protection should be kept to a maximum and imposed work to a minimum. Work is determined by making an X-Y plot of flow vs. facepiece pressure. The area inside the loop is a measure of work. NIOSH should specify 0.0 minimum facepiece pressure and maximum work limits.

Breathing Work Data (From Naval Report 2-80)

Breathing work is defined as the external respiratory work required by a diver to operate his breathing apparatus. Since pressure multiplied by change in volume equals work by definition, the area enclosed by the pressure volume loop (Figure 4) is equal to the work of breathing required to operate the scuba regulator.

The previous NEDU (Navy Experimental Diving Unit) performance requirement for scuba regulators was based on a mil spec which cited peak inhalation and peak exhalation pressures as the standards for evaluation. Breathing resistance is a reasonable method of evaluating scuba regulator performance. Because peak breathing effort normally occurs at the peak inhalation and exhalation flow rates in a conventional, non-assisted regulator, breathing resistance and breathing work are approximately proporational. Therefore, breathing resistance is a valid measure of comparing the performance of this group of regulators.

However, few scuba regulators produced today are purely non-assisted. Most have venturi, vortex or pilot assisted boosters to assist second stage inhalation performance. The result is that while the peak inhalation pressures from an assisted and non-assisted regulator may be similar, the breathing work for the assisted regulator drops

6

DEPARTMENT OF THE NAVY
NAVY EXPERIMENTAL DIVING UNIT
PANAMA CITY, FLORIDA 32407

NAVY EXPERIMENTAL DIVING UNIT

REPORT NO. 2-80

EVALUATION OF COMMERCIALLY AVAILABLE OPEN CIRCUIT SCUBA REGULATORS

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MARCH 1980

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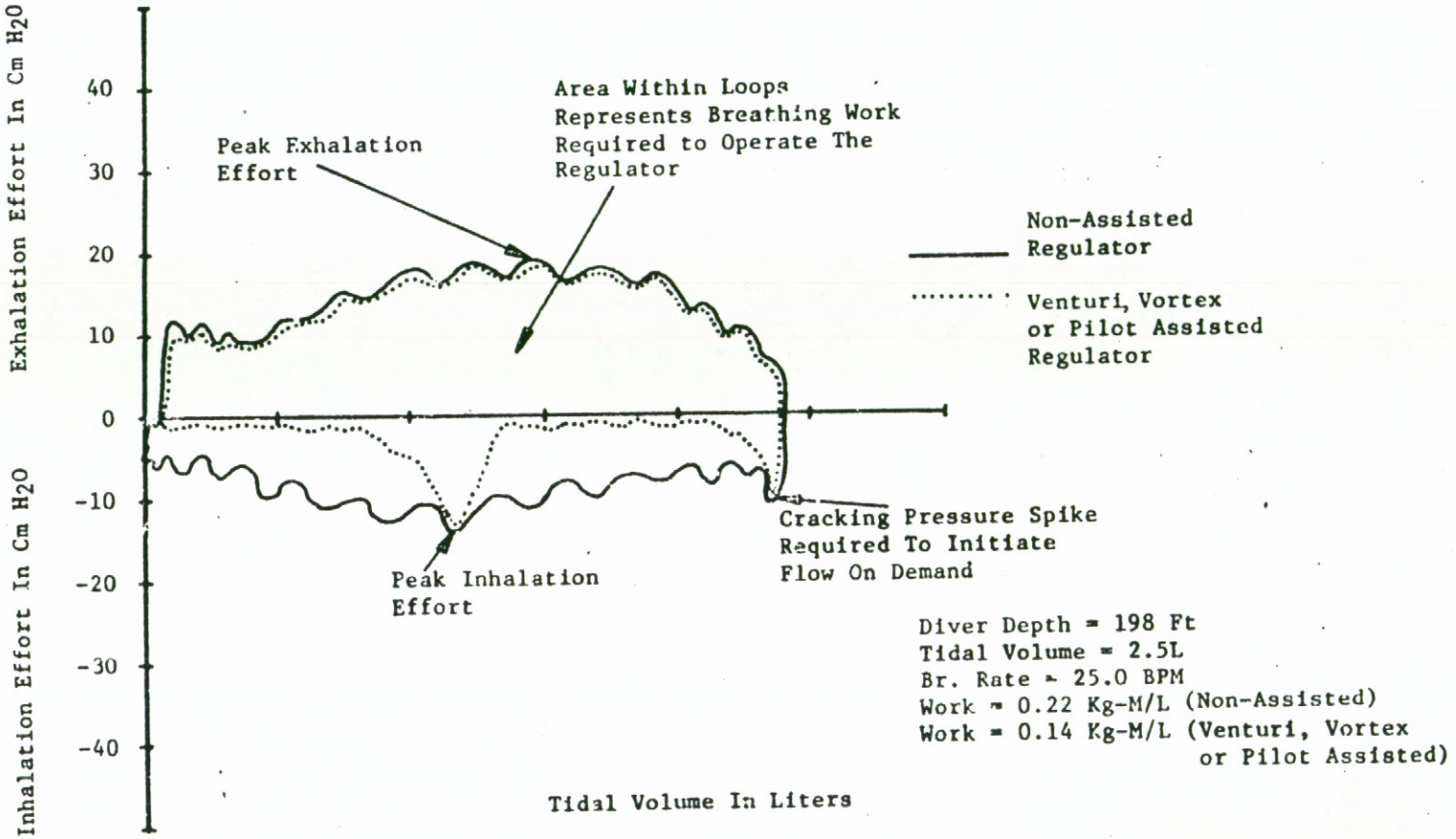


Figure 4. Sample Breathing Resistance Versus Tidal Volume Loop (P-V Loop)

significantly since this peak inhalation pressure occurs for a much shorter period of time. This fact is illustrated in Figure 4. Work of breathing, defined as the area enclosed within the P-V loop, is seen to be much larger for the non-assisted regulator (solid curve) than the area representing the assisted unit (dotted curve). Consequently, while peak pressures on two different regulators may be identical, the actual respiratory work required from the diver can be significantly different. In addition, how "hard", or "easy" a regulator breathes is a direct function of whether or not the diver has to maintain the peak inhalation and exhalation pressures for the entire breathing cycle.

It was for this reason that breathing work rather than breathing resistance is the more valid approach for setting performance standards.

84.248-7(a)(4) Bypass Gas Flow.

Does this mean the user cannot adjust the valve at flow rates less than 85 lpm or is 85 to 130 lpm with bypass valve full open?

84.248-9 Service Time for Closed Circuit.

Please state the SCBA must last for rated duration for all manned tests that last that long and that manned test 4 is the only test to last longer than two hours, and, therefore, the only test required for full duration for long duration units. Will paragraph 84.229, 95% of target population apply during service time?

Clifton believes there is a "field requirement" for a mixed-gas (oxygen enriched stored gas), semi-closed circuit apparatus which incorporates a regulator similar to the open circuit apparatus, for use with long-term, self-contained chemical protective ensemble. (Please see U.S. Department of Commerce NTIS Pub. PB 84-168640.) However, for this type of apparatus the long duration (two hours) service time test can best be determined with a machine test similar to the open circuit apparatus.

84.248-11 Low Temperature Test.

(a) Please state how, when and what samples are to be taken continuously. Does .5% CO_2 apply, and 19.5% O_2 etc.

(b) Cold soak for 16 hours, was 4; some elastomers keep getting harder after 4 hours.

84.248-12 Shock and Vibration Tests.

(a) The vibration IAW MIL-STD-810 needs additional definitions on test procedure and test conditions, etc., amplitude, frequency and duration. Clifton suggests Test Procedure I, Test Condition I 3.2.10, Test Level I 3.2.12, Fig. 514.3-36, test duration one hour in axis the SCBA is mounted in.

84.248-13 Use Test.

NIOSH should perform use tests with periodic sampling and treadmill tests with workrate increasing from rest to running to determine how unit performs with man at all workrates. Also, they should figure a way to continuously monitor manned tests.

84.248-17 Flammability.

Should have flammability requirements for complete SCBA, including case and harness.

84.248-18 Regulator Overpressurization.

How will the regulator be blocked? Will it be possible to put a relief valve in the regulator somewhere to prevent diaphragm rupture?

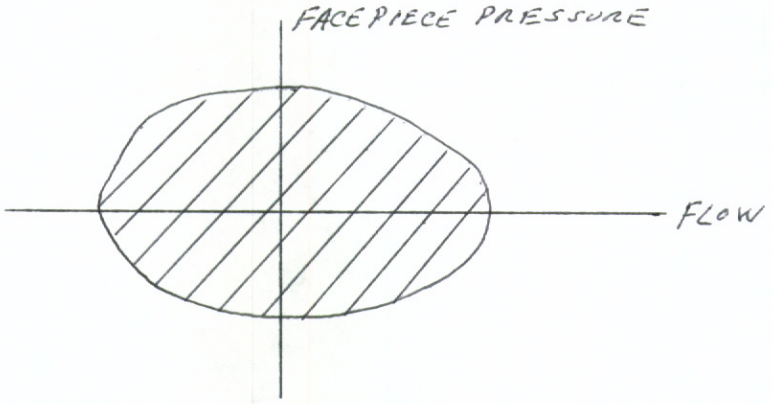
Appendix A - Assumed Conditions of Use (Page 32442)

(j)(3) The concentration of oxygen may exceed 23% maximum in ANSI Z86 standard for type 1, grade D in mixed compressed gaseous breathing air, but shall not exceed a mean average of 30% in the breathing loop. However, momentary

peaks above 35% oxygen shall be acceptable.

Clifton has a general suggestion on the testing and evaluation of SCBA.

If NIOSH would determine work of breathing incurred on the user by the SCBA similar to what the Navy does,



Where an X-Y Plot of breathing volume (flow) vs. face piece pressure is measured, the area within the loop is work of breathing imposed on the wearer by the SCBA. The work of breathing could be measured at 40 and 100 lpm and those values along with protection factor would then be marked on the approval label of the SCBA.

An additional suggestion that would assist SCBA buyers and users is for NIOSH to measure work imposed on the wearer by the face piece pressure (work of breathing) and for NIOSH to require the printing of the work of breathing and protection factor values on the approval label, perhaps with the minimum required value required by NIOSH along side for comparison, or perhaps some measure in which the SCBA meets or exceeds the required NIOSH limits. For example: This unit imposes x.xx watts of work on the user due to breathing, this unit sustains a protection factor of x:xxx., with notes concerning the fact that these are lab results, etc. The information could be used in the same way as a car's miles per gallon

rating is used for automobiles.

The work of breathing could be a time weighted average based on manned test #4 with Pulmonary Ventilation Values based on steady state value predicted by kamon.

Clifton Precision appreciates the opportunity to review this proposed revision and offer our comments and recommendations to 42 CFR Part 84.

Sincerely,

LITTON SYSTEMS, INC.
CLIFTON PRECISION INSTRUMENTS AND LIFE SUPPORT DIVISION

Duane Hinds
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