National Institute for Occupational Safety and Health
National Personal Protective Technology Laboratory
Respirator Branch
626 Cochrans Mill Road
Pittsburgh, Pennsylvania 15236

Date: November 17, 2001	NOTE: The Respirator Branch maintains an updated index of current procedures.

LABORATORY RESPIRATOR PROTECTION LEVEL TEST QUANTITATIVE (HIGH-FLOW DEEP PROBE CORN OIL) FOR SELF-CONTAINED BREATHING APPARATUS WITH FULL FACEPIECES STANDARD TESTING PROCEDURE (STP)

1. PURPOSE

This test establishes the procedures for ensuring the level of respiratory protection provided under special Chemical, Biological, Radiological, and Nuclear (CBRN) requirements for Self-Contained Breathing Apparatus (SCBA) with Full Facepieces submitted for Approval, Extension of Approval, or examined during Certified Product Audits, meet the minimum certification standards set forth in 42 CFR, Part 84, Subpart G, Section 84.63(c). The purpose of this test is to ensure that CBRN SCBA have (1) good face-fitting characteristics that can accommodate a wide variety of facial sizes and shapes, and (2) instructions for facepiece size selection and donning that are easily understood, easily followed, and effective. To that end, each CBRN SCBA respirator will be evaluated on a panel of 25 to 40 test subjects having facial sizes and shapes that approximate the distribution of sizes and shapes of the general population.

2. GENERAL

This procedure describes the Laboratory Respirator Protection Level (LRPL) Test [Quantitative High-Flow Deep-Probe Corn Oil] for Self-Contained Breathing Apparatus with Full Facepieces in sufficient detail that a person knowledgeable in the appropriate technical field can select equipment with the necessary resolution, conduct the test, and determine whether or not the product passes the test.

3. EQUIPMENT/MATERIALS

3.1. The list of necessary test equipment and materials follows:

3.1.1. Corn oil - 99%. Source – Commercial Product Name; Maise Oil, Maydol, Mazola Oil, Maize Oil (Must comply with Chem. Abstract No. 8001-30-7)

3.1.2. Environmental test chamber & plenum system with at least 24 square feet of interior floor space and an interior height of at least 7 feet, or equivalent. The chamber shall be designed so that the individual performing the test is visible at all times while in the chamber. The chamber design should include an entry vestibule designed to allow entry and exit from the chamber with minimal disturbance to the aerosol concentration and uniformity. The vestibule shall be large enough to accommodate

door swing and a test subject with the other door closed. The test chamber shall be capable of maintaining spatial uniformity within ±10 percent in the vicinity of the respirator being tested. The challenge aerosol concentration shall not vary as a function of time more than ±10 percent over the duration of a single test (approximately 15 minutes). The aerosol challenge shall be characterized to verify that the aerosol is within specified physical parameters.

3.1.3. DataAire Model DAP-2 Environmental Control System (20-80% RH $\pm$ 5%, 65-95 $\pm$ 5^{o}F), normal operating conditions (ambient target) for LRPL Tests (70^{o}F, 50% RH), or equivalent

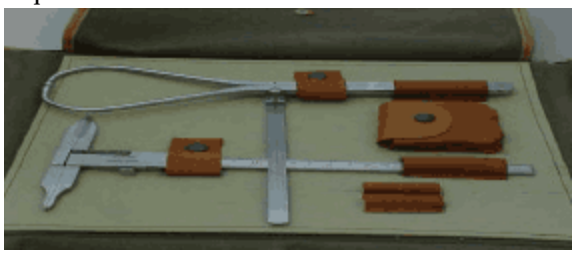
3.1.4. TSI Laser Photometer Model 8520, or equivalent, having a minimum limit of detection $\leq$ .01 mg/m^3 or 0.01 percent, shall be used to measure the aerosol challenge/leak concentration and accurately measure fit factors of at least 10,000.

3.1.5. MSP Model 2045 High Output Aerosol Generator, or equivalent, delivering 15 to 40 mg/m^3 corn oil challenge aerosol concentrations with a Mass Median Aerodynamic Diameter (MMAD) of 0.4 to 0.7 µm in the test chamber. The geometric standard deviation shall be less than 2.0. The chamber aerosol concentration shall not vary as a function of time more than ±10 percent over the duration of a single test (approximately 15 minutes). The test chamber shall be capable of maintaining spatial uniformity within ±10 percent in the vicinity of the respirator being tested. The challenge aerosol shall not be recycled.

3.1.6. A means of providing two-way communication between the test subject and test conductor shall be provided.

3.1.7. Each applicant for approval shall provide 11 to 25 full facepieces with nosecups of good quality and condition in each size according to the testing requirements set forth in Appendix B. The inward leakage of the respirator will be determined by continuous sampling the concentration of challenge aerosol inside the facepiece with a probe inserted into the facepiece (or nosecup if the respirator is so equipped). The probe shall be of the shape defined by Liu [AIHAJ (45):278-283, 1984] and shall not interfere with the fit or function of the respirator.

3.1.8. Sliding measurement calipers, Seritex model GPM 104, 0-200 mm length, 0-50 mm depth or equivalent.



3.1.9. Spreading measurement calipers, Seritex model GPM 106, 0-300 mm width or equivalent.

3.1.10. Twenty-five to forty test subjects meeting requirements of the NIOSH Human Subject Review Board (HSRB) approved Protocol. Refer to HSRB-01-NPPTL-01, "Protocol for the Testing of Respiratory Protective Devices." See Appendix E for the proper consent form and complete details on the use of human test subjects in respirator certification testing.

4. TESTING REQUIREMENTS AND CONDITIONS

4.1. At a minimum, all measuring equipment utilized for this testing must have been calibrated within the preceding 12 months using a method traceable to the National Institute of Standards and Technology (NIST), or more frequently if specified by the equipment manufacturer. Equipment calibration records shall be available for examination at each testing facility. Prior to beginning any testing, a statement that all test equipment is within calibration shall be attested by the lab technician on each test report.

4.2. The test subjects shall be subjected to initial and annual physicals along with supplemental facial measurements. The facial measurements shall be used to determine facial size.

4.3. Prior to conducting the test, the Users Instructions provided by the manufacturer shall be reviewed to verify that the instructions for facepiece size selection are easily understood, easily followed, and practical. Test subjects will familiarize themselves with the manufacturer's selection, donning and fitting procedures for the SCBA facepiece, and may receive training from manufacturer representatives.

4.4. If the respirator facepiece is available in multiple facepiece sizes, the manufacturer's instructions for size selection shall be followed to determine consistency with LANL Panel cells. Inconsistencies should be noted in test reports. The test subject must be fitted with the facepiece size determined by facial measurements.

4.5. Each full facepiece shall be probed for purposes of measuring concentrations of corn oil inside the facepiece nosecup. The primary sampling location shall be in the oral/nasal region. When sampling in the oral/nasal cavity, the optimum sampling probe position is approximately 1/4 inch from the skin at the point of quadrilateral symmetry of the mouth and nose, i.e. midway between the nose and upper lip. The exact position(s) of the sample probe(s) will depend upon the design of the mask being evaluated.

4.6. Each test subject shall perform an unassisted donning of the respirator facepiece in accordance with the manufacturer's instructions. Each test subject will be permitted time to make the appropriate adjustments to the facepiece until they are satisfied that they are wearing the full facepiece in compliance with the manufacturer's Users Instructions. Each test subject shall wear the respirator facepiece for approximately 15 minutes before entering the test chamber.

4.7. A short length of tubing will then connect the sample probe(s) in the mask to the aerosol detector unit. Air shall be sampled out of the respirator at a range of 2 to 5 ± 0.1 Lpm. The method in which the sampling probe(s) is used shall not interfere with respirator performance and shall minimize sampling biases.

4.8. Protection level testing of full facepieces used on positive-pressure SCBA's under this procedure will be accomplished by following the manufacturer's instructions for temporarily converting the facepiece into a negative-pressure respirator with appropriate P100 filters. The manufacturer must furnish the adapter for this conversion. Facepiece modifications made to accommodate this testing shall not significantly alter the fit of the respirator. The weight and other characteristics of the facepiece assembly used during this protection level testing should be representative of the facepiece used on the SCBA.

4.9. Fit chamber conditions must be:

4.9.1. Temperature Range = 68-80 ^{o}F

4.9.2. Corn Oil Challenge Concentration = 15-40 mg/m^{3}

4.9.3. The oxygen level shall be at least 20% for the duration of each test.

4.10. Normal laboratory safety practices must be observed. This includes all safety precautions described in the current NIOSH Appalachian Laboratory for Occupational Safety and Health (ALOSH) Facility Laboratory Safety Manual, U.S. Army Soldiers and Biological Chemical Command Laboratory Safety Manual, or equivalent.

4.11. Each applicant submitting a SCBA respirator for approval must provide donning instructions and sizing requirements if more than one size respirator is being tested. All manufacturers must provide the test facility with at a minimum, 11 to 25 good quality respirator facepieces in each size range as defined in Appendix to the test facility. If the respirator has a non-destructive sampling port then it will be used. If not, the respirator may have to be destructively probed.

5. PROCEDURE

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

5.1. Close the inside and outside vents, and turn off exhaust fan. Ensure all covers are closed and sealed in side bulkhead fittings.

5.2. Add neat corn oil to the aerosol generators and allow 15 minutes for the chamber concentration distributions to stabilize. The test challenge must be a non-toxic aerosol approved for human use.

5.3. Test subjects shall be representative of the target population based on the Los Alamos Study Anthropometric Distribution. Test subjects shall be selected to cover all panels of the Los Alamos Study (refer to Appendix A). A minimum of 50 data points shall be collected by two donnings by test subjects of each facepiece size for each respirator submitted to NIOSH. At a minimum, the anthropometric measurements, face length (Menton-Nasal Root Depression or Menton-Sellion) and face width (Bizygomatic diameter) shall be taken for mask size determination. In addition, neck circumference shall be recorded for systems that use a neckdam or second skirt.

5.4. The masks shall be properly sized and fitted on clean-shaven human test subjects. Prior to LRPL testing, training will be conducted by test personnel or manufacturer's representatives based on the manufacturer's instructions. The instruction period will be a minimum of 10 minutes and a maximum of 30 minutes. All test subjects shall be trained. Manufacturers may request the opportunity to observe LRPL testing.

5.5. Procedures must ensure that test subject entering and exiting the chamber do not adversely affect chamber test conditions.

5.6. Twenty-five test subjects will successively wear the self-contained breathing apparatus facepiece into the chamber. An exercise routine intended to stress the face seal and approximate field use conditions shall be used. Each exercise shall be performed for one minute in duration. The LRPL Test consists of a set of eleven standard exercises (eleven minutes total) using a routine devised to stress the face seal of the respirator facepiece. During the test, each test subject will be asked to perform the following eleven exercises for one-minute each (8 OSHA standard exercises plus 3 additional first responder exercises*):

1. Normal Breathing
2. Deep Breathing
3. Turn Head Side to Side
4. Move Head Up and Down
5. Recite the Rainbow Passage
6. Sight the Rifle*
7. Reach for the Floor and Ceiling
8. On Hands and Knees, Turn Head Side to Side*
9. Grimace Exercise
10. Climb the stairs at regular pace*
11. Normal Breathing

5.7 The test subject anthropometric panels must meet the requirements outlined in Appendix B.

5.8 At the conclusion of testing, each test subject will exit the chamber. The subject shall quickly exit from the test chamber and leave the test area.

5.9 All test subject's comments will be written on the test data sheet (Appendix D).

Note: Extension of Approval testing will be conducted only on self-contained breathing apparatus facepieces. (Is this note necessary?)

Note: This test should be done on a minimum of 11 to 25 respirators in the required size ranges (new approval), or more if additional testing is required [reference 42 CFR, Part 84 Sections 84.63(c) and Appendix B].

6. Analysis and Presentation of Data

6.1. Results of all Laboratory Respiratory Protection Level (LRPL) testing will be reported in terms of values that were observed under the standard referenced test conditions. As a minimum, LRPL testing reports shall include the following:

(a) Test conditions (see Appendix C)

(b) Overall LRPL results for each subject, anthropometric panel cell number, along with LRPL's by exercise set. (see Appendix C)

(c) Record of Comments of Test Panel subjects. (see Appendix D)

6.2. Data Analysis:

6.2.1. All LRPL test data will be subjected to the following analysis. Respirator facepiece performance will be quantified in terms of a laboratory respiratory protection level (LRPL). The LRPLe for each exercise equals the ratio of the challenge aerosol concentration to the in-facepiece aerosol concentration as quantified by the photometer. An LRPL for each test subject (LRPLi) is calculated from the individual exercise data. The harmonic average of individual LRPLi are then used to calculate an overall LRPL for a subject (LRPLo) as follows:

$$LRPLi = \sum_{e\text{-}1 \text{ to } 11} LRPLe / 11$$

where e is the number of exercises,

$$LRPL_o = \frac{\text{Number of Test Subjects}}{1/LRPL_1 + 1/LRPL_2 + 1/LRPL_3 + \ldots\ldots\ldots\ldots + 1/LRPL_n}$$

where n is the number of test subjects. The overall LRPL provides a time-integrated measure of the protection level afforded. Under the conditions of this test and the sensitivity of the photometer, the maximum LRPL that can be reported is 100,000. Each LRPL will be calculated by a computer and stored to disk.

7. PASS\FAIL CRITERIA

7.1. The criterion for passing this test is set forth in the NIOSH Guide to Industrial Respiratory Protection (DHHS (NIOSH) Publication No. 87-116) and 29 CFR 1910.134. The respirator will be considered to be in compliance when at least 24 of the 25 test subjects achieve values of LRPL that are equal to or greater than the value listed in the following table:

APPROVAL STANDARD		
Respirator /Class	Pass Percentages	LRPL Levels
SCBA – negative pressure mode	95%	500 Minimum

7.2. This test establishes the standard procedure for ensuring that:

84.63 Test requirements; general.

(a) Each respirator and respirator component shall when tested by the applicant and by the Institute, meet the applicable requirements set forth in subparts H through L of this part and NFPA 1981 – current edition.

(c) In addition to the minimum requirements set forth in subparts H through L of this part, the Institute reserves the right to require, as a further condition of approval, any additional requirements deemed necessary to establish the quality, effectiveness, and safety of any respirator used as protection against hazardous atmospheres.

(d) Where it is determined after receipt of an application that additional requirements will be required for approval, the Institute will notify the applicant in writing of these additional requirements, and necessary examinations, inspections, or tests, stating generally the reasons for such requirements, examinations, inspections, or tests.

7.3. The wearer shall not be subjected to any undue discomfort or encumbrance because of the fit, air delivery, or other features of the respirator during the testing period.

8. RECORDS\TEST SHEETS

8.1. All test data will be recorded on the LABORATORY RESPIRATOR PROTECTION LEVEL TEST QUANTITATIVE (HIGH-FLOW DEEP PROBE CORN OIL) FOR SELF-CONTAINED BREATHING APPARATUS WITH FULL FACEPIECES test data sheets (Appendices C & D).

8.2. All videotapes and photographs of the actual test being performed, or of the tested equipment shall be maintained in the task file as part of the permanent record.

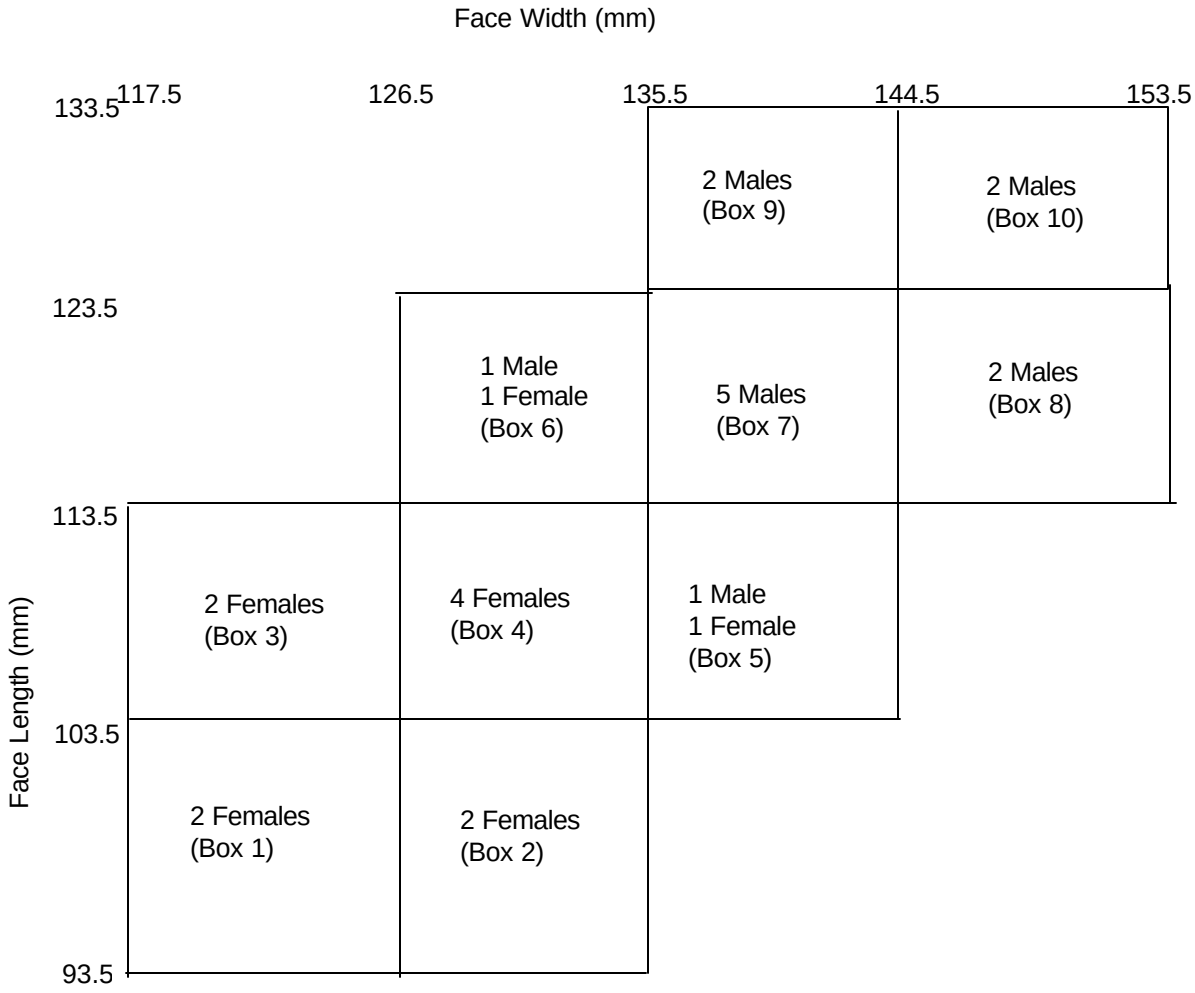
8.3. All equipment failing any portion of this test will be handled as follows;

8.3.1. If the failure occurs on a new certification application, or extension of approval application, the SBCCOM Mask Fit Test Facility Manager will send a test report to the NIOSH Respirator Certification Team (RCT) Leader and prepare the hardware for return to the manufacturer.

8.3.2. If, the failure occurs on hardware examined under an Off-the-Shelf Audit the hardware will be examined by a SBCCOM technician, SBCCOM Mask Fit Test Facility Manager, and the RCT Leader for cause. All equipment failing any portion of this test may be sent to the manufacturer for examination and then returned to NIOSH. However, the hardware tested shall be held at the testing laboratory until authorized for release by the RCT Leader, or his designee, following the standard operating procedures outlined in Procedure for Scheduling, and Processing Post-Certification Product Audits, RB-SOP-005-00.

RECORD OF CHANGE:

Appendix A



Los Alamos Scientific Laboratory
Male-and-Female, 25 Member Panel for
Testing of Full-Face Masks

Note: For the purpose of this testing, test subjects in each box may be male or female.

Appendix B

Test panels used for the Laboratory Respirator Protection Level Tests

Group 1

Manufactures with 3 Facepiece Sizes: Total panel of 25 test subjects, two replicates each

Small size

Panel face sizes –Boxes 1, 2, 3, 4; panel size 10 (2 or 3 each size for 10 total samples)

Medium size

Panel face sizes - Boxes 3, 4, 5, 6, 7, 8; panel size 17 (2 or 3 each size for 17 total samples)

Large size

Panel face sizes – Boxes 7, 8, 9, 10; panel size 11 (3 each size for 11 total samples)

Manufactures with 2 Facepiece Sizes: Total panel of 25 test subjects, two replicates each

Small/medium size

Panel face sizes 1, 2, 3, 4, 5, 6; panel size 14 (2 each size for 14 total samples)

Medium/large size

Panel face sizes 5, 6, 7, 8, 9, 10; panel size 15 (2 or 3 each size for 15 total samples)

Criteria: Only one failure will be allowed for two facepiece sizes, and 2 failures allowed for 3 facepiece sizes. These SBCA respirators are designed to fit specific facial size ranges (such as small) but are not expected to fit all subjects of that size range. When a small sample size is used (<25), statistical analysis is not practical.

Group 2

Manufactures with a Single Facepiece size

Universal (one size fits all)

Panel size – Every Box 1-10; panel size 25 (2 or 3 for each size for 25 total samples)

Criteria:
Whenever a full panel of sizes 1 through 10 is used to evaluate a respirator, 1 failure will be allowed. This is because, when a 25 person panel size is used consisting of all 10 facial sizes, it is statistically unlikely that any respirator design can be expected to fit all individuals due to the human variability in facial structure.

Appendix C

LABORATORY RESPIRATOR PROTECTION LEVEL TEST
QUANTITATIVE (HIGH-FLOW DEEP PROBE CORN OIL) FOR
SELF-CONTAINED BREATHING APPARATUS WITH FULL FACEPIECES
Test Data Sheet

Task #		**Test Date:**	
Manufacturer Name:			
Model Number/Serial No.			
Facepiece Number/Name			
Test Temperature & RH:			
		Operators Initials	
Equipment Calibrations Current		**Yes/No:**	

Test Subject Number	Test Suject Identification	LANL Panel Cell #	$LRPL_1$	$LRPL_2$	Individual Test Subject Average
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					
21					
22					
23					
24					
25					
26					
27					
28					
29					
	Grand Average				

Requirement: The respirator will be worn in an atmosphere containing 15 to 40 mg/m3 corn oil vapor with a Mass Median Aerodynamic Diameter (MMAD) of 0.4 to 0.7 µm, and the minimum Laboratory Respirator Protection Level shall be 500 with not one of the test subjects shall detect any odor of the test gas or vapor in the air breathed during any such test, and the wearer shall not be subjected to any undue discomfort or encumbrance because of the fit, air delivery, or other features of the respirator during the testing period. Reference: (42 CFR, Part 84.63c)

APPROVAL			Operators Initials	
Respirator /Class	**Pass Percentages**	**LRPL Levels**	**Pass**	**Fail**
SCBA – negative	**95%**	**500 Minimum**		

Test Administrator Signature: _____ **Date of Completion:** _____

Appendix D

LABORATORY RESPIRATOR PROTECTION LEVEL TEST
QUANTITATIVE (HIGH-FLOW DEEP PROBE CORN OIL) FOR
SELF-CONTAINED BREATHING APPARATUS WITH FULL FACEPIECES

Comment Sheet

Task #	
Manufacture Name	
Model Number/Name	
Test Date	

	Test Subject Identification	
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		
12		
13		
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15		
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22		
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25		
26		
27		
28		
29		

Test Administrator Signature: _____ **Date of Completion:** _____

Appendix E

Laboratory Respirator Protection Level Test

Quantitative Corn Oil Fit Testing Procedure

For Chemical, Biological, Radiological, Nuclear Respirator Evaluations

Medical Screening and Test Subject Consent Forms

Original: 10/18/2001
Revised:

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH (NIOSH)
CENTERS FOR DISEASE CONTROL AND PREVENTION
U.S. PUBLIC HEALTH SERVICE
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

AND

SOLDIERS AND BIOLOGICAL CHEMICAL COMMAND (SBCCOM)
U.S. ARMY

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

You have been asked to participate in a joint NIOSH and SBCCOM research study. We explain here the nature of your participation, describe your rights, and specify how NIOSH and SBCCOM will treat your records.

I. DESCRIPTION

1. Project Title: "LABORATORY RESPIRATOR PROTECTION LEVEL TEST QUANTITATIVE (HIGH-FLOW DEEP PROBE CORN OIL) FOR SELF-CONTAINED BREATHING APPARATUS WITH FULL FACEPIECES STANDARD TESTING PROCEDURE (STP)"
   Document A: Medical Screening and Test Subject Consent

2. Sponsor and/or Project Officer: This project is a collaborative study by NIOSH and SBCCOM with Co-Project Officers:
   John M. Dower, NIOSH
   Alex G. Pappas, SBCCOM Mask Fit Test Facility Manager

3. Purpose and Benefits: The purpose of our overall study is to evaluate and certify respirators to make sure they are safe and work properly. The procedures for testing respirators have been developed jointly by senior scientists and engineers from NIOSH and SBCCOM. Because of unique test system requirements, the testing will be conducted at the SBCCOM Fit Testing Facilities, Edgewood, Maryland under provisions of an Interagency Agreement with the NIOSH Respirator Branch. Under the provisions of this Interagency Agreement, SBCCOM will function as NIOSH's testing agent.

   Information generated by this research project will benefit:

a. you, the participant, by providing a better understanding of respirators and their performance. Also, you will receive a free limited annual medical examination if you qualify to participate in the testing program. However, annual medical physicals will be terminated at the end of the program.

b. workers who routinely use this same type of respirator, by ensuring that respirators in the field perform as they were certified by NIOSH to perform, and thus provide the expected level of respiratory protection.

c. those involved in testing, certifying, and manufacturing respirators by providing feedback on how respirators perform in the field.

d. workers such as HazMat responders, firemen, police, and emergency medical service personnel for protection against terrorism agents, toxic compounds and oxygen deficiency.

II. CONDITIONS OF THE STUDY

1. Participation in this study consists of two parts. The first part is a brief medical screening. If the results of your medical screening indicate that you can participate in the testing of respirators, you will be invited to enter a pool of subjects who will be called upon from time to time to perform a series of simple tasks such as walking up stairs, turning their head from side to side, or sighting a rifle while wearing a respirator. At this time, we are only asking for your consent to perform the medical screening. If you are eligible for the testing program, we will invite you back and explain the respirator test program in greater detail.

   The medical screening consists of:

   a) a brief health questionnaire, asking general questions about current physical condition, medical history, pulmonary illness or disease, and experience with respirators and masks.
   b) a resting EKG to test your heart. This involves attaching some electrodes to the surface of the skin on your chest and legs and measuring your heart beat. This is a painless procedure although some individuals may develop a slight skin irritation or a mild rash from the electrode paste.
   c) a breathing test (pulmonary function test) to measure your lung capacity. This involves blowing as hard as you can into a tube. Some individuals may become temporarily winded or lightheaded during the breathing test. On rare occasions, an individual may faint.
   d) a standard hearing test. The hearing test consists of a series of sounds of different intensities and frequencies. All you need to do is to signal every time you hear a noise through a set of earphones. There are no apparent risks associated with the hearing test.

e) a measurement of your face to determine what size or model respirator is most appropriate for you should you be called back for later testing.

The physical examination will be provided by a licensed physician at no cost to you. . All hearing tests are given by qualified technicians. The first portion of the test will take about 45 minutes.

You will be asked not to take part in uncomfortable or strenuous activity, smoke, eat, or drink anything (other than plain water) for at least 2 hours before the physical examination.

2. Recruitment and Screening of Test Subjects: The U.S. Army Soldiers and Biological Chemical Command will maintain a pool of perspective human test subjects for use in the testing of respirators. All test subjects will be healthy volunteers between the ages of 18 and 49 years. Compensation will be given to non-Federal Government employees at the rate of $25.00 to $50.00 depending upon the test being conducted. Compensation will not be given to Federal Government employees. No NIOSH employees will be included.

Prospective human test subjects are recruited by word-of-mouth.

Prospective test subjects will be screened for fitness to be added to the NIOSH-SBCCOM LRPL human test subject pool.

Prior to testing all test subjects are given an annual physical examination (which includes completing the OSHA Respirator Medical Evaluation Questionnaire and Clinical History and Exam Form) by a qualified physician. Any new test subjects (when required) will be given an interview and get their faces measured (for size according to the Los Alamos schedule for face sizes), have a physical, and be added to a pool of approximately 40-100 test subjects. Testing dates for respirator testing vary with respirator manufacturer's request. On average for certification testing, 25 to 40 subjects will be selected from this pool (approximately 30 times per year) to perform LRPL Quantitative Respirator Test. The frequency of certification testing is dependent on the types of request from manufacturers but subjects can expect to be called on approximately 10 times per year for testing. If selected for testing in the NIOSH-SBCCOM research projects, there are from 20 to 30 tests per project per year for one or two projects per year for each test subject selected and tests are usually scheduled weekly. Selection from the pool is determined by the availability of the test subject. Prior to performing the LRPL Quantitative Test, test subjects are administered the Screening Questionnaire for the LRPL Test. This is to make certain the test subject does not have any problem completing a moderate work test.

Criteria of the American College of Sports Medicine and the American Heart Association will be used by a qualified physician to determine fitness to do the LRPL tests. However, these criteria are meant to cover the testing of all subjects, including

many individuals who are tested for clinical management purposes because they have various types of cardiac disease. Since this project is interested in respirator performance and not an individual's results, it will use essentially healthy test subjects. Therefore, additional criteria are included to screen out certain subjects who may have an increased risk during exercise.

SBCCOM contracts with a local health care provider to conduct the medical examination and screening procedure. As part of this contract, the health care provider provides a written summary of the examination and test results to each prospective test subject. This written summary includes a statement of the subject's suitability for participation in the testing at SBCCOM. Each of the attached consent forms includes a draft of an example notification letter. The actual letter is sent by the health care provider and is updated from time to time.

The physician will evaluate all medical data and recommend those test subjects suitable for addition to the NIOSH-SBCCOM test subject pool. The physical examination will be repeated every year to determine a subject's continued suitability of inclusion on the NIOSH-SBCCOM test subject pool.

If selected for the program, we will ask you back in about one month to start the actual respirator testing. We will explain the procedures in detail to you at that time and have you sign a separate consent form. Once enrolled in the program you will be given this health evaluation every 12 months for as long as you choose to continue in the testing program.

Inclusion Criteria. The majority of the test volunteers will be military volunteers. As military personnel, they receive regular physical examinations by a physician. Furthermore, they are required to be examined by a physician if they should suffer any ailment or physical injury. The use of military personnel will thus help to ensure that the volunteers will be in satisfactory health prior to testing. Any individual who is in satisfactory health and judged by the test director fit to wear a respirator and/or protective clothing can participate as a test subject.

Exclusion Criteria. An inquiry of the health of the volunteers will be made before they are allowed to be tested. Subjects will be excluded from testing if there is any evidence of the following conditions: Heart or circulatory dysfunctions, emphysema or other major respiratory dysfunctions, claustrophobia, head injury, or any other bodily injury which would prohibit the subject from wearing a mask and/or protective clothing and performing the exercises. In addition, volunteers will not undergo testing if they are currently for any reason deemed unfit such that the performance of light to moderate exercise (under the test conditions specified) might pose any significant health risk to the individual. The test director will ensure that the individuals having the previously listed medical conditions will be excluded from participating in the mask fit testing. To certify that the subject has been questioned regarding the status of his current health and relevant history of the medical criteria

associated with this type of test, the questionnaire will be provided for signature as part of the Volunteer Agreement Explanation. Exclusion from the test will be determined by the test director's review of the questionnaire.

Source of Subjects. The majority of the test volunteers will be military volunteers. For most studies, U.S. Army military personnel will be recruited as volunteers from troops stationed at Aberdeen Proving Ground, Maryland. However, civilian test volunteers may also be used occasionally.

Subject Identification System. Prior to testing, each subject will be assigned an identification number using a sequential numbering system. All test data generated will be identified by subject number only to insure confidentially of the subjects identity.

3. If you have any reaction to the medical screening procedures, you should contact Mr. Alex G. Pappas, Mask Fit Test Facility Manager, SBCCOM (410-436-3338) or John M. Dower, Senior IH Project Manager, NIOSH, Respirator Branch, (304) 285-5907.

4. Injury from this project is unlikely. But if injury occurs, medical care, other than emergency treatment, will not be provided. If you are injured during testing through negligence of a SBCCOM or NIOSH employee, you may be able to obtain compensation under Federal Law. If you want to file a claim against the federal government your contact point is: Public Health Service Claims Office (301) 443-1904. If you are injured through the negligence of a NIOSH contractor, your claim would be against the contractor, not the federal government.

   Any serious incident of adverse reaction that should arise during the conduct of this study at SBCCOM will be reported within one hour to Timothy Williams, CIH, CSP, Master Industrial Hygienist and SBCCOM Human Use Chairman at (410) 436-2302.

   If you are injured during testing, you should also contact: Mr. Alex G. Pappas, Mask Fit Test Facility Manager, SBCCOM (410-436-3338); John M. Dower, Senior IH Project Manager, NIOSH, Respirator Branch, (304) 285-5907; Dr. Michael J. Colligan, Chairperson, NIOSH Human Subjects Review Board (513) 533-8222; or Timothy Williams, CIH, CSP, Master Industrial Hygienist and SBCCOM Human Use Chairman at (410) 436-2302.

5. If you have questions about this research, contact: Mr. Alex G. Pappas, Mask Fit Test Facility Manager, SBCCOM (410-436-3338) or John M. Dower, Senior IH Project Manager, NIOSH, Respirator Branch, (304) 285-5907. If you have questions about your treatment or rights as a member of this study, contact: Michael J. Colligan, Ph.D., Chair, NIOSH Human Subjects Review Board at (513) 533-8222; or Timothy Williams, CIH, CSP, Master Industrial Hygienist and SBCCOM Human Use Chairman at (410) 436-2302.

6. SBCCOM Mask Fit Test Facility staff will retain the results of each military and civilian test subject's medical screening. SBCCOM, NIOSH, the test subject and their authorized private physician will have access to medical screening reports. The results of the medical examination will be maintained in a locked file cabinet at the SBCCOM Mask Fit Test Facility and will only be accessible to members of the research staff. NIOSH will provide you and your doctor (if you wish) with all findings from your medical tests and physical examination.

   Your participation in the medical screening for this project is voluntary and you may withdraw your consent and your participation in this study at any time without penalty or loss of benefits to which you are otherwise entitled. The frequency of respirator testing is dependent on the types of request from manufacturers but subjects can expect to be called on approximately 10 times per year for testing.

   For the Medical Screening Test you will receive $50.00. If you are eligible for the respirator testing program you will receive $25.00 per test depending upon the length of the test for each visit or partial visit that you participate in this study. Each visit may consist of multiple 45-minute tests over a 1 to 4 hour testing period depending upon the respirator being tested.

7. Overall results of the testing of the respirators will not contain information useful to you personally. In addition, the results contain certain trade secrets and confidential design operation information that NIOSH and SBCCOM will not release to the public. Because of this, we cannot directly provide you with the overall study testing results. However, the test report with all personal identifiers and trade secret information removed would be available upon written request under the Freedom of Information Act, 5 U.S.C. 552. Send your written request to:

   Freedom of Information Act Officer
   Centers for Disease Control and Prevention
   1600 Clifton Road
   Atlanta, Georgia 30337

NIOSH-SBCCOM SCREENING QUESTIONNAIRE FOR
Laboratory Respirator Protection Level Quantitative Fit Test.

1. Are you in good general health?

2. Do you have any pain when you:

	Yes	No
a. Perform normal breathing	_____	_____
b. Perform deep breathing	_____	_____
c. Nod or turn your head from side to side	_____	_____
d. Move your head up and down	_____	_____
e. Recite the passages from literature	_____	_____
f. Reach for the floor and ceiling	_____	_____
g. Crawl on your hands and knees	_____	_____
h. Perform facial expressions like a grimace	_____	_____
i. Climb the stairs at regular pace	_____	_____

3. Have you ever been treated by a physician for any of the following ailments?

	Yes	No
a. Collapsed lung	_____	_____
b. Dizziness or fainting spells	_____	_____
c. Chronic respiratory illness	_____	_____
d. Asthma	_____	_____
e. Claustrophobia or anxiety reaction	_____	_____
f. Shortness of breathe or breathing problems	_____	_____
g. Heart problems	_____	_____
h. High blood pressure	_____	_____

4. Have you taken medication or seen a physician for any of the following ailments within the last 15 days?

	Yes	No
a. Dizziness or fainting spells	_____	_____
b. Chronic respiratory illness	_____	_____
c. Asthma	_____	_____
d. Shortness of breath	_____	_____
e. Heart trouble	_____	_____
f. High or low blood pressure	_____	_____
g. Ear, nose, or throat trouble	_____	_____
h. Sinusitis	_____	_____
i. Susceptibility to skin reactions	_____	_____
j. History of allergic diseases	_____	_____
k. Upper respiratory tract infection	_____	_____

	Yes	No
5. Have you ever worn a respirator or military mask before?	_____	_____
If so, did you have an adverse reaction before, during, or after wearing the mask?	_____	_____

TEST SUBJECT'S INITIALS _____ DATE_____

III. USE OF INFORMATION

The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), an agency of the Department of Health and Human Services, is authorized to collect this information, including your social security number (if applicable), under provisions of the Public Service Act, Section 301 (42 U.S.C. 241); Occupational Safety and Health Act, Section 20 (29 U.S.C. 669); and the Federal Mine Safety and Health Act of 1977, Section 501 (30 U.S.C. 95). The information you supply is voluntary and there is no penalty for not providing it.

The data will be used to assess the performance of various respiratory protective devices, to make sure they are safe and work properly. Data will become part of CDC Privacy Act system 09-20-0159 "Records of Subjects in Certification, Testing, Studies of Personal Protective Devices, and Accident Investigations" and may be disclosed; to appropriate state or local health departments to report certain communicable diseases; to the State Cancer Registry to report cases of cancer where the state has a legal reporting program providing for the information's confidentiality; to private contractors assisting NIOSH; to collaborating researchers under certain limited circumstances to conduct further investigations; to one or more potential sources of vital statistics to make a determination of death; to the Department of Justice in the event of litigation, and to a congressional office assisting individuals in obtaining their records. An accounting of the disclosures that have been made by NIOSH will be made available to you upon request. Except for these and other permissible disclosures expressly authorized by the Privacy Act, or in limited circumstances when required by the Freedom of Information Act, no other disclosure may be made without your written consent.

IV. SIGNATURES

I have read this consent form and I agree to participate in this study.

PARTICIPANT _____ DATE _____
(signature)

I, the SBCCOM representative, have accurately described this collaborative study to the participant.

REPRESENTATIVE _____ DATE _____
(signature)

REQUEST AND AUTHORIZATION FOR RELEASE OF INFORMATION

I, _____, request and permit the project officer or attending physician to inform the following physicians or health care facilities (whose names and addresses I have entered below) of any significant findings from this study that concern me. (Do not leave blank. Write "No" where you do not wish to give a name and address.)

1. My personal physician(s):

Dr. _____
Street _____
City _____State____Zip_____

2. Other physician or health care facilities:

Name _____
Street _____
City _____State____Zip_____

_____ Date
Participant

1 copy to participant
1 copy to project officer

Document B

Laboratory Respiratory Protection Level Quantitative Fit Test

Original – 10/30/2001
Revised -

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH (NIOSH)
CENTERS FOR DISEASE CONTROL AND PREVENTION
U.S. PUBLIC HEALTH SERVICE
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND

SOLDIERS AND BIOLOGICAL CHEMICAL COMMAND (SBCCOM)
U.S. ARMY

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

You have been asked to participate in a joint NIOSH and SBCCOM research study. We explain here the nature of your participation, describe your rights, and specify how NIOSH and SBCCOM will treat your records.

I. DESCRIPTION

1. Project Title: "LABORATORY RESPIRATOR PROTECTION LEVEL TEST QUANTITATIVE (HIGH-FLOW DEEP PROBE CORN OIL) FOR SELF-CONTAINED BREATHING APPARATUS WITH FULL FACEPIECES STANDARD TESTING PROCEDURE (STP)"
   Document B: Quantitative Laboratory Respirator Protection Level Test

2. Sponsor and/or Project Officer: This project is a collaborative study by NIOSH and SBCCOM with Co-Project Officers:
   John M. Dower, NIOSH
   Alex G. Pappas, SBCCOM Mask Fit Test Facility Manager

3. Purpose and Benefits: The purpose of our overall study is to evaluate and certify respiratory protective devices, to make sure they are safe and work properly. The purpose for this test is to determine if the respirator meets the performance test requirements listed in the regulations.

   Information generated by this research project will benefit:

   a. you, the participant, by providing a better understanding of respirators and their performance. Also, you will receive a free annual medical examination if you qualify to participate in the testing program.

b. workers who routinely use this same type of respirator, by ensuring that respirators in the field perform as they were certified by NIOSH to perform, and thus provide the expected level of respiratory protection.

c. those involved in testing, certifying, and manufacturing respirators by providing feedback on how respirators perform in the field.

e. workers such as HazMat responders, firemen and mine rescue personnel for protection against terrorism agents, toxic compounds and oxygen deficiency.

II. CONDITIONS OF THE STUDY

1. Laboratory Respirator Protection Level Quantitative Fit Tests --

Before the tests begins, you will be asked a few questions to make sure you can safely perform the required activities of this test. You will be asked if you have any serious illnesses or injuries or chronic pain associated with the body movements to be performed during this test. You will not be allowed to participate in this testing if you cannot safely perform the required tasks.

During the testing, you will wear a full facepiece for a self-contained breathing apparatus equipped with high efficiency 100-series particulate air filters that is being evaluated by NIOSH. The tests which you will be doing include various movements like those commonly performed in various industries by a person wearing a respirator.

The test, a quantitative fit test, uses a corn oil mist. This test is designed to evaluate the respirator's ability to achieve a good fit to the user's face.

You will be given a respirator and asked to don it according to the manufacturer's instructions. The investigator will help you. If appropriate, you will then be asked to perform a facepiece seal check on the respirator, again according to the manufacturer's instructions. The investigator will show you the proper methods for donning and testing the respirator.

The fit test will last about 45 minutes at most.

1.a. Corn Oil Quantitative Fit Test --

NIOSH and SBCCOM use corn oil aerosol because it is easy to measure and non-toxic.

When you are asked to perform the corn oil test, you will don a respirator, wear it for about 20-30 minutes, enter a chamber containing a low concentration (about 15 to 40 milligrams per cubic meter) of corn oil, and perform the following movements:

(1) one minute normal breathing;
(2) one minute deep breathing;
(3) one minute turn head side to side;
(4) one minute move head up and down;
(5) one minute reciting the Rainbow Passage;
(6) one minute sight the rifle;
(7) one minute reach for the floor and ceiling;
(8) one minute on hands and knees, turning head side to side;
(9) one minute making facial expressions;
(10) one minute climbing the stairs at regular pace;
(11) one minute normal breathing.

The investigator will demonstrate the above activities to you. Actual corn oil testing will last about 15 minutes (11 minutes for activities and 4 minutes of instrument calibrations). We will be comparing the corn oil measurements in the chamber with the corn oil measurements inside the respirator using a measuring probe in the face of the respirator. If the respirator is working, there should be very little corn oil inside the respirator compared to the chamber. If the investigator determines the respirator is not working properly, the test will be stopped. You may then be asked to adjust the respirator and do the test over.

The corn oil is similar to products you buy at the store and cook with every day. The amount of corn oil in the chamber will range from 15-40 milligrams per cubic meter of air. The amount inside the respirator should be much less than that, around 0.31 milligrams per cubic meter. NIOSH has said that exposure to corn oil at 10 milligrams per cubic meter can be a nuisance. The test will be stopped if the levels of corn oil in the respirator reach 10 milligrams per cubic meter. Corn oil has no known toxic properties.

2. During testing, you might experience slightly higher breathing resistance than you are normally used to. You may also experience slight discomfort from the facepiece, nosecup, and uncomfortable harnesses or belts.

3. No other test procedures can be substituted for the Laboratory Respirator Protection Level Quantitative Fit Test.

4. The procedures for the Laboratory Respirator Protection Level Quantitative Fit Test will be clearly explained in detail before the testing is started. Feel free to ask any questions.

5. If you have any reaction to the medical screening procedures, you should contact Mr. Alex G. Pappas, Mask Fit Test Facility Manager, SBCCOM (410-436-3338) or John M. Dower, Senior IH Project Manager, NIOSH, Respirator Branch, (304) 285-5907.

6. Injury from this project is unlikely. But if injury occurs, medical care, other than emergency treatment, will not be provided. If you are injured during testing through negligence of a SBCCOM or NIOSH employee, you may be able to obtain compensation under Federal Law. If you want to file a claim against the federal government your contact point is: Public Health Service Claims Office (301) 443-1904. If you are injured through the negligence of a NIOSH contractor, your claim would be against the contractor, not the federal government.

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7. If you have questions about this research, contact: Mr. Alex G. Pappas, Mask Fit Test Facility Manager, SBCCOM (410-436-3338) or John M. Dower, Senior IH Project Manager, NIOSH, Respirator Branch, (304) 285-5907. If you have questions about your treatment or rights as a member of this study, contact: Michael J. Colligan, Ph.D., Chair, NIOSH Human Subjects Review Board at (513) 533-8222; or Timothy Williams, CIH, CSP, Master Industrial Hygienist and SBCCOM Human Use Chairman at (410) 436-2302.

8. Your participation is voluntary and you may withdraw your consent and your participation in this study at any time without penalty or loss of benefits to which you are otherwise entitled.

   You will receive $25.00 per test per visit or partial visit that you participate in this study.

9. Overall results of the testing of the respirators will not contain information useful to you personally. In addition, the results contain certain trade secrets and confidential design operation information that NIOSH and SBCCOM do not release to the public. Because of this, we cannot directly provide you with the overall study testing results. However, the test report with all personal identifiers and trade secret information removed would be available upon written request under the Freedom of Information Act, 5 U.S.C. 552. Send your written request to:

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