


<p>National Institute for Occupational Safety and Health National Personal Protective Technology Laboratory Respirator Branch 626 Cochrans Mill Road Pittsburgh, Pennsylvania 15236</p>		
Date: May 30, 2003	NOTE: The Respirator Branch maintains an updated index of current procedures.	

**DETERMINATION OF LABORATORY RESPIRATOR PROTECTION LEVEL (LRPL)
 QUANTITATIVE, MEDIUM FLOW, DEEP PROBE, CORN OIL, FIT FACTOR PERFORMANCE TEST
 FOR CHEMICAL, BIOLOGICAL, RADIOLOGICAL AND NUCLEAR (CBRN) FULL FACEPIECE
 RESPIRATORY PROTECTIVE DEVICES (RPD) STANDARD TESTING PROCEDURE (STP)**



1. PURPOSE:

1.1. This test establishes the procedures for ensuring the level of respiratory protection provided by Chemical, Biological, Radiological, and Nuclear (CBRN) Full Facepiece Respiratory Protective Devices (RPD) requirements submitted for New Approval, Extension of Approval, or examined during certified product audits, meet the minimum certification standards set forth in this Standard Test Procedure (STP) as prescribed in 42 CFR, Part 84, Subpart G, Section 84.63(a)(c)&(d); Federal Register, Volume 60, Number 110, June 8, 1995.

Approvals:	1 st Level	2 nd Level	3 rd Level
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1.2 The purpose of this STP is to describe the test conditions and procedures necessary to test and certify civilian manufacturer submitted CBRN Full Facepiece Respiratory Protective Devices (RPD) certification applications for NIOSH approval. A CBRN Full Facepiece Respiratory Protective Device being a complete tight fitting, full facepiece respirator, properly outfitted with NIOSH recognized manufacturer unique components and a compatible negative pressure air-filtering device or supplied air cylinder that is installed per the manufacturer’s current user instructions. The STP is used to test CBRN RPD against corn oil aerosol while worn by a human test subject breathing in a dynamic eleven exercise specific sequence. Aerosol quantified instrumentation is remotely sensing internal and external corn oil concentrations via the attachment of tubing to a specific oral/nasal probe mounted in the tested RPD. The requirement for this STP is to ensure that all CBRN RPD, seeking NIOSH CBRN approval, have:

1.2.1. Good self-donning face-fitting characteristics that can accommodate a wide variety of facial sizes and shapes

1.2.2. User instructions for facepiece size selection and donning that are easily understood, applicable to all components and current.

1.2.3. Achieve a pass or fail result based on completing 11 LRPL or MLRPL exercises/trials as determined by appropriate pass criteria per class of respirator.

1.2.4 Each CBRN RPD is evaluated in negative pressure or a positive pressure mode on a panel of 25 to 38 test subjects having facial sizes and shapes that approximate the distribution of sizes and shapes of the general applicable statement of standard user population.

2. GENERAL:

2.1 This document describes the Determination of Laboratory Respirator Protection Level (LRPL) Quantitative, Medium-Flow, Deep Probe, Corn Oil, Fit Factor performance test for the CBRN Full Facepiece RPD in sufficient detail that a team of persons knowledgeable in the appropriate technical field can select equipment with the necessary resolution, conduct the test, and determine whether or not the RPD passes the specified test. The procedure is a separate test under the NIOSH/NPPTL Respirator Branch heading of RB-CET-STP-CBRN-0352 for challenge of Corn Oil Aerosol. The procedure is designed to rigorously test the evaluated RPD on a human test subject as a dynamic respiratory protective system and generate repeatable, independent pass or fail results under defined laboratory conditions.

2.2 Any laboratory using this procedure to supply certification test data to NIOSH will be subject to the provisions of the NIOSH Supplier Qualification Program (SQP). This Program is based on the tenets of ISO/IEC 17025, the NIOSH Manual of Analytical Methods and other NIOSH guidelines. An initial complete quality system audit and follow on audits are requirements of the program. Additional details of the program and its requirements can be obtained directly from NIOSH/NPPTL.

- 2.3 This test is considered a human factors test that requires participation of a minimum of 25 to a maximum of 38 human subjects to quantify the LRPL performance level required of the CBRN RPD. The successful completion of NIOSH/NPPPTL designated Live Agent Test (LAT) performance requirements, specific for the type of RPD being considered for LRPL testing, must be shown before LRPL testing commences on the submitted RPD.
- 2.4 This STP shall be used to test several different types of CBRN full facepiece RPD for satisfactory Laboratory Respirator Protection Level performance. The full facepiece CBRN RPD include but are not limited to: Self-Contained Breathing Apparatuses (SCBA, Open Circuit and Closed Circuit), Supplied Air Respirators (SAR), Air-Purifying Respirators (APR), Air-Purifying Escape Respirators (Escape), Supplied Air Escape Respirators (Escape SAR), SCBA/APR Combination Respirator (SCBA/APR Combo), Powered Air-Purifying Respirators (PAPR) and Follow On CBRN Respirator concepts.

3. TEST EQUIPMENT / TEST ITEMS/ HUMAN SUBJECTS

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

- 3.1.1. Corn oil - 99%. Commercial Product Name; Maise Oil, Maydol, Mazola Oil, Maize Oil. Corn oil utilized must comply with Chemical Abstract No. 8001-30-7 prior to test commencing. Material Safety Data Sheets (MSDS) for the type of corn oil used must be posted for review by all test subject and laboratory personnel in accordance with EPA Right to Know regulations, applicable OSHA HAZCOM requirements and this STP.
- 3.1.2. Environmental test chamber and plenum system or equivalent. The chamber shall be designed so that the individual(s) performing LRPL testing are visible at all times while in the chamber. The chamber design must meet local fire codes for enclosed spaces including an entry vestibule designed to allow safe entry and exit from the chamber with minimal disturbance to both aerosol concentration and uniformity. The vestibule shall be large enough to accommodate entry vestibule door swing and eight test subjects while the main entry chamber door is 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 continually by a known quantitative system to verify that the aerosol is within specified parameters as detailed in section 6.3. An example is shown in Figure 1.

Figure 1. Environmental Test Chamber



3.1.3 Environmental Control System or equivalent. The Environmental Control System shall be capable of maintaining (20-80% RH \pm 5%, 65-95 \pm 5°F) normal operating conditions (ambient target) for LRPL Tests (70 °F, 50 % RH) An example of an Environmental Control System, the DataAire Model DAP-2 Environmental Control System, is shown in Figure 2.

Figure 2
Environmental Control System



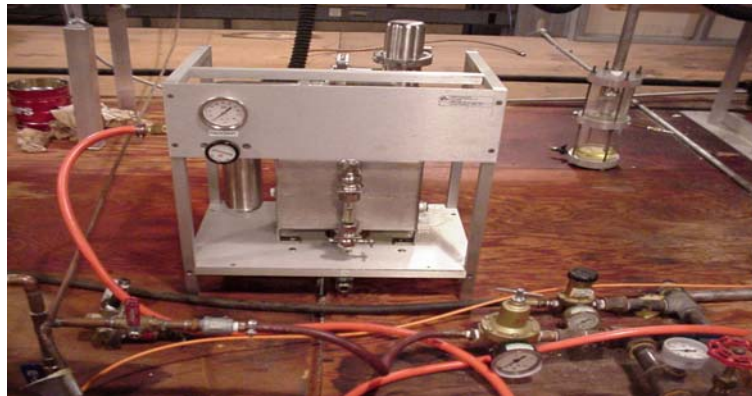
3.1.4 Aerosol Measurement System: The Aerosol Measurement System shall be used to measure the aerosol challenge/leak concentration and accurately measure fit factors of at least 100,000. It will have a minimum limit of detection $\leq 0.01\text{mg/m}^3$, or 0.01 percent. Examples of Aerosol Measurement Systems are the TSI Laser Photometer Model 8520 and 8587 rear light scattering laser photometers.

Figure 3, Aerosol Measurement Systems



- 3.1.5 Aerosol Generator or equivalent. The Aerosol Generator shall be capable of maintaining 20 to 26 mg/m³ 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 equipment shall be capable of operation with out using recycled air. An example of an Aerosol Generator system, the MSP Model 2045 High Output Aerosol Generator, is shown in Figure 3.

Figure 4
Aerosol Generator

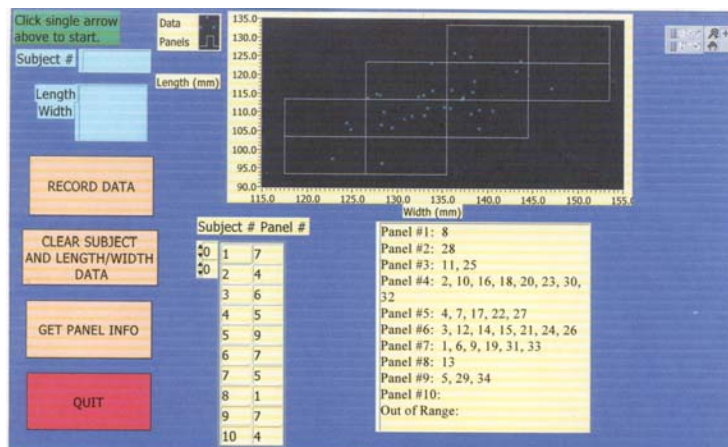


- 3.1.3. Chamber Concentrations. The chamber aerosol concentration shall not vary as a function of time more that ± 10 percent over the duration of a single test (approximately 15 minutes). The test chamber shall be capable of maintaining spatial uniformity within ± 10 percent in the vicinity of the respirator being tested. An example of an instrument to verify spatial uniformity and chamber concentrations is the TSI DustTrak photometers (no figure available on the TSI DustTrak photometer).
- 3.1.4. Communications. A means of providing two-way communication between the test subject(s) and the test conductor(s) shall be provided. Non-verbal communication between test subjects inside test chamber and attending laboratory technicians is acceptable.
- 3.1.5. Facial Size Measurement, Calipers or equivalent. Calipers shall be used to measure the test participants to the requirements identified in Appendix A. Examples of calipers are sliding measurement calipers, Seritex model GPM 104, 0-200 mm length, or spreading measurement calipers, Seritex model GPM 106, 0 – 300 mm width. See figure 5, Facial Size Measurement Calipers. Figure 6 is an example of software available to manage the panel test measurements and placement of subjects.

Figure 5, Facial Size Measurement Calipers



Figure 6, Sample LANL Panel Calibration Software



- 3.1.6. Tubing. Tygon tubing (1/4-inch i.d.) and connectors to mate the facepiece probes to photometers.
- 3.1.7. Facepiece Probes. The probes 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. Figure 6, below is an interior view of a sample RPD probed in the oral nasal region of the nose cup. Figure 7, is an exterior view of a probed RPD showing the metal interface for tubing and penetration through the lens and nose cup.

Figure 7, Sample Interior RPD Probe



Figure 8, Exterior View of sample LRPL Probed RPD



3.2. Required CBRN APR Test Items:

- 3.2.1. Test RPD Facepieces. Each applicant shall provide 25 to 38 full facepiece RPD of production quality, in the NIOSH agreed configuration, in each size according to the testing requirements set forth in Appendix B of this STP. Figure 8, is a representative sample photograph of ongoing probing of RPD covering specific

determined sizes. User instructions for self-donning and system attachments or other hardware are required for each RPD submitted for test. Test factors such as weight of accessories, weight of critical components, type of head harness used and identical LAT configuration tested must be adhered to. Twenty-five (25) RPD are required if one universal size is tested. Twenty-nine (29) RPD if two sizes (14 Small/Medium and 15 Medium/Large) are tested. And thirty-eight (38) RPD if three sizes (10 Small, 17 Medium and 11 Large) are submitted per manufacturer sizing instructions specified in applicable RPD user instructions.

Figure 9, Probed and Un-probed Sample RPD



3.3. Human Factors:

- 3.3.1 Test Subjects. Twenty-five to thirty-eight human test subjects are required for this test. All procedures and requirements specified in the NIOSH Human Subject Review Board (HSRB) Protocol HSRB-03-NPPTL-06XP entitled, “Determination of Laboratory Respirator Protection Level (LRPL) Testing (Quantitative) for Respiratory Protective Devices” dated March xx, 2003, shall be followed and met. Informed consent will be obtained from each volunteer upon completion of the Volunteer Agreement Affidavit and Volunteer Agreement Affidavit Explanation contained in Protocol No, HSRB-02-NPPTL-06XP. The test subjects shall be subjected to medical examinations as defined in HSRB-02-NPPTL-06XP and supplemental facial measurements. The electronic and manual caliper facial measurements shall be used to determine facial size and panel placement prior to each test subject donning a new type of RPD or new manufacturer application.
- 3.3.2 Test Administrator(s). Shall have successfully completed the CDC/ATSDR Scientific Ethics Training, the DHHS/NIH Human Participant Protections Education for Research Teams or an equivalent NIOSH sanctioned course. Note: The NIOSH Human Subject Review Board will determine if specific courses not stated above are equivalent.

4. TESTING REQUIREMENTS AND CONDITIONS:

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- 4.1. Calibration. Prior to beginning any testing, all measuring equipment utilized for final measurements as part of this testing must have been calibrated within the preceding 12 months, or as specified by the equipment manufacturer, using a method traceable to the National Institute of Standards and Technology (NIST). Equipment calibration records shall be available for examination at each testing facility. Laboratory technicians will check calibration prior to the conduct of the testing. A statement that all test equipment is within calibration shall be attested by the lab technician on each NIOSH test report.
- 4.2. Safety. Normal laboratory safety practices must be observed. This includes safety precautions described in the current NIOSH Bruce Research Center Laboratory Safety Manual or site-specific procedures that are applicable to health and safety requirements.
- 4.3. Certification Inventory. Test facility personnel will confirm that the model of RPD facepiece submitted for LRPL testing is the same model and configuration as submitted under the NIOSH application for certification with the required accessories as defined by the manufacturer and successfully live agent tested. Part number inspection, location and referencing must be accurate and complete before test begins. Any accessories that effect form, fit, function, or provide a protective quality shall be installed on the RPD facepiece and subject to LRPL testing. NIOSH/NPPTL Guidelines for Identification of Test Configurations for Exposure to GB/HD, dated March 7, 2003, establishes the RPD current testable configuration for LAT and ultimately that configuration should match the configuration tested for LRPL and Modified LRPL fit factors. Facility personnel are required to keep a certification inventory, when complete, prior to LRPL commencing. Individual manufacturer RPD equipment stocks are required to be separated & covered between manufacturers.
- 4.4. Probing. Each RPD facepiece shall be probed and verified functional prior to issue to test subjects by lab personnel for purposes of measuring concentrations of corn oil inside the facepiece nosecup or requested configuration in accordance with paragraph 3.1.7 of this STP. For those RPD without nose cups defining the oral nasal region, sampling probe must still extend into the breathing zone per Para 3.1.7 of this STP. The test facility administrator or his staff probes the RPD. The RPD sampling location shall be in the oral/nasal region only. 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 final position of the sample probe will depend upon the design of the RPD being evaluated.
- 4.5. User Instructions. Prior to conducting the test, the Users Instructions provided with the test equipment shall be reviewed by the test facility personnel and the test subjects. Test subjects will be taught by the principal investigator or a facility representative on the areas of manufacturer's size selection, donning, fit check, doffing, and other fitting procedures for the RPD facepiece. Any clarifications or supplemental instructions provided by manufacturer representatives at the time of certification inventory, during the test or after the test must be NIOSH reviewed prior to incorporation into revised User Instructions before final NIOSH approval is granted.
- 4.6. Self Donning. Each test subject shall perform an unassisted donning of the RPD facepiece in

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accordance with the manufacturer’s instructions prior to entering the corn oil LRPL chamber. Each test subject conducting self –donning under supervision of test facility personnel is 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 prior to entering the chamber. Self-Donning relies on the clarity of the user instructions addressing head harness pull-tab sequence, faceblank orientation and other RPD component orientations.

4.7. Air Flow Sampling. Air shall be sampled out of the respirator oral nasal region at a range of 2.2 ± 0.2 Lpm. The method in which the sampling probe is installed shall not interfere with RPD performance and shall minimize sampling biases.

4.8. RPD Protection Level Adaptation Measures. All RPD that require adaptation to support LRPL testing must have accurate user instructions that address conversion of that RPD to a manufacturer sanctioned negative pressure testable configuration in accordance with the applicable NIOSH/NPPTL RPD STP in effect. LRPL protection level testing of full facepieces used on CBRN SCBAs and SARs under this procedure will be accomplished by following the manufacturer’s instructions for temporarily converting the facepiece into an Air-Purifying Respirator with appropriate P100 filter(s). The manufacturer must furnish the adapter and like user instructions 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 or SAR. Accessories must be provided on CBRN SCBA and SAR facepieces submitted for testing when the operation of the accessory could affect form, fit or function.

4.9. LRPL Exposure Chamber Conditions:

4.9.1. Temperature Range = 68-80 °F

4.9.2. Relative Humidity Range = 50 ± 10 %

4.10.3 Corn Oil Challenge Concentration = 22 ± 2.0 mg/m³

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

5. PROCEDURE:

Note: Paragraph 3 of this STP contains examples of LRPL equipment and select manufacturer's RPD. Review the manufacturer’s operation and maintenance manuals for calibration instructions, operational use, and maintenance procedures prior to commencing this STP.

5.1.1. General. This procedure describes the Laboratory Respirator Protection Level (LRPL) performance test for ensuring that the level of respiratory protection provided by the CBRN Full Facepiece Respiratory Protective Devices (RPD) meets or exceeds the requirements defined in the Statement of Standard for that particular CBRN RPD being tested. Refer to the current Statement of Standard for the CBRN RPD being tested for specific data. This procedure describes the required sample size, test

equipment, data collection methods, human use protocol requirements, and the specific performance requirement for RPD being tested. SCBA, open circuit, is LRPL tested in a negative pressure configuration using the identical LAT configuration with the deletion of the regulator and cylinder hardware but with the addition of a negative pressure adapter using P100 filters.

5.2. Number of Test Samples.

- 5.2.1. See paragraph 3.2.1 and Appendix B of this STP for quantities per size.
- 5.2.2. All CBRN RPD shall be individually numbered with an indelible pen or tagged in a sequence that the number can be correlated to the NIOSH application number (TN), manufacturer, and administrative sequence number so it can be tracked throughout the LRPL.
- 5.2.3. The administrative sequence numbers are replicated in the test summary data sheets and indicate product performance per the stated requirement.

5.3. Test Equipment and Chamber Set-Up:

- 5.3.1. Test facility staff will install the sampling probe in each facepiece submitted under the applicable NIOSH TN and verify the integrity of probes before physical testing is began. A short length of tubing will then connect the sample probes in the masks to the aerosol detector unit.
- 5.3.2. In accordance with local operational standard procedures, add corn oil to the aerosol generators and allow 15 minutes for the chamber concentration to stabilize.
- 5.3.3. Electronic and manual caliper facial measurements shall be used to determine facial size and panel placement prior to each test subject donning a new type of RPD or starting a new manufacturer RPD application
- 5.3.4. Probes that do not clearly enter the oral nasal region, penetrate just the eye lens without penetrating the oral nasal nose cup, penetrate through a faceblank molded seam creating a possible seal leak or enter the nose cup but are blocked by internal respirator parts are considered inadequate test probes.

5.4. Conducting the LRPL Test:

- 5.4.1. Panels: Test subjects shall be selected to cover all the cells within the panels referenced in Appendix A. Each LRPL test shall consist of 2 trials. A minimum of 50 data points and a maximum of 72 data points shall be collected from two self-donnings by test subjects of each facepiece size of each RPD submitted to NIOSH, as prescribed in Appendix B. At a minimum, anthropometrical measurements face length (Menton-Nasal Root Depression or Menton-Sellion) and face width (Bizygomatic diameter) shall be taken for facepiece size determination per LRPL. In addition, neck circumference shall be recorded for respirator systems that use a neck

dam or second skirt. The test subject anthropometrical panel results must fall out into the panel box requirements outlined in Appendix B. These results determine what size RPD is issued to the test subject. Those test subjects that are determined to be on the border line between various indicated panel cells must be re-measured prior to LRPL testing starting and confirmed what panel box they fall into. For those cases, where a test subject is rated in a dual size category panel box (M/L or S/M), the use of expert sizing by test facility personnel is required to determine what size is initially tested twice. If test subjects fail one dual size category twice, test facility personnel are authorized to resize the individual if panel test subject availability is in demand.

- 5.4.2. Training. The RPD facepieces shall be properly sized and assigned to clean-shaven test subjects by trained test facility personnel. Prior to LRPL testing, test subject training will be conducted by test facility personnel based on the manufacturer's NIOSH recognized Users Instructions. After initial instruction and eleven exercise hands on demonstration, each test subject shall practice donning (15 minutes) and wearing the RPD continuously for 15 minutes before entering the test chamber. Test subjects do not attach critical components to the RPD. Test facility personnel attach all critical components, per the manufacturer's user instructions. The instruction period will be a minimum of 10 minutes and a maximum of 30 minutes. All test subjects shall be trained. Mentoring of training time and training subjects is required to ensure effective instruction and follow on actions are performed correctly. Procedures for doffing, trouble shooting, negative seal checks, head harness tightening, and accessory interfacing with required power/air cylinder sources must be taught to test subjects by test facility personnel. Manufacturers may request the opportunity to observe LRPL testing of their equipment, with prior notification to NIOSH/NPPTL.
- 5.4.3. Ready Line. After the test subjects are trained in donning and doffing the RPD, issued administrative numbers, complete applicable administrative paperwork, the subjects are moved to the ready line in groups of eight or an equivalent number based on the number of operational photometer test input lines.
- 5.4.4. Entry and Exit. Test subjects entering and leaving the corn oil-charged chamber must be processed in accordance with paragraph 3.1.2 of this STP and not adversely affect chamber test conditions in between trials. Chamber concentration is required to be monitored continuously and compliant during the entire conduct of each individual LRPL test.
- 5.5.3 LRPL Exercises. The LRPL test consists of a set of eleven standard exercises that use eight (8) basic US Department of Labor, Occupational Safety and Health Administration (OSHA) Quantitative Fit Test (QNFT) exercises plus three (3)* additional QNFT exercises generated from emergency response forums. They are one-minute routines devised to stress the face seal and material integrity of the respirator facepiece while it is worn by a human test subject. The appropriate number of test subjects (based on Appendix B) will successively don and wear the CBRN RPD into the chamber. The exercise routine listed below shall be used to stress the face seal and approximate field use conditions under controlled laboratory

settings. During each trial of a LRPL test, each human subject will perform the following eleven exercises for one-minute each **:

- 5.5.3.1 Normal Breathing: In a normal standing position with hands to the sides or rear, without talking, the subject shall breathe normally for one minute. A recommended procedure is to inhale through the nose and exhale through the nose at a normal pace. Do not touch any portion of the RPD during any part of the LRPL active test, to include the RPD's sample line.
- 5.5.3.2 Deep Breathing: In a normal standing position as above, the subject shall breathe slowly and deeply for one minute, being careful not to hyperventilate. A recommended procedure is to inhale deeply through the nose and exhale through the mouth.
- 5.5.3.3 Turn Head Side to Side: Standing in place, with arms to side, the subject shall slowly turn head from side to side for one minute between the extreme positions on each side. The head shall be held at each extreme momentarily so the subject can inhale at each side. Do not deliberately hit the shoulder with any part of the RPD during the conduct of the exercise.
- 5.5.3.4 Move Head Up and Down: Standing in place, the subject shall slowly move head up and down, starting at level plane, move the head up slowly so the eyes are looking straight up at the ceiling, inhale and hold for one second. Slowly move down past the horizontal level start point to the end point where the chin just touches the chest. Continue the process until told to stop at the level position.
- 5.5.3.5 Recite the Rainbow Reading Passage or equivalent: The subject shall talk out loud while reading a copy of the passage entitled Rainbow Passage. Normal breathing is required. Volume of speaking should be loud enough so as to be understandable by the test facility personnel in the control office. Subject will keep reading the passage until told to stop.
- 5.5.3.6 Sight a Mock Rifle*. While in normal breathing, pick up the mock half-length rifle sample. Test subjects shoulder the mock rifle in the favored shooting posture shoulder position. Bend the head while keeping the RPD fitted so as to allow a realistic sight picture to be attained by placing the cheek unhindered by RPD components (such as a canister) as close as possible to the rifle stock and rear sight aperture. Hold the cheek to stock position for one second. While bending the head to attain a modified sight picture, extend the non-shooting arm and hand to simulate holding the remaining stock of a standard rifle. After attaining this posture, drop the arms, while still holding on to the mock rifle, to the side. Continue taking up realistic sight pictures with the mock rifle as described until told to stop or one minute. Place the mock rifle down.
- 5.5.3.7 Reach for Floor and Ceiling (Modified Bending Over exercise 29CFR1910): While in normal breathing, standing, feet shoulder width apart and at arms

length from each test subject, subject bends at the waist as if to touch toes/floor. After touching/reaching fully for the toes/floor, subject comes back up at a normal pace, extending arms fully and reaching for the maximum length of arms to the ceiling direction. Keeping the arms locked, continue the procedure until told to stop or for one minute.

5.5.3.8 On Hands and Knees, Look Side to Side *: Before starting, test subject ensures enough room is available between equipment, sample line and other test subjects. In normal breathing, at a normal pace, drop to all fours and extend the head looking straight out. Starting at the center, move the head to the right or left full extreme and hold for one second. Inhale after that one second while holding the head at the extreme extension. Continue doing this exercise, not hitting the RPD aggressively, for one minute or told to stop. At a normal pace, return to the standing position.

5.5.3.9 Facial Grimace: While in normal breathing and standing, the test subject will grimace the face by smiling or frowning. Starting with the mouth closed, create a smile or frown that is physically felt by the test subject while wearing the tested RPD. It is recommended that smiling and frowning be alternated during the one-minute exercise.

5.5.3.10 Climb the Stairs At Regular Pace*: Test subjects pair off in twos, while in normal breathing, one test subject of the a pair holds the appropriate stair case or ladder while the other test subject climbs up at a normal pace and back down at a normal pace. Upon the first subject completing one repetition of up and down, the second subject climbs while the first subject holds the ladder, if necessary. Continue the cycle until one minuet expires or told to stop. Return to the floor standing position. Ensure sample lines are not restricting movement during the climb.

5.5.3.11 Normal Breathing: In a normal standing position with hands to the sides or rear, without talking, the subject shall breathe normally for one minute. A recommended procedure is to inhale through the nose and exhale through the nose at a normal pace. Do not touch any portion of the RPD during any part of the LRPL active test. Disconnect the sample line as instructed.

- * One of three additional emergency response exercises added for CBRN tests.
- ** Exercises must be done in this sequence, starting with number one (1) normal breathing and ending with number eleven (11), normal breathing.

5.8 At the conclusion of each trial, test subjects shall exit from the test chamber, return to the ready line and await further instructions. All those subjects identified to doff will commence doffing and those subjects that are being reviewed for test failure protocol will remain with RPD donned until told to doff.

5.9 All comments and observations by test subjects, which are voluntary, will be written on the test data sheet.

5.10 After a brief intermission (1-10 minutes), each test subject will re-don the same

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respirator facepiece and repeat Steps 5.5.6 through 5.9 to complete the 2nd trial for the test. Each test consists of two trails using the same RPD for each trial with the same test subject for each trial.

- 5.11 If a RPD is identified as a failure upon trial termination, test facility personnel will conduct failure assessment protocol of the RPD in two phases. First phase is to inspect the RPD while it is still donned on the test subject. Second phase is to inspect the RPD when it is doffed. Post test failure analysis should consist of inspection of the test subjects eye to eye lens positioning, head harness positioning, head harness strap twists, nose cup scrunched up on face, hair in the faceblank seal area, canister not on securely, probe lose, missing or on a molded seal or surface causing seal gap or any other case dependent situations. If noted deficiencies are confirmed with the RPD being improperly probed, reassign another like, but serviceable RPD to the test subject and retest for two complete trials. If the RPD has a serviceable probe but continues to fail, log it as a LRPL failure. Only inspect the probe assembly if test results are flat lined or suddenly go flat lined after successful exercise results are indicated. Probe failures such as ripped faceblank material or inadequate probe sealing areas are cause for reanalysis of the determined probe entry point. In cases, where the RPD cannot be probed successfully by the test facility, manufacturer Quantitative Fit Test (QNFT) kits can be reviewed and considered for use, but only as a last resort. If manufacturer instructions specify use of pre-test Port-a-Count Fit Tester during test subject respirator selection process, ensure serviceable and calibrated Port-A-Count Fit Tester is available, conduct test and determine suitability of test subject before starting LRPL or MLRPL testing.
- 5.12 MLRPL for Negative Pressure Fullface Respirators (CBRN APR) Test Sequence: Modified LRPL (MLRPL) Canister (Weight Enhanced Canister) must weigh 500 grams as weighed in by test agency. Canister must measure 5 inches. In order to do this task, the testing laboratory will accept the canisters submitted with the application. Select 8 canisters at random to be modified to meet the statement of standard requirements. No surrogate canisters are authorized. Testing laboratory will apply required measures to make the submitted canister weigh 500 grams and measure 5 inches in width. Required measures for enhancing each canister must be of sound engineering design, maintain enhanced design through out the entire test and have minimal impact on field of view. Examples consist of dye cut Styrofoam outserts with known value metal weights secured inside, weighted metal tape of known weight or other recognized weight enhancement systems. It is critical that the weight be uniformly distributed over the entire outside dimension of the canister, whether it is on the circular surface or the flat inlet/outlet surfaces. The final design enhancement technique must be submitted and demonstrated through Verification Testing (V-Test) to NIOSH for final approval prior to actual testing commencing. Deviations from this final approved design concept are not authorized unless requested in advance to NIOSH and changes demonstrate increased test proficiency. At random, 8 subjects are chosen out of the original LRPL test panel. The respirators assigned to those 8 subjects will have the CBRN canister for normal LRPL replaced with the Modified LRPL (MLRPL) canister as directed by the testing laboratory and NIOSH. Two trials of the MLRPL are required and a passing LRPL of 2000 per trial must be met. The MLRPL overall pass value is 94%. MLRPL can have one test failure out of 16 trials using the same 8 test subjects with properly configured MLRPL canisters. If two test different of identical test subjects out of 16 trials fail the MLRPL, the

application is a failure and will be denied. MLRPL test results will be included in final CBRN APR LRPL test data sheets and designated as Modified LRPL Test Subject -01-16 with corresponding size and TN as required. The same test procedure for traditional LRPL for CBRN APR applies to the conduct of the MLRPL with 2000 being the passing LRPL value per test subject.

6. PASS/FAIL CRITERIA

6.2. This test establishes the standard procedure for ensuring the following:

6.2.1 The criterion for conduct of this test is set forth in 42 CFR, Part 84, Subpart G, Section 84.63 (a, c, and d) Volume 60, Number 110, June 8, 1995 and applicable RPD current statement of standards in final approved form. Each respirator and respirator component shall when tested by the applicant and by the Institute, meet the applicable requirements set forth in 42 CFR Part 84, subparts G, H, I J, K, and applicable portions of L, N and KK. All applicable manufacturer user instructions that address seal enhancement kits and other critical seal components/tasks must be clearly depicted in final NIOSH approved documents and present during testing.

6.2.2 CBRN SCBA (Open Circuit): Each CBRN Open-Circuit, Pressure Demand, Self Contained Breathing Apparatus respirator facepiece minus air pressure hardware and cylinder is adapted to negative pressure configuration, probed by test lab and configured with all identical LAT accessories and components prior to testing. This configuration is worn by a human test subject in an atmosphere containing 20 to 26 mg/m³ of corn oil aerosol with a Mass Median Aerodynamic Diameter (MMAD) of 0.4 to 0.7 um and the minimum LRPL shall be equal to or greater than 500 (minimum) Fit Factor for 95 +/- 0.26 % of the test subjects evaluated in accordance with NIOSH Procedure No. RCT-CBRN-STP-0202, Appendix B or the current RPD LRPL STP in effect. Each 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 test period.

6.2.3 CBRN APR:

6.2.3.1 Traditional LRPL for CBRN APR: The measured LRPL for each full facepiece, air purifying respirator shall be 2000, when the APR facepiece is worn by a human test subject and tested in an atmosphere containing 20-40 mg/m³ of corn oil aerosol of a MMAD of 0.4 to 0.6um. NIOSH procedure No. RB-CET-STP-CBRN-0352 specifies the procedure. All submitted accessories effecting weight, form, fit or function are required to be on the APR prior, during and in post testing phases.

6.2.3.2 Modified LRPL (Practical Performance) for CBRN APR: A modified LRPL (MLRPL) shall be performed using respirators, provided in the original CBRN APR certification application, fitted with the submitted canister adapted to become a NIOSH weight enhanced canister weighing a maximum of 500 grams and sized to the maximum permissible dimensions specified in CBRN APR Statement of Standard, Para 3.4 and 3.11. Such dimensions

should exist that the canister shall pass through a five (5) inch diameter opening with the threaded connector perpendicular to the five (5) inch diameter opening while weighing maximum of 500 grams in a as is/ready to use canister configuration modified to be a weight enhanced canister. A minimum/maximum of eight (8) CBRN APR shall be tested under traditional LRPL protocol using modified canister enhancements to fulfill passing fit factors of 2000 for all eight (8) respirators, separate from the completion of traditional CBRN APR LRPL requirements. If three sizes are submitted the test tariff is 2 SM, 4 MED and 2 LRG. If two sizes are submitted the test tariff is 4 SM/MED and 4 MED/LRG. If one size, universal, is submitted all eight (8) are “one size fits all/universal”. NIOSH Procedure NO. RB-CET-STP-CBRN-0352 specifies the procedure. One failure is authorized out of 16 test trials at 8 test subjects per trial (a 93.75% Passage Rate rounded up to 94%).

6.2.3.3 CBRN ESCAPE APR: To be published.

6.2.3.4 CBRN Self - Contained ESCAPE Respirator: To be published

6.2.3.5 CBRN SCBA/APR/PAPR Combination: To be determined.

6.2.3.6 CBRN PAPR: To be determined.

6.2.3.7 CBRN SCBA (Closed Circuit): To be published.

6.2.3.8 CBRN Follow On Concept Respirators: To be determined

6.2.3.9 In addition to the stated requirements NIOSH/NPPTL 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 CBRN atmospheres.

6.2.3.10 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.

6.2.3.11 RPD facepieces shall provide for the optional use of corrective spectacles or lenses, which shall not reduce the respiratory protective qualities of the apparatus.

6.2.3.12 RPD facepiece shall be designed to prevent eyepiece, spectacle and lens fogging.

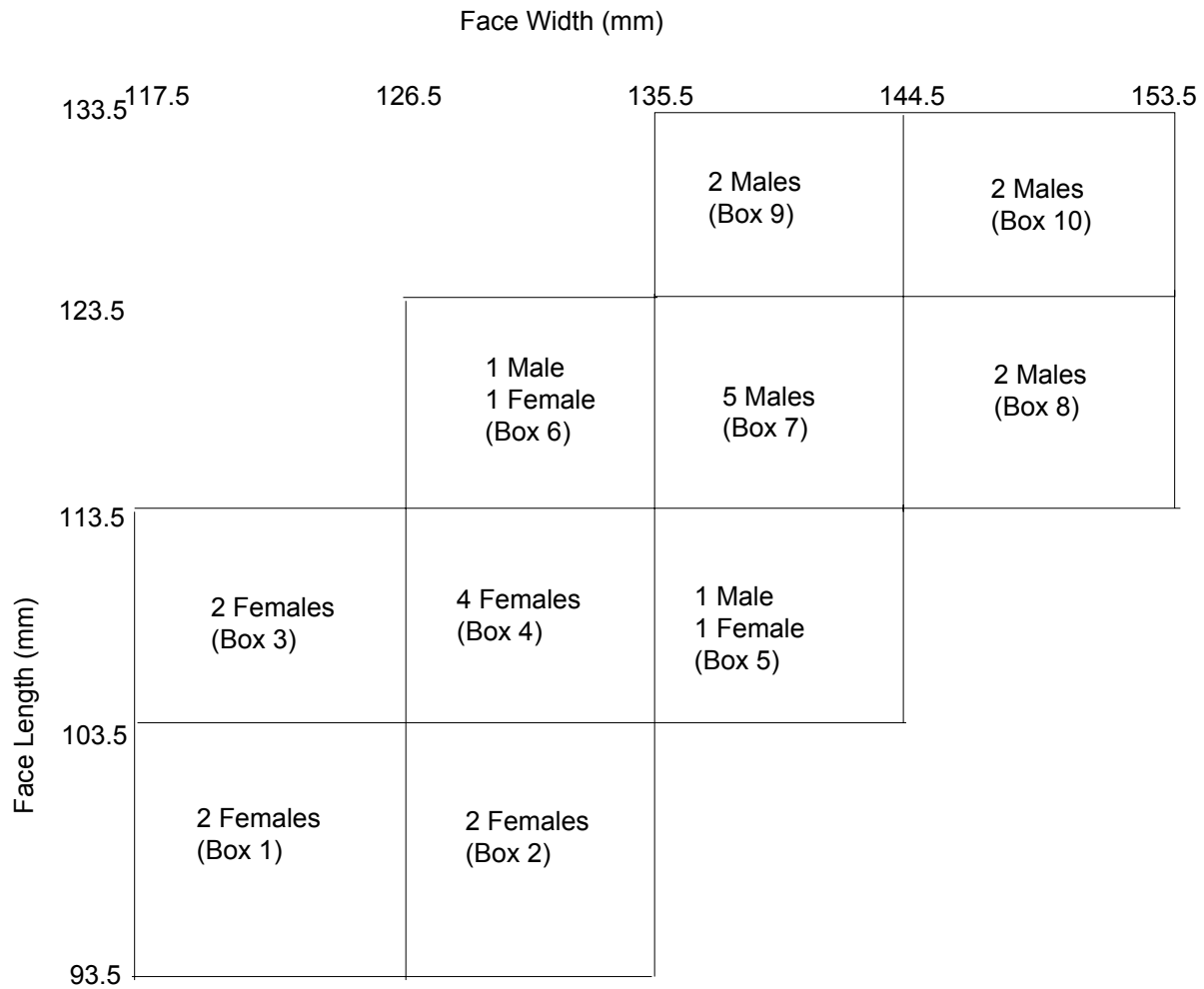
7. RECORDS\TEST SHEETS

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- 7.1 All test data will be recorded on the LABORATORY RESPIRATOR PROTECTION LEVEL TEST QUANTITATIVE ,MEDIUM-FLOW, DEEP PROBE, CORN OIL FIT FACTOR PERFORMANCE TEST FOR CBRN FULL FACEPIECE RESPIRATORY PROTECTIVE DEVICES WITH FULL FACEPIECES test data sheets (See Appendix C.)
- 7.2 All videotapes and photographs of the actual test being performed and of the tested equipment shall be maintained in the task file as part of the permanent record.
- 7.3 All equipment failing any portion of this test will be handled as follows;
 - 7.3.1 If the failure occurs on a new certification application, or extension of approval application, the Test Facility Manager (Principal Investigator or designee) will send a test report to the NIOSH Certification Evaluation and Testing (CET) Section Chief and prepare the hardware for return to the manufacturer.
 - 7.3.2 If the failure occurs on hardware examined under an Off-the-Shelf Audit, the hardware will be examined by a laboratory technician and the CET Section Chief 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 CET Section Chief, or his designee, following the standard operating procedures outlined in Procedure for Scheduling, and Processing Post-Certification Product Audits, RB-SOP-005-00.
 - 7.3.3 If a RPD fails the criteria specified in Para 6.0 of this STP, ensure all measures are taken to ascertain the reason/cause for failure, conduct all post test inspections in accordance with Para 5.11 of this STP that support the accuracy of the reported failure and provide NIOSH with written Test Incident Reports (TIR), digital photos of assessment and recommendations as required.

RECORD OF CHANGE:

Appendix A, One Size Fits All/Universal Panel, to CBRN RPD LRPL STP-0352



25 Test Subject, One Size/Universal, Member Panel for
Testing of NIOSH CBRN Full-Face RPD

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

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Appendix B

Test Panels Used for the Laboratory Respirator Protection Level Tests

1. Manufacturers with 3 Facepiece Sizes: 38 test subjects, two replicates, and total 76 data points. The maximum number of subjects equals the maximum number of facepieces required in the following tariff:

Small size: 10 each

Panel face sizes –Boxes 1, 2, 3, 4; panel size 10 (2 or 3 each size, 10 subjects, 20 total samples)

Medium size: 17 each

Panel face sizes - Boxes 3, 4, 5, 6, 7, 8; panel size 17 (2 or 3 each size, 17 subjects, 34 total samples)

Large size: 11 each

Panel face sizes – Boxes 7, 8, 9, 10; panel size 11 (2 or 3 each size, 11 subjects, 22 total samples)

2. Manufacturers with 2 Facepiece Sizes: 29 test subjects, two replicates, and total 58 data points. The maximum number of subjects equals the maximum number of facepieces required. The tariff requires an equal number of each size facepiece.

Small / Medium size: 14 each

Panel face sizes 1, 2, 3, 4, 5, 6; panel size 14 (2 or 3 each size, 14 subjects, 28 total samples)

Medium / Large size: 15 each

Panel face sizes 5, 6, 7, 8, 9, 10; panel size 15 (2 or 3 each size, 15 subjects, 30 total samples)

3. Manufacturers with a One-Size-Fits-All Facepiece: 25 test subjects, two replicates, and total 50 data points. Panel size – Every Box 1-10; panel size 25 (2 or 3 each size, 25 subjects, 50 total samples)

PASS/FAIL Criteria: Whenever a full panel of sizes 1 through 10 is used to evaluate a one-size-fits-all CBRN RPD facepiece, 2 failures, 96%, 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. Only 3 failures, 94.83 % (~ 95%), will be allowed for two facepiece sizes, and 4 failures, 94.74% (~ 95%), will be allowed for 3 facepiece sizes. Multiple-sized RPD facepieces 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. If more than three sizes are submitted, NIOSH will determine which sizes to test based on manufacturer recommendations. If sizing enhancement tools or products are used to maintain user seal, these products must demonstrate LAT passing criteria in accordance with applicable RPD LAT STP. Each test subject will perform testing with 2 donnings of the same size respirator facepiece per panel member. The second donning will be a redonning of the same facepiece. **NOTES:** Some panel members may be the same individuals in a dual role filling the cell requirements of 2 panels for the facepiece sizes. The data for each test subject donning (sample) are judged individually against the pass/fail criteria. This information also supports MLRPL testing.

Appendix C

CBRN RPD LRPL Test Data Sheets

**To Be Published (TBP)
To Be Determined (TBD)**

C1. CBRN SCBA: Current DEIMS Format To Be Integrated

C.2. CBRN APR: TBP

C.3. CBRN Air-Purifying Escape Respirator (APER): TBP

C.4. CBRN Self-Contained Escape Respirator (SCER): TBP

C.5. CBRN SCBA/PAPR/APR Combination Respirators: TBD

C.6. CBRN PAPR: TBD

C.7. CBRN SCBA, Closed Circuit: TBD

C.8 CBRN Follow On Concept Respirators: TBD

Appendix D

Laboratory Respirator Protection Level Test

Quantitative Corn Oil Fit Testing Procedure

For Chemical, Biological, Radiological and Nuclear RPD Evaluations

Medical Screening and Test Subject Consent Forms

TO BE UDPATED/APPROVED BASED ON FINAL SBCCOM HUC AND NIOSH HSRB INPUT FOR FINAL STP. AS OF 5/30/2003, NIOSH DOCUMENT NOT OUT OF SBCCOM HUC SIGNATURE REVIEW. AFTER SBCCOM REVIEW IT MUST GO TO NIOSH HSRB REVIEW PRIOR TO BEING USED AS AN OFFICIAL NIOSH LRPL DOCUMENT FOR RPD CERTIFICATION. TKC, 5/30/2003, PITTSBURGH, PA.

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 (MEDIUM-FLOW DEEP PROBE CORN OIL) FOR RPD 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 Deleted. (New NIOSH Name to be Determined) 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

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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 from Edgewood Area, APG.

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 confidentiality 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, (Dower Deleted, Name to be Determined) 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.

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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, (Dower Deleted, Name to be Determined) NIOSH, Respirator Branch, (304) 285-5907; Dr. Michael J. Colligan, Chairperson, NIOSH Human Subjects Review Board (513) 533-8222.

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, (Dower Deleted, Name to be Determined) 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:

- | | <u>Yes</u> | <u>No</u> |
|--|------------|-----------|
| 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 | _____ | _____ |
| j. Sight a rifle | _____ | _____ |

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

- | | <u>Yes</u> | <u>No</u> |
|--|------------|-----------|
| a. Collapsed lung | _____ | _____ |
| b. Dizziness or fainting spells | _____ | _____ |
| c. Chronic respiratory illness | _____ | _____ |
| d. Asthma | _____ | _____ |
| e. Claustrophobia or anxiety reaction | _____ | _____ |
| f. Shortness of breath 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?

- | | <u>Yes</u> | <u>No</u> |
|--------------------------------------|------------|-----------|
| 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 | _____ | _____ |

5. Have you ever worn a NIOSH respirator or military respirator/mask before?

If so, did you have an adverse reaction before, during, or after wearing the mask?

	<u>Yes</u>	<u>No</u>
	_____	_____
	_____	_____

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

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Document B

Laboratory Respiratory Protection Level Quantitative Fit Test

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 (MEDIUM-FLOW DEEP PROBE CORN OIL) PERFORMANCE TEST FOR RPD 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, (Delete Dower, Add New Name to be Published) 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.

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- 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.

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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, (Delete Dower, ADD New Name to be Published) 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.

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, (Delete Dower, ADD New Name to be Published) NIOSH, Respirator Branch, (304) 285-5907; and Dr. Michael J. Colligan, Chairperson, NIOSH Human Subjects Review Board (513) 533-8222.

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, (Delete Dower, ADD New Name to be Published) 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:

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

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(signature)

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REPRESENTATIVE _____ DATE _____
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