



National Institute for Occupational Safety and Health
 National Personal Protective Technology Laboratory
 Respirator Branch
 626 Cochrans Mill Road
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Date: December 20, 2004

NOTE: The NIOSH NPPTL maintains an updated index of current procedures.

DETERMINATION OF LABORATORY RESPIRATOR PROTECTION LEVEL (LRPL) VALUES USING A QUANTITATIVE, MEDIUM FLOW, DEEP PROBE, CORN OIL PERFORMANCE TEST FOR CHEMICAL, BIOLOGICAL, RADIOLOGICAL AND NUCLEAR (CBRN) SELF-CONTAINED BREATHING APPARATUS FACEPIECES OR CBRN TIGHT FITTING, FULLFACE, AIR-PURIFYING RESPIRATOR, STANDARD TESTING PROCEDURE (STP)

1. PURPOSE:

1.1 This test establishes the procedures for determining respiratory protection factors provided by Self-Contained Breathing Apparatus (SCBA), pressure-demand, with full facepieces, converted to a SCBA facepiece negative pressure configuration or Air-Purifying Respirator (APR), tight fitting, canister mounted, full facepiece configurations 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.

1.2 The purpose of this STP is to describe the test conditions and procedures necessary to test and certify Full Facepiece SCBA and APR applications for NIOSH CBRN protection approval. A CBRN Full Facepiece SCBA or CBRN APR is a complete respirator system consisting of the following parameters:

1.2.1 Individual systems have proper NIOSH required designations, user instructions and production quality consistent with NIOSH published requirements and

1.2.2 Individual systems consist of a complete tight fitting, full facepiece respirator, properly outfitted with a compatible negative pressure particulate air-filtering device for the SCBA facepiece or a CBRN Capacity 1, 2, 3 or 4 rated canister for the APR and installed per the manufacturer's current user instructions.

Approvals:	1 st Level Terrence K. Cloonan	2 nd Level	3 rd Level	4 th Level
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- 1.2.3 The STP is used to test CBRN SCBA and APR facepieces against corn oil aerosol while worn by human test subjects in a laboratory controlled environment and conducting eleven physical sequential exercises. During the exercise regimen, quantified instrumentation senses human subject breathing zone areas of the tested respirator and compares that value to detected external laboratory corn oil concentrations via the attachment of tooled oral-nasal probe mounted in the respirator.
- 1.3 The requirement of this STP is to ensure that all submitted SCBA or APR, seeking NIOSH CBRN approval, have the following four characteristics:
 - 1.3.1 Good self-donning face-fitting characteristics, under controlled laboratory observation, that can accommodate a wide variety of facial sizes and shapes (minimum 95%).
 - 1.3.2 User instructions for facepiece size selection and donning that are easily understood, applicable to all submitted components (both electronic and written) and are compliant at the time of NIOSH CBRN protection approval letter.
 - 1.3.3 Achieve a pass or fail test result based on completing all eleven (11) LRPL exercises, two trials per facepiece, as determined by appropriate pass and fail criteria.
 - 1.3.4 Been evaluated on a complete panel of human test subjects having facial sizes and shapes that reflect the distribution of facial sizes and shapes of the applicable NIOSH CBRN statement of standard user population and the complete panel test subject protocol is compliant to the applicable approved NIOSH Human Subject Review Board (HSRB) protocol in effect at the time of testing.
 - 1.3.5 The aerosol measurement system is required to have a minimum limit of detection $\leq 0.0002 \text{ mg/m}^3$ to accurately measure protection factors of a minimum 100,000 for the specified chamber exposure conditions of 20 to 40 mg/m^3 with a geometric standard deviation less than 2.0.

2. GENERAL:

- 2.1 This document describes the determination of laboratory respirator protection level (LRPL) quantitative, medium-flow, deep probe, corn oil parameters and evaluations of human subjects wearing a chemical, biological, radiological and nuclear (CBRN) SCBA full facepiece respirator or a CBRN APR 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 respirator passes the specified test. The procedure is a separate test under NIOSH/NPPTL entitled RB-APRS-ASRS-STP-CBRN-0352, dated December 20 2004 and supercedes procedure no. RCT-CBRN-STP-0001, dated November 17, 2001 and the interim guidance dated May 30, 2003. The procedure is designed to rigorously test the evaluated respirator 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 STP to supply certification test data will be subject to the provisions of the NIOSH supplier qualification program (SQP). The SQP is based on the tenets of ISO/IEC 17025, NIOSH Manual of Analytical Methods and other applicable guidelines. A complete quality system audit and follow on audits are requirements of the program. Additional details of the program 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. The successful completion of NIOSH/NPPPTL designated Live Agent Test (LAT) performance requirements, specific for the type of respirator being considered for LRPL testing, are recommended, but not required, before SCBA or APR LRPL testing commences on the submitted respirator.
3. TEST EQUIPMENT, TESTED ITEMS & HUMAN SUBJECTS:
- 3.1. Corn Oil - 99% Pure. CAS Number 8001-30-7. Normally used as a salad and cooking oil, its commercial product names are Maise/Maize Oil, Maydol and Mazola Oil, A clear, light yellow, oil liquid with a flash point of 254 degree C. While combustible when exposed to heat and flame, the auto ignition temperature of this compound is 393 degree C. Prolonged exposure to air causes the compound to thicken and become rancid. It is admissible in acetone and sensitive to light. With a faint taste and odor, this compound is a mild skin irritant and may be an allergen. Material safety data sheets (MSDS) for the type of corn oil used must be available in the test laboratory for review by all test subjects and laboratory personnel in accordance with local hazard communications requirements and this STP.
- 3.2 Environmental test chamber/plenum 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 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 interior of an uncharged corn oil chamber is depicted in Figure 1. An example of a charged corn oil chamber is provided in Figure 2.

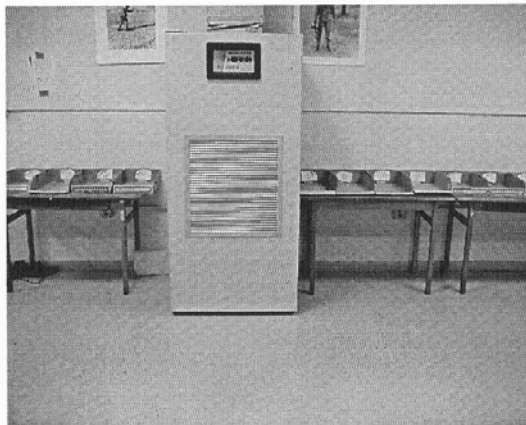
Figure 1. Uncharged Test Chamber



Figure 2. Charged Corn Oil LRPL Chamber

- 3.1.3 Environmental Chamber Control System or equivalent. The environmental control system shall be capable of maintaining 20-80% RH \pm 5% and 65-95 \pm 5° F as normal operating range of conditions (ambient target) for LRPL Tests conducted ideally at 70 °F, 50 % RH. An example of an equivalent environmental control system, the DataAire Model DAP-2 Environmental Control System, is shown in Figure 3.

**Figure 3,
Environmental Control System**



Aerosol Measurement System or equivalent: The aerosol measurement system(s) shall be used to measure the individual aerosol challenge and leak concentrations per sampling point and accurately generate quantitatively measured LRPL factors of up to and including 100,000. An example of a LRPL aerosol measurement system is the TSI Rear Light Scattering Laser Photometer, model 8587, with applicable software, as indicated in the Figure 4. Additional photometers used in determining before, during and after chamber ambient test concentrations and MMAD spatial distribution for compliance are the TSI model 8520, DustTrak Aerosol Monitor and the Scanning Mobility Particle Sizer (SMPS). Model 8587 operates by measuring voltage proportional to aerosol concentration. The capability of the photometer to accurately measure protection factors of at least 100,000 is dependent on the photometer's limit of detection and the aerosol chamber concentration. Mathematically calculated, at the chamber conditions of 20 mg/m³ (the lower limit of the specified CBRN concentration range) the photometer system has a minimum limit of detection of (20 mg/m³ / 100,000) = 0.0002 mg/m³ and can accurately measure a protection factor of

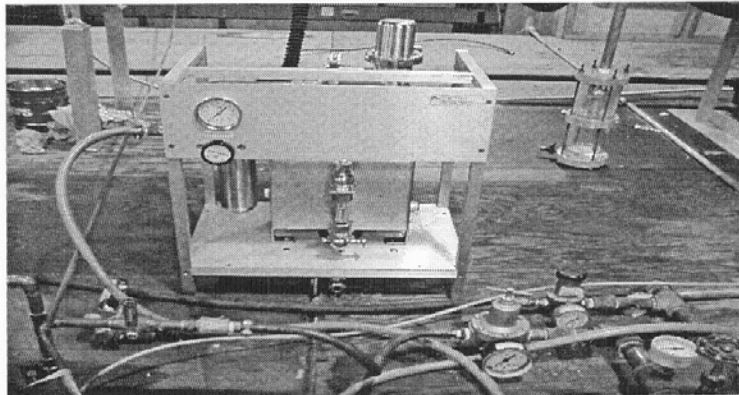
100,000. The photometer is able to accurately and reliably measure 0.001% percent of the chamber concentration when the chamber is at 20 mg/m³. Mathematically calculated: $0.0002 \text{ mg/m}^3 / 20 \text{ mg/m}^3 \times 100\% = \underline{0.001\%}$.

Figure 4, Aerosol Measurement System



- 3.1.5 Aerosol Generator or equivalent. The aerosol generator shall be capable of maintaining 20 to 26 mg/m³ of corn oil challenge aerosol concentrations for the required test duration with a Mass Median Aerodynamic Diameter (MMAD) of 0.4 to 0.6 μm in the test chamber. The geometric standard deviation shall be less than 2.0 mg/m³. The equipment shall be capable of operation without using recycled air. All generator parts require manufacturer quality assurance and maintenance specification compliance. An example of an aerosol generator system, the MSP Model 2045 High Output Aerosol Generator, is shown in Figure 5.

**Figure 5,
Aerosol Generator**



- 3.1.1. Chamber Concentrations. The chamber aerosol concentration shall not vary as a function of time more than ± 10 percent over the duration of a single test trial (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 photometer supplemented by a TSI PORTACOUNT instrument, see Figures 6 and 7.

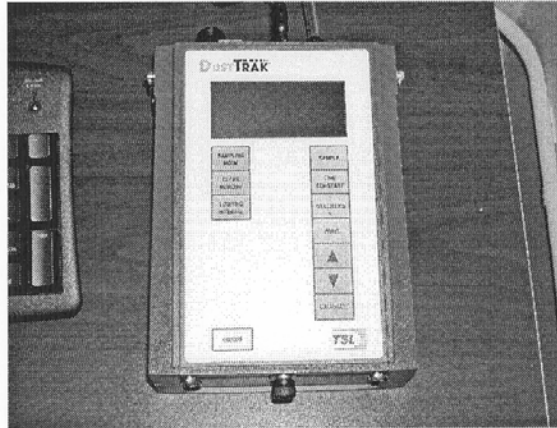


Figure 6, TSI Dust Trak photometer

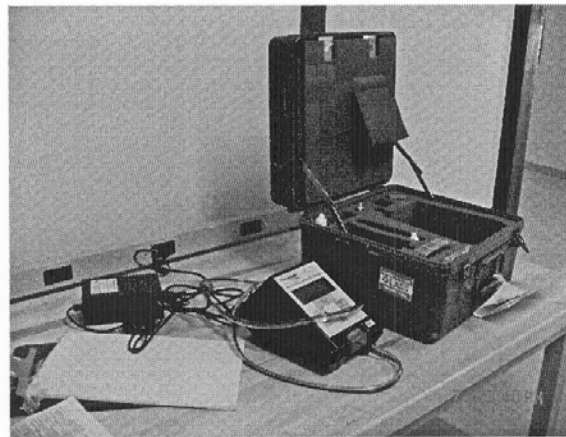
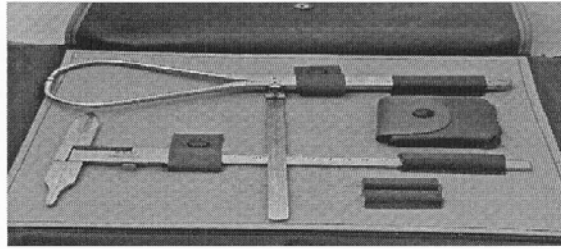
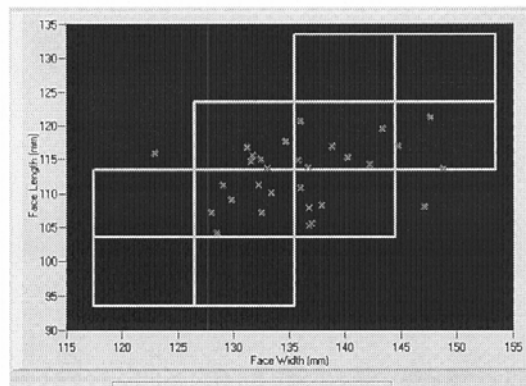


Figure 7, TSI PORTACOUNT Instrument

- 3.1.2. Communications Method. A means of providing two-way communication between the test subject(s) and the test conductor(s) is required. Non-verbal communication such as hand and arm signals, clear line of sight and other non-verbal means from test subjects inside the test chamber to attending laboratory technicians outside the chamber meets this requirement provided the test subjects and the test proctors can clearly see each other and communicate with non-verbal signals. Electronic audio communications (chamber loudspeaker) from laboratory technicians to test subjects is also required to ensure test subjects can clearly hear when to start and stop the test exercise regimen.
- 3.1.3. Facial Size Measurement, Calipers or equivalent. Calibrated face sizing calipers shall be used to measure the human test subject 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 8, Facial Size Measurement Calipers. Additionally, Figure 9 is an example of software to manage the panel test measurements and the placement of subjects in the test panel distribution.

Figure 8, Facial Size Measurement Calipers**Figure 9, Sample LRPL Panel Distribution Software**

- 3.1.4. Tubing. Fully serviceable Tygon tubing (1/4-inch in diameter) and washer connectors are required to mate the facepiece probes to photometer sample lines. A Flexible canula probe assembly is permissible for use in spanning the distance between the nose cup and the APR interior surface (visor or faceblank material).
- 3.1.5. Facepiece Direct Probes. The sample 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 7, below is an interior view of a sample respirator probed in the oral-nasal region of the nose cup. Figure 8, is an exterior view of a probed respirator showing the metal interface for tubing and penetration through the lens and nose cup.

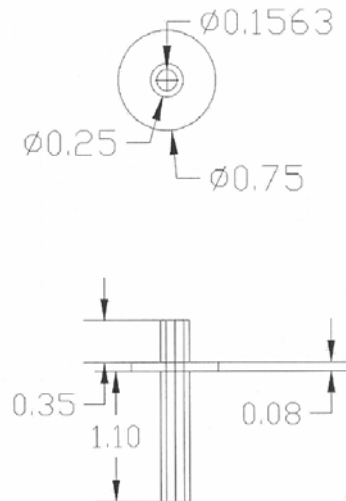
Figure 10, Interior View of LRPL Probed Sample

Figure 8, Exterior View of LRPL Probed Sample



3.1.8 Facepiece Direct Probe Tygon Tubing Connector: Figure 11 is an example of mechanical drawings depicting metal connector dimensions for the appropriate Tygon Tubing connector required for LRPL direct probe sampling. This connector is built to span the distance required that allows destructive probing of the tested LRPL respirator. Typically, the connector is stainless steel metal and allows for tygon tubing to be pressed on at the leading end and a flat face hexagon open washer is on the sampling end.

Figure 11, Probe Tubing Connector, two drawings.



3.1.9 Corn Oil Particle Size Distribution Aerosol Monitor or equivalent. Scanning Mobility Particle Sizer (SMPS), TSI model # 3934 determines the 0.4 to 0.6 MMAD particle size distributions. This determination is required to be weekly. Figure 12 is an SMPS.

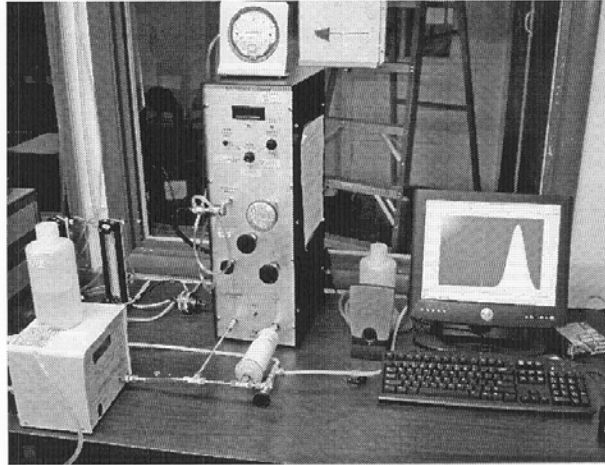


Figure 12, Scanning Mobility Particle Sizer (SMPS)

3.2. Required CBRN SCBA or APR Test Items:

- 3.2.1. Test Facepieces. Each applicant shall provide 25 to 38 production quality full facepiece respirators, of the NIOSH agreed configuration and in each size according to the testing requirements set forth in Appendix B. Figure 13, is a representative photograph of direct probing covering specific determined sizes. One set of User instructions for the respirator and all its accessories seeking CBRN protection approval are required for each respirator submitted for test. Respirator configuration factors such as weight of respirator, weight of accessories, number of canister ports, canister left and right mounted configurations, types of head harness requested and matching the LRPL to LAT configuration are required to be considered when forecasting LRPL test hardware and test time management. Twenty-five (25) respirator systems are required if one universal size is tested. Twenty-nine (29) respirator systems are required if two sizes (14 Small/Medium and 15 Medium/Large). And thirty-eight (38) respirator systems are required if three sizes (10 Small, 17 Medium and 11 Large) are submitted per manufacturer sizing instructions specified in applicable respirator user instructions.

Figure 13, Probed and Un-probed Respirators During the Course of Preparing for LRPL Testing



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-06P, entitled, "Determination of Laboratory Respirator Protection Level (LRPL) Testing (Quantitative) for Respiratory Protective Devices", 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-04XP. The test subjects are required to complete a Health History Questionnaire as part of the volunteer agreement affidavit explanation contained in Protocol No. HSRB-02-NPPTL-04XP. Electronic caliper and manual caliper instruments are used to determine facial head sizes for subject panel placement and assignment of APR sizes.
- 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. It is the responsibility of the testing laboratory principal investigator to ensure all appropriate scientific ethics training requirements are met prior to testing.

4. TESTING REQUIREMENTS AND CONDITIONS:

- 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 by the NIOSH or its representative, at each testing facility. Laboratory technicians will ensure required calibration methods and actions are in place prior to the conduct of each NIOSH test. A statement that all test equipment is within calibration shall be stated by the lab technician on each NIOSH test data sheet applicable.
- 4.2. Safety. Standard laboratory safety practices are required. This includes safety precautions described in the current NIOSH Bruceston Research Center Laboratory Safety Manual or site-specific procedures that are applicable to health and safety requirements for laboratory tests.
- 4.3. Certification Inventory. Test facility personnel will confirm with NIOSH that the model of facepiece submitted for LRPL testing is the same model and configuration as submitted under the NIOSH application for certification with all required accessories per the manufacturer and this model has successfully been live agent tested or is in the process of being LAT by NIOSH. Part number inspection, location and referencing must be accurate and complete before test begins. It is the testing laboratory's responsibility to determine what the best method is to manage this. For labs that do not have access to NIOSH DEIMS server capabilities, an on site physical inspection of incoming respirator hardware is highly recommended. Any accessories that effect form, fit, function (weight, types of head harness etc...), or provide a perceived, implied or actual protective quality, shall be installed on the facepiece prior to actual LRPL testing. NIOSH/NPPTL Guidelines for Identification of Test Configurations for Exposure to GB/HD, dated March 7, 2003, provides guidance on the current testable configuration for LAT and that configuration should match the configuration tested for LRPL and Modified LRPL (MLRPL) testing. Facility personnel are required to keep a

certification equipment inventory log, prior to LRPL commencing, while in progress and upon termination Individual manufacturer respirator equipment stocks are required to be separated &, if multiple manufacturers are on the test site the same day, hardware should be covered or out of direct visual inspection by competing manufacturers, applicants or customers.

- 4.4. Probing. Each facepiece shall be probed and the probe verified functional, prior the facepiece being issued to test subjects by lab personnel in accordance with paragraph 3.1.7 of this STP. The test facility administrator or his staff destructively probes all submitted respirators uniformly. The respirator sampling probe location shall terminate in the oral/nasal region. 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 respirator being evaluated. Final position of the probe should have no, to minimal, impact on the designed function of the facepiece, nose cup or faceblank area that the probe is penetrating. Destructive probing techniques using the probes outlined in paragraph 3.1.8 shall be used unless otherwise changed by NIOSH. When probing submitted respirators, test facility should not attach the probe through material seams since the seam penetration will contribute to failing results. Nose cups that become rigid as a result of destructive probing should be analyzed for possible use of a flexible cannula probe that will span the distance and create less tension on the nosecup.
- 4.5. User Instructions. Prior to conducting the test, the Users Instructions (UI) provided with the test equipment shall be reviewed by all test facility personnel. Test subjects will be taught by the principal investigator or a facility representative on the areas of manufacturer's size selection, donning, positive and negative seal checks, doffing, and other donning procedures related to the accessories as specified by the UI. Any clarifications or supplemental instructions presented in multimedia format or 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 written User Instructions prior to NIOSH approval.
- 4.6. Self Donning. Each test subject shall perform an unassisted donning of the respirator in 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 UI 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 component orientations. Buddy assisted and expert donning are not approved for use in the conduct of this test. Failure analysis of respirators may incorporate expert donning as a trouble shooting measure to determine where/how tested respirator is failing.
- 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 respirator performance and shall minimize sampling biases. The aerosol challenge shall be characterized continually by a known quantitative system to verify that the aerosol is within specified parameters.
- 4.8. Respirator Adaptation Measures. All respirators, SCBA in particular, that require facepiece adaptation to support LRPL testing must have accurate user instructions that address

conversion of that respirator to a manufacturer approved negative pressure configuration in accordance with the applicable NIOSH/NPPTL STP . LRPL testing of full facepieces used on CBRN SCBAs under this procedure will be accomplished by following the manufacturer's instructions for temporarily converting the facepiece into an Air-Purifying Respirator by adding an adapter and 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 testing should be representative of the facepiece used on the SCBA. Accessories must be provided and attached to the CBRN SCBA or APR facepieces submitted for testing.

4.9. Corn-Oil Chamber Physical Constant Conditions:

4.9.1. Temperature Range = 68-80 °F

4.9.2. Relative Humidity Range = 50 ± 10 %

4.10.3 Corn Oil Challenge Concentration = 20 to 26 mg/m³

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

4.10.5 Appropriate lighting will be available to allow clear observation of test subjects.

5. PROCEDURE:

Note: 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 respirator meets or exceeds the requirements defined in the Statement of Standard for that particular CBRN respirator being tested. Refer to the current Statement of Standard for the CBRN respirator 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 respirator being tested. Open-circuit, pressure demand, SCBA, are tested in a negative pressure configuration fully outfitted with all submitted accessories minus SCBA hardware and use the identical LAT configuration. Full face, tight fitting Air-Purifying Respirators (APR) are tested in received minimum packaging configurations fully outfitted with all submitted accessories.

5.2. Number of Test Samples.

5.2.1. Each applicant shall provide the maximum amount of production quality respirators, per the agreed NIOSH configuration. See paragraph 3.2.1 and Appendix B of this STP for quantities per size.

5.2.2. All CBRN RESPIRATOR 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

- 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 laboratory staff will install the sampling probe in each facepiece submitted and verify the integrity of probes before testing. A length of tubing will then connect the sample probes from the respirator to the aerosol detector unit.
- 5.3.2. In accordance with the test laboratory local operational standard procedures, corn oil is added to the aerosol generator and 15 minutes is allowed 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 respirator.
- 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. If nosecup function is restricted by probe, testing laboratory may consider alternate equivalent probe locations.

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 respirator 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 RESPIRATOR 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, were 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 RESPIRATOR 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 RESPIRATOR continuously for 15 minutes before entering the test chamber. Test subjects do not attach critical components to the RESPIRATOR. 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 RESPIRATOR, 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 and three (3)* additional 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 will successively don and wear the CBRN respirator 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 in the below listed sequence.**
- 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 respirator during any part of the LRPL active test, to include the RESPIRATOR'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 RESPIRATOR 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 will keeping the RESPIRATOR fitted so as to allow a realistic sight picture to be attained by placing the cheek unhindered by RESPIRATOR 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 RESPIRATOR 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 RESPIRATOR. 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 RESPIRATOR 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 RESPIRATOR 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 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 RESPIRATOR for each trial with the same test subject for each trial.

5.11 If a RESPIRATOR is identified as a failure upon trial termination, test facility personnel will conduct failure assessment protocol of the RESPIRATOR in two phases. First phase is to inspect the RESPIRATOR while it is still donned on the test subject. Second phase is to inspect the RESPIRATOR 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 RESPIRATOR being improperly probed, reassign another like, but serviceable RESPIRATOR to the test subject and retest for two complete trials. If the RESPIRATOR 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 RESPIRATOR cannot be probed successfully by the test

facility, manufacturer QNFT kits can be reviewed and considered for use, but only as a last resort.

- 5.12 MLRPL for Negative Pressure Fullface Respirators (CBRN APR): Modified LRPL (MLRPL) canister, a weight enhanced canister, must weigh 500 grams as weighed in by the test laboratory. Submitted canister non-enhanced cannot weigh more than 500gm. Canister must measure no more than 5 inches in diameter. In order to do this task, the testing laboratory will accept the canisters submitted with the application. No surrogate canisters are authorized for MLRPL testing. Testing laboratory will apply required measures such as weighted tape, to make the submitted canister weigh 500 grams and measure 5 inches in width. For the MLRPL testing, 8 subjects are selected randomly out of the original LRPL test panel. The subjects must have passed the original LRPL with the assigned respirator. 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. Two trials of the MLRPL are required and a passing LRPL of 2000 per trial is required. MLRPL requires 100% passage rate. MLRPL does not apply for SCBA.

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 RESPIRATOR 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.
- 6.2.2 CBRN SCBA (Open Circuit): Each CBRN Open-Circuit, Pressure Demand, Self Contained Breathing Apparatus respirator facepiece only will be 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. 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 tested in an atmosphere containing 20-40 mg/m³ of corn oil aerosol of a MMAD of 0.4 to 0.6um.
- 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 a submitted canister or 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 canister configuration or as 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-0353, MLRPL, 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%).

6.2.3.9 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 Respirator 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 Respirator facepiece shall be designed to prevent eyepiece, spectacle and lens fogging.

7. RECORDS\TEST SHEETS

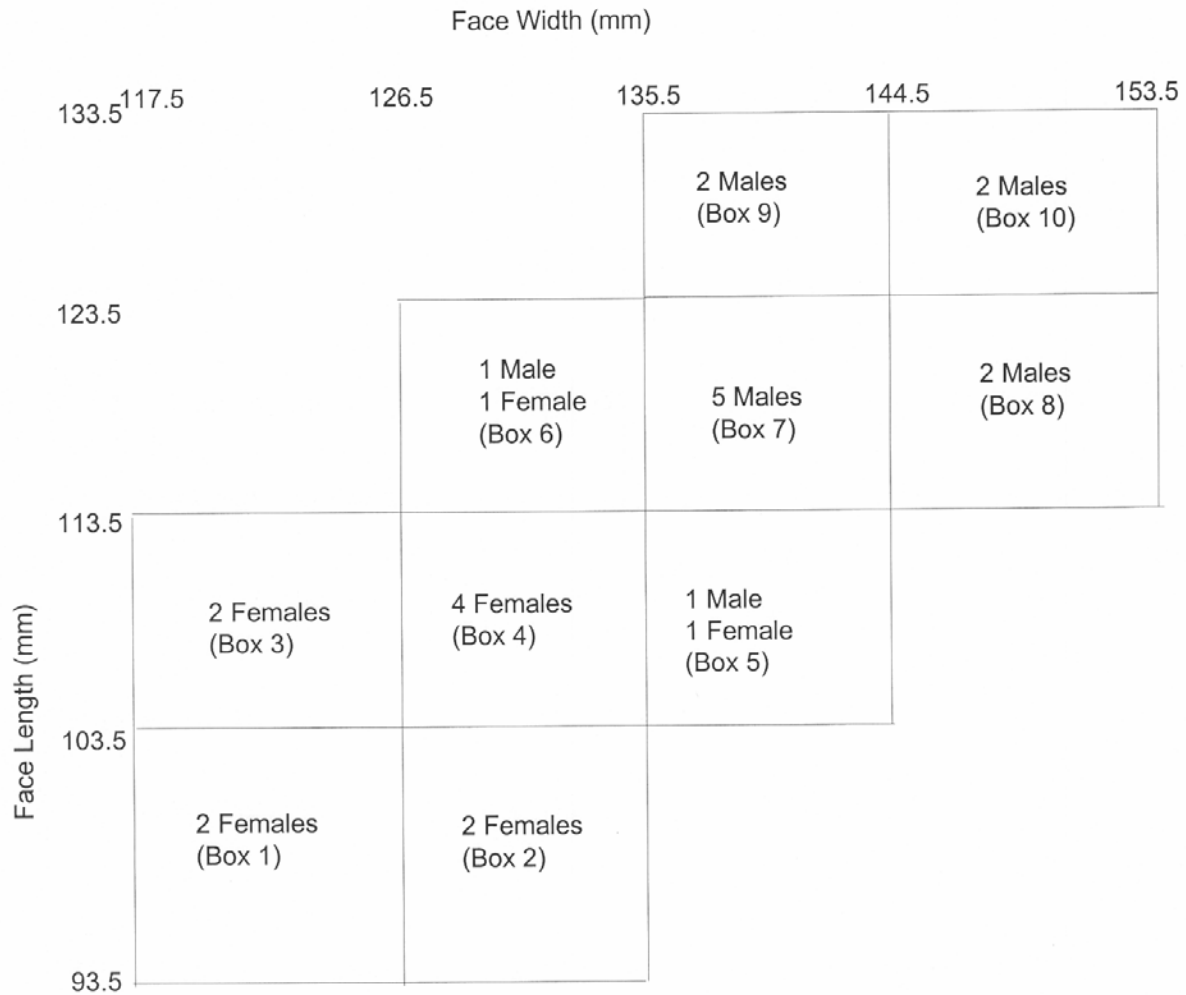
- 7.1 All test data will be recorded on the LABORATORY RESPIRATOR PROTECTION LEVEL TEST QUANTITATIVE ,MEDIUM-FLOW, DEEP PROBE, CORN OIL FIT FACTOR PERFORMANCE TEST FOR CBRN FULL FACEPIECE SCBA or APR test data sheets.
- 7.2 All videotapes and photographs of the actual test being performed and of the tested equipment shall be maintained in the task file as part of the permanent record.
- 7.3 Failure Analysis: 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) conducts on site failure analysis, determines validity of failure, confirms failure and sends a test summary data sheet and test incident reports (TIR) to the NIOSH. Testing is then placed on hold or pause and coordination with NIOSH and the applicant for test result resolution begins. If determined that a denial letter will result, the LRPL laboratory prepares the final test data sheet and full or partial quantities of 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 respirator 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 summary test data, TIRs and digital photographs.
- 7.3.4 If the respirator LRPL failure is determined to be attributed to a component that is not an integral component of LRPL performance, the LRPL failure will be expunged as a data point. Components of a respirator which are not integral to the LRPL performance test are those additional components or modifications made to existing components which are employed or modified for LRPL testing but which are not evaluated under Live Agent Penetration / Permeation or LRPL testing in accordance with CBRN STP 0200,0201, 350, 351 or 352. Such non-integral LRPL performance components, where applicable based on design, may include: P100 filters and associated filter connections used to convert a CBRN SCBA facepieces to a negative pressure testing configuration for purposes of LRPL testing.
- 7.3.5 If the respirator failure is determined to be attributed to a component that is an integral component of LRPL performance, the LRPL failure will be recorded and used in the overall determination of the LRPL Pass / Fail level. Components which are integral components of LRPL performance are those components that are evaluated under Live Agent penetration / permeation and LRPL in accordance with CBRN STP # 200, 201, 350, 351 or 352. The components of the RESPIRATOR, where applicable based on design, that are integral components of LRPL performance are: the sealing surface of tight-fitting face and/or neck seals, adjustable head harness straps, head harness buckles or clasps, head strap base-plates which sit on the back of the head, additional accessory weight generated by manufacturer specific accessories seeking CBRN protection approval, canister interface to faceblank, canister air flow impingement generating base line or sub standard LRPL fit numbers on CBRN APR, hydration tube accessory failure, all inhalation/exhalation valve assembly components on CBRN SCBA and APR, all canister port housing assemblies and all material seams and component attachment points on the facepiece that are evaluated during LAT and LRPL testing.

RECORD OF CHANGE:

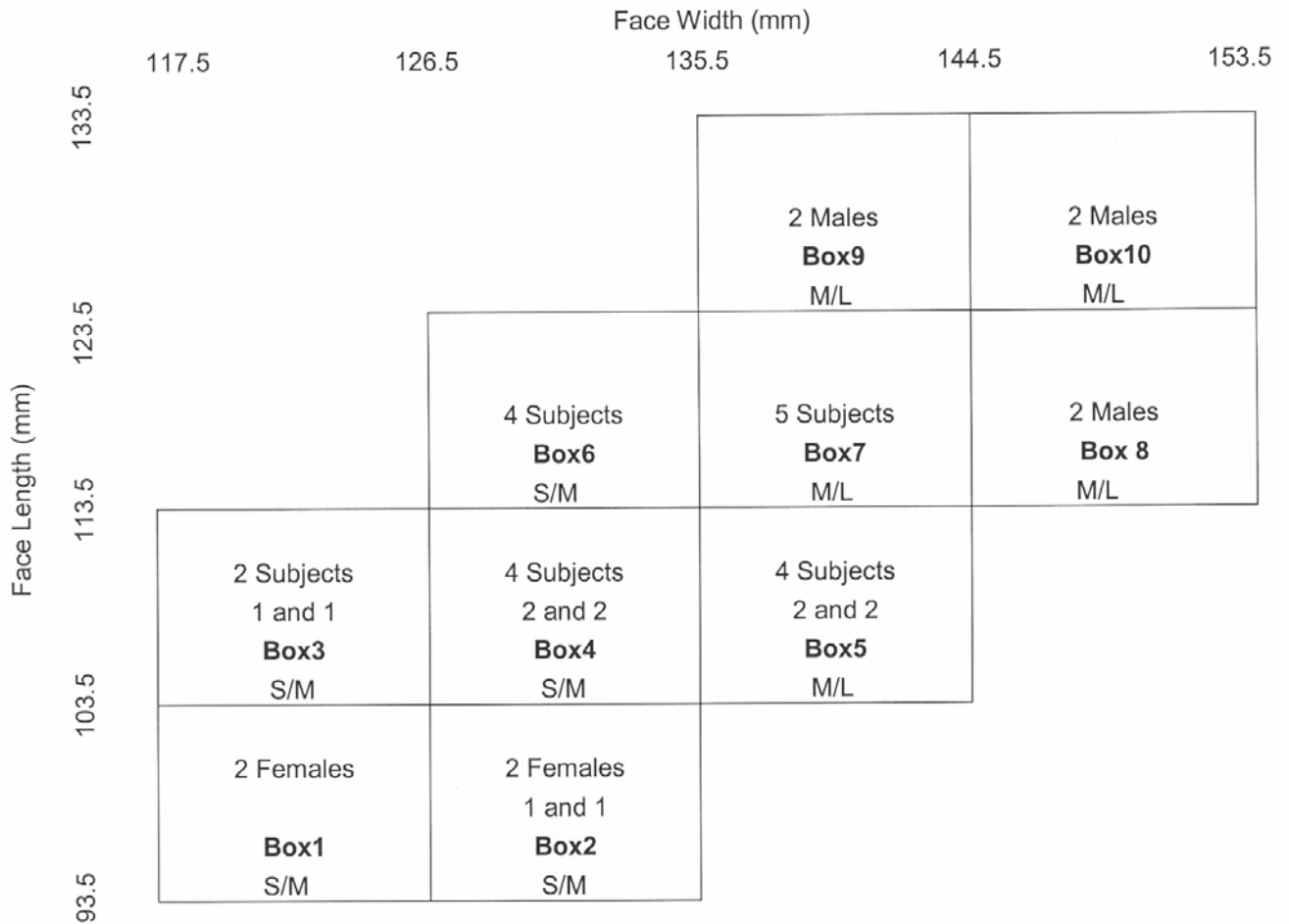
1. November 17, 2001: NIOSH Procedure No. RCT-CBRN-STP-001 issued as SCBA LRPL STP, interim
2. May 30, 2003: NIOSH Procedure RCT-CET-STP-CBRN-0352 compiled SCBA and APR LRPL standard test procedures together under STP-0352. Interim guidance document dated May 30, 2003 posted to internet.
3. December 20, 2004: NIOSH procedure RB-APRS-ASRS-STP-CBRN-0352 finalized. It supersedes RCT-CBRN-STP-001 and RCT-CET-STP-CBRN-0352. 2 and 3 respirator size distribution matrices added.

Appendix A



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

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



Male and Female, 29 Member Panel for Testing of 2 Sizes CBRN SCBA or APR, LRPL

Note: For the purpose of testing available human test subjects, the gender in each box can be all one type or a mixture of male and female. 2 size distribution of medium and large or small and medium is annotated by S/M or M/L.

		Face Width (mm)				
		117.5	126.5	135.5	144.5	153.5
Face Length (mm)	133.5			3 Subjects Box 9 Large	3 Subjects Box 10 Large	
	123.5		3 Subjects Box 6 Med	6 Subjects (3 Med and 3 Large) Box 7 Med or Large	5 Subjects (2 Med and 3 Large) Box 8 Med or Large	
	113.5	4 Subjects Box 3 Med	6 Subjects Box 4 Med	3 Subjects Box 5 Med		
	103.5	2 Subjects (2 Females or 1&1) Box 1 Small	3 Subjects (2 Females & 1 Male) Box 2 Small			
93.5						

Male and Female, 38 Member Panel Distribution for Three Sizes of Facepiece, CBRN SCBA or APR, LRPL

Note: For the purpose of testing available human test subjects, the gender in each box can be all one type or a mixture of male and female. 3 size distribution of small, medium and large is annotated by Small, Med and Large. For those submissions that contain Extra Small, use Box 1 as an Extra Small (XSML). For those submissions that contain Extra Large use Box 10 as an Extra Large (XL).

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

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

Medium size: 17 each

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

Large size: 11 each

Panels – 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 RESPIRATOR 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. 4 failures also apply for those submissions that have 4 or 5 sizes addressed in user instructions due to the use of foam seal inserts or extra small or extra large faceblanks. Multiple-sized 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 such as foam seal inserts, are used to maintain user seal, these products must demonstrate LAT passing criteria in accordance with applicable 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 is not applicable to criteria for MLRPL.

National Institute for Occupational Safety and Health
 Respirator Branch
 Test Data Sheet



Task Number: STP No.: 202
 Manufacturer: Reference No. 42 CFR 84.63(a)(e)(d)
 Test: Laboratory Respirator Protection Level Test - Quantitative (Medium-Flow Deep Probe
 Corn Oil) for Self-Contained Breathing Apparatus with Full Facepieces

Model Number/
 Trade Name: CBRN SCBA
 Facepiece/
 Part Number: Worst Case Configuration per SAF and Rationalization
 Statement

NIOSH Approval Numbers	
13F	CBRN
13F	CBRN
13F	CBRN

Test Temperature: 72 F
 Relative Humidity: 31 %
 Facepiece Size: Three size (25-38 subjects)

Test Subject Number	Test Subject Identification	LANL Panel Cell #	LRPL1	LRPL2
1	1A	4	103	100000
2	2A	4	254.2	100000
3	3A	4	100000	100000
4	4A	8	70313.4	99255.1
5	5A	4	100000	97332.8
6	6A	4	58895	100000
7	7A	6	100000	95720
8	8A	6	100000	100000
9	9A	2	100000	100000
10	10A	7	100000	100000
11	11A	6	100000	100000
12	12A	5	94094.2	100000
13	13A	5	99848.5	30165.8
14	14A	5	100000	100000
15	15A	9	100000	100000
16	16A	4	100000	100000
17	17A	9	100000	100000
18	18A	8	100000	100000
19	19A	1	100000	100000

Task Number: STP No.: 202
 Manufacturer: Reference No. 42 CFR 84.63(a)(c)(d)
 Test: Laboratory Respirator Protection Level Test - Quantitative (Medium-Flow Deep Probe
 Corn Oil) for Self-Contained Breathing Apparatus with Full Facepieces

20	20A	3	88762	93311
21	21A	9	100000	100000
22	22A	3	100000	89928
23	23A	10	95678.7	100000
24	24A	2	100000	100000
25	25A	7	100000	100000
26	26A	1	559.3	12097.3
27	27A	3	100000	100000
28	28A	3	8296.4	100000
29	29A	7	100000	100000
30	30A	8	99211.4	93435.1
31	31A	7	100000	100000
32	32A	8	100000	100000
33	33A	7	100000	100000
34	34A	8	100000	100000
35	35A	8	100000	100000
36	36A	10	100000	100800
37	37A	8	100000	100000
38	38A	3	108.4	99.8

Overall Pass Percentage: 94.74 %

Overall Result: PASS

Requirement:

Each CBRN Open-Circuit, Pressure-Demand, Self-Contained Breathing Apparatus respirator facepiece will be worn in an atmosphere containing 20 to 26 mg/m3 corn oil vapor with a Mass Median Aerodynamic Diameter of 0.4 to 0.7 μ m, and the minimum Laboratory Respirator Protection Level shall be equal to or greater than 500 (minimum) for 95 \pm 0.26 percent of the test subjects, evaluated in accordance with Procedure No. RCT-CBRN-STP-0202 Appendix B. 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 testing period.

Was all equipment verified to be in calibration throughout all testing? Yes No

Were the part numbers verified against the hardware? Yes No

[NAR - Non-Applicable Research Data]

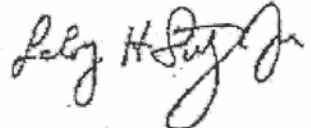
Pass Percentages	LRPL Levels	Result
=> 95%	500 Minimum	PASS

Comments:

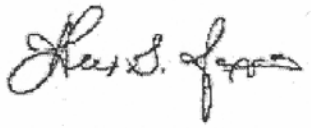
**CBRN SCBA Data Sheet to Appendix C, CBRN LRPL Test Data Sheets,
NIOSH Procedure Number: RB-APRS-ASRS-STP-CBRN - 0352**

Task Number:	STP No.:	202
Manufacturer:	Reference No.	42 CFR 84.63(a)(c)(d)
Test:	Laboratory Respirator Protection Level Test - Quantitative (Medium-Flow Deep Probe Corn Oil) for Self-Contained Breathing Apparatus with Full Facepieces	

Subjects 1 and 2 failures - Poor Don. Subject 38 failures - Subject is in panel 3, an overlapping panel, and was given the larger size (medium). Subject's face was just too small for that mask. During probing of facepieces, a mask was torn. Mask failure was identified during the test, and was linked to the tear in the mask. It was replaced by another facepiece by ~~XX~~. SBCCOM recognizes that this LRPL data corresponds to both TN 12~~XX~~ and TN 12~~XX~~.

Signature: 
Laboratory Technician

Date: _____

Concurrence: 
Laboratory Supervisor

Note: Electronic signatures above are for example use only..

Appendix C, continuum, CBRN APR LRPL Data Sheet Example

NIOSH Data Sheet

Test Number 0352, LRPL Testing for APR with CBRN Protection

Task Number TN XXXXX
 Manufacturer XXXXX
 Equipment
 Type APR
 Date
 Completed xx/xx/2003/4
 Number of
 Sizes 3
 Failures
 Allowed 4

Laboratory Walk In Chamber Physical Conditions:
 REQUIREMENT:

Current Passing Percentages

Subj	Panel	Mask Size	LRPL	PASS/FAIL	PF	Frequency	Cumulative	
							%	Pass %
1	4	S	100000.0	PASS	0	0	0.00%	100.00%
			100000.0	PASS	10	2	5.26%	94.74%
2	4	S	94878.1	PASS	20	0	5.26%	94.74%
			91170.3	PASS	50	2	10.53%	89.47%
3	4	S	100000.0	PASS	100	0	10.53%	89.47%
			100000.0	PASS	500	2	15.79%	84.21%
4	4	M	14683.0	PASS	1000	0	15.79%	84.21%
			45533.7	PASS	1667	0	15.79%	84.21%
5	4	M	100000.0	PASS	2000	0	15.79%	84.21%
			216.4	FAIL	6667	2	21.05%	78.95%
6	4	M	26.2	FAIL	10000	0	21.05%	78.95%
			24.8	FAIL	20000	2	26.32%	73.68%
7	5	M	100000.0	PASS	50000	4	36.84%	63.16%
			93318.3	PASS	100000	24	100.00%	0.00%
8	5	M	100000.0	PASS	Total Trials	38		
			100000.0	PASS				
9	5	M	84598.5	PASS				
			164.5	FAIL				
10	6	M	7.6	FAIL				
			100000.0	PASS				
11	6	M	36150.0	PASS				
			31086.0	PASS				

Total Passes	32
Total Failures	6
Overall Result	FAIL

Appendix C, continuum, CBRN APR Data Sheet, MLRPL example

Subj	Panel	Mask Size	MLRPL
1	4	S	100000.0
			51109.3
2	4	S	81429.5
			79647.6
4	4	M	6476.8
			90.7
7	5	M	100000.0
			100000.0
8	5	M	100000.0
			59289.1
11	6	M	30270.3
			100000.0
16	7	L	100000.0
			100000.0
19	8	L	7432.7
			10493.5

Passes	15
Failures	1
Result	Fail

Appendix D, HSRB Extract, Medical Screening and Test Subject Consent Forms

TITLE

Determination of Laboratory Respirator Protection Level (LRPL) for Respiratory Protective Devices (RPD) Submitted for NIOSH Certification

PRINCIPAL INVESTIGATOR

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LOCATION AND DURATION

Testing will be conducted in the Materiel Evaluation Team's Protection Factor Test Facility located in building E-5604, APG-EA, MD 21010-5424. Since testing is dependent on subject availability and the number of respirator systems submitted for certification, the data collection associated with this protocol will occur over an indefinite period of time.

BACKGROUND

The National Institute for Occupational Safety and Health (NIOSH), part of the Centers for Disease Control and Prevention (CDC), is responsible for conducting research and providing recommendations for the prevention of work-related injury and disease. In this regard, NIOSH has statutory obligation for the approval of respiratory protective devices for industrial use as stated in 42 CFR Part 84 titled "Respiratory Protective Devices; Final Rules and Notice," dated June, 1995. With the increase in terrorist activities against U.S. targets, both domestically and abroad, the potential use of military-type chemical or biological weapons has become a major concern for the first responder community of fire, police, and emergency medical personnel who would be called

upon in such cases. Since the expertise concerning protection against military chemical and biological threats lies within the U.S. Army Soldier and Biological Chemical Command (SBCCOM), a partnership between NIOSH and SBCCOM/RDECOM was formed for collaboration and support in developing respiratory protection equipment standards and testing methodology in support of national domestic preparedness/homeland security. These standards will be used to certify multiple respirator classes for use by military and first responder personnel in any chemical or biological terrorist attack.

Chemical, Biological, Radiological, and Nuclear (CBRN) respiratory protective devices (RPD) performance standards developed jointly by SBCCOM and NIOSH include the Laboratory Respirator Protection Level (LRPL) testing. This test will be performed to quantify the ability of the equipment to protect the individual from CBRN agents. A non-toxic corn oil aerosol is used as the challenge. A ratio is obtained of the concentration of the challenge aerosol to the concentration of the aerosol within the facepiece of the protective device. Protection Factor (PF) is a measure of the device's ability, particularly the facepiece, to keep the aerosol from entering the subject's oral/nasal passage. The PF is the concentration of aerosol outside of the facepiece compared to the concentration of aerosol inside the mask.

NIOSH/RDECOM RELEVANCE

A memorandum of understanding (MOU) agreed upon in the year 2000 between NIOSH and SBCCOM formed a partnership between the organizations for collaboration and support in developing respiratory protective equipment standards for domestic preparedness equipment. In addition, the organizations agreed to develop NIOSH testing, certification, and approval processes for respirators. The overarching goal of the partnership between NIOSH and SBCCOM is to ensure that all emergency responders to a chemical or biological terrorist event, whether military support or civilian personnel, will be protected against airborne contaminants regardless of which make or model of RPD they use as long as it has been certified to established NIOSH CBRN performance standards. The LRPL testing serves as a portion of the certification process and is similar to the standard military PF testing.

METHODS

VOLUNTEER SUBJECTS

Both male and female volunteers between the ages of 18 and 50 will be recruited to participate in this study. Volunteers will be recruited from civilian and military personnel stationed or employed at SBCCOM and the Edgewood CB Center. Volunteers will be thoroughly briefed on the nature and purpose of the study. Informed consent will be obtained from each volunteer upon completion of the Volunteer Agreement Affidavit and Volunteer Agreement Affidavit Explanation. Each volunteer will receive a verbal explanation of the points covered by the affidavit and affidavit explanation and will be given every opportunity to discuss concerns or questions regarding their participation before being asked to sign the volunteer agreement affidavit and agreement explanation.

SAFETY AND HEALTH

(1) *Health Screening.* All volunteers will be questioned about their medical history and current health status. A Health History Questionnaire will be provided for signature as part of the Volunteer Agreement Affidavit Explanation. The questionnaire addresses current health status and relevant history of the medical criteria associated with this test.

(2) *Daily Examination.* Prior to testing, the principal investigator will question each volunteer to safeguard that no apparent condition exists in the volunteer that would jeopardize his/her safety or health. Examples of such conditions would be an upper respiratory tract infection, excessive fatigue, recent excessive use of alcohol, or other illness that may compromise subject safety. Individuals who report to have or appear to have any such conditions will not be allowed to participate in testing.

(3) *Safeguards.*

- a. Members of the testing staff will be in close proximity to the test subjects to assist them in the event that any problems arise during testing. If a subject asks to terminate the test or a respirator becomes dislodged or damaged, testing will be stopped and the RPD will be removed.
- b. The test subject shall be constantly monitored during the test to determine that the CBRN RPD is functioning satisfactorily and that they are not experiencing undue discomfort because of air-flow restrictions or other physical changes in the operation of the apparatus.
- c. The Edgewood Medical Clinic (ext. 5-3726) will be notified of the testing being performed prior to commencement. If emergency medical services are not available from the Clinic at any time, calling 911 will be used to activate the emergency response system.
- d. The physical work associated with the various tasks outlined in this study is considered to be light to moderate in nature. Therefore, the chance of volunteers becoming excessively stressed during completion of the exercises is unlikely.
- e. All RPD will be cleaned with sanitary respirator wipes before use.
- f. The principal investigator will ensure that the procedures outlined in this protocol are strictly followed and that no alterations in the approved design will be made.

(4) *Risks/Benefits.* The procedures and circumstances encompassed by this protocol provide for a high degree of safety. Possible benefits include experience and training with the tested equipment.

TEST ITEMS

This protocol covers all RPD submitted to NIOSH for CBRN certification and includes but is not limited to:

Air-Purifying Respirators (APR)

EXPERIMENTAL PROCEDURES

The chamber is designed so that the volunteers performing LRPL testing are visible and have 2-way communication with the test administrators while in the chamber. The chamber design meets local fire codes for enclosed spaces including an entry vestibule designed to allow entry and exit from the chamber with minimal disturbance to both aerosol concentration and uniformity. The vestibule is large enough to accommodate door swing and a test subject with the other door closed. The test chamber is capable of maintaining spatial uniformity within ± 10 percent in the vicinity of the respirator being tested. The challenge aerosol for the LRPL test is a 99% corn oil aerosol. There are several commercially available types of corn oil. Their commercial names are Maise Oil, Maydol, Mazola Oil, Maize Oil (Must comply with Chemical Abstract No. 8001-30-7). Material Safety Data Sheets for each of these products are posted for review in accordance with EPA Right to Know regulations. This mono-dispersed aerosol is distributed throughout the test chamber to maintain the appropriate concentration as provided by the NIOSH LRPL Standard Test Procedure (STP), typically 22 ± 2.0 mg/m³. The challenge aerosol used in this test is comprised of a non-toxic corn oil mist, the same used in cooking and foodstuffs. A Laskin nozzle produces a coarse aerosol cloud, which is directed into an impaction plate to remove the larger particles and yield an aerosol in the desired size range. The Laskin nozzle yields an aerosol in the Mass Median Aerodynamic Diameter (MMAD) of 0.4 to 0.7 μm with a geometric standard deviation of less than 2. The concentrated aerosol from the generator is diluted with filtered ambient air to control the challenge aerosol concentration in the exposure chamber to 22 ± 2.0 mg/m³ with an oxygen level of at least 20% for the duration of each test. The temperature range of the test chamber is 68-80 °F with a relative humidity of 50% +/- 10%.

A 6-decade, 45 degree off-axis light-scattering laser photometer, sampling at a flow rate of 1 – 2 liters per minute (lpm), is used to quantify concentration of the challenge corn oil aerosol in the chamber and the aerosol which penetrates the RPD, particularly around the facepiece peripheral seal. For a given particle size, the quantity of scattered light is proportional to the aerosol concentration. The photometer converts the quantity of scattered light to a voltage, which was then digitized and recorded by a computer.

Each RPD facepiece is fitted with a probe and verified by lab personnel for purposes of measuring concentrations of corn oil inside the facepiece nosecup or requested configuration. 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 RPD. The sampling location shall be in the oral/nasal region of the facepiece. 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

For each RPD application submitted to NIOSH for certification, twenty-five to thirty-eight human subjects are required to complete the LRPL test. It is required that the subjects be clean shaven of facial hair to avoid creating a leak path between the interface of the RPD's facepiece and subject's face. Anthropometrical data from each subject will be taken, such as face length and width. Other measurements such as neck diameter may be taken depending upon the type of RPD being tested. The subjects will then be assigned their RPD according to their anthropometrical data as set forth in the NIOSH LRPL STP. Test facility personnel, or a manufacturer's representative, will familiarize the subjects with the RPD to ensure that it is worn properly and in accordance with the manufacturer's user's instructions. Each test subject shall practice donning (15 minutes) and wear the respirator facepiece continuously for approximately 15 minutes before entering the test chamber. The instruction period will be a minimum of 10 minutes and a maximum of 30 minutes. The subjects will then be divided into groups, each capable of fitting into the chamber. The first group of subjects will don their equipment and enter the chamber. Upon entering the chamber, a sample line from the facepiece will be attached to a photometer outside of the chamber. During the test, each test subject will be asked to perform eleven exercises for one-minute each [8 OSHA standard exercises (29 CFR 1910.134) plus 3 additional first responder exercises identified by the U.S. Army Soldier and Biological Chemical Command]. These exercises include but are not limited to:

- Normal breathing
- Deep breathing
- Head side to side
- Head up and down
- Recite the Rainbow Passage
- Sight a rifle
- Reach for the floor and ceiling
- On your hands and knees look left and right
- Facial expressions
- Climb the stairs
- Normal Breathing

Other exercises may include:

- Bending forward and touching toes
- Jogging in place
- Raising arms above head and looking upward
- Bending knees and squatting
- Crawling on hands and knees
- Standing with arms folded in front of chest and twisting torso from side to side
- Climb stepladder
- Move 3 lbs boxes from floor to table and back
- Roll walls and ceiling with paint roller

Bag clothes
Loosen bolts

Any additional exercises outlined in the NIOSH LRPL STP for a specific piece of equipment will be submitted to the Risk Reduction Office for approval prior to testing. These exercises are designed to test the seals of the RPD Facepiece.

Once eleven one-minute exercises are completed, the subject shall exit the chamber, leave the chamber area, report to the technician reporting line, doff the facepiece, and await instructions for the next test. The entire process of donning the equipment, performing the exercises, exiting the chamber and removing the equipment is one complete trial. If required, the subject will complete more trials.

MEASUREMENTS

All LRPL test data will be subjected to the following analysis. Respirator facepiece performance will be quantified in terms of a Laboratory Respirator Protection Level (LRPL). The LRPL_e for each exercise equals the ratio of the challenge aerosol concentration to the in-facepiece aerosol concentration as quantified by the photometer.

$$LRPL_e = \frac{\text{Challenge Aerosol Concentration During Each Exercise}}{\text{In-facepiece Aerosol Concentration During Each Exercise}}$$

LRPL_o is the overall harmonic average of the individual exercise data and is calculated as follows:

$$LRPL_o = \frac{\text{Number of Exercises (11)}}{\text{_____}}$$

where e is the number of the test exercise. 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 Overall LRPL will be calculated by a computer and stored to disk for timely upload to the NIOSH DEIMS Record System.

CONFIDENTIALITY

All data and medical information about volunteers will be considered privileged and will be held in confidence. Volunteers will not be identified in any presentation or publication of the results. Records of this study including the Volunteer Agreement Affidavits and Volunteer Agreement Affidavit Explanations will remain on file in the Risk Reduction Office for a minimum of 65 years following the completion of data collection and analysis.

APPENDIX E to NIOSH Procedure NO. RB-APRS-ASRS-STP-CBRN-0352

Volunteer Agreement Affidavit

Volunteer Registry Data Entry Sheet

Volunteer Agreement Affidavit Explanation

VOLUNTEER AGREEMENT AFFIDAVIT

For use of this form, see AR 70-25 or AR 40-38; the proponent agency is OTSG

PRIVACY ACT OF 1974

Authority: 10 USC 3013, 44 USC 3101, and 10 USC 1071-1087.

Principle Purposes: To document voluntary participation in the Clinical Investigation and Research Program. SSN and home address will be used for identification and locating purposes.

Routine Uses: The SSN and home address will be used for identification and locating purposes. Information derived from the study will be used to document the study; implementation of medical programs; adjudication of claims; and for the ~~mandatory reporting of medical conditions as required by law. Information may be furnished to Federal, State and local agencies.~~

~~Disclosure: The furnishing of your SSN and home address is mandatory and necessary to provide identification and to contact you if future information indicates that your health may be adversely affected. Failure to provide the information may preclude your voluntary participation in this investigational study.~~

PART A (1) - VOLUNTEER AFFIDAVIT

Volunteer Subjects in Approved Department of the Army Research Studies

Volunteers under the provisions of AR 40-38 and AR 70-25 are authorized all necessary medical care for injury or disease which is the proximate result of their participation in such studies.

I, _____, SSN _____

having full capacity to consent and having attained my _____ birthday, do hereby volunteer/give consent as legal representative for _____, to participate in

Determination of Laboratory Respirator Protection Level for Respiratory Protective Devices Submitted for NIOSH Certification

(Research study)

under the direction of Alex G. Pappas

conducted at USA Edgewood Chemical Biological Center, Aberdeen Proving Ground, MD 21010-5424

(Name of Institution)

The implications of my voluntary participation/consent as legal representative; duration and purpose of the research study; the methods and means by which it is to be conducted; and the inconveniences and hazards that may reasonably be expected have been explained to me by Alex G. Pappas or:

I have been given an opportunity to ask questions concerning this Investigational study. Any such questions were answered to my full and complete satisfaction. Should any further questions arise concerning my rights/the rights of the person I represent on study-related injury, I may contact

Human Use Committee Chairman

at (410) 436-2302

(Name, Address and Phone Number of Hospital (Include Area Code))

I understand that I may at any time during the course of this study revoke my consent and withdraw/have the person I represent withdrawn from the study without further penalty or loss of benefits; however, I/the person I represent may be required (military volunteer) or requested (civilian volunteer) to undergo certain examination if, in the opinion of the attending physician, such examinations are necessary for my/the person I represent's health and well-being. My/the person I represent is refusal to participate will involve no penalty or loss of benefits to which I am/the person I represent is otherwise entitled.

PART A (2) - ASSENT VOLUNTEER AFFIDAVIT (MINOR CHILD)

I, _____, SSN _____

having full capacity to assent and having attained my _____ birthday, do hereby volunteer for _____ to participate in

under the direction of
conducted at

(Name of Institution)

(Continue on Reverse)

DA FORM 5303-R, MAY 89

PREVIOUS EDITIONS ARE OBSOLETE

PART A(2) - ASSENT VOLUNTEER AFFIDAVIT (MINOR CHILD) (Cont'd.)

The implications of my voluntary participation; the nature, duration and purpose of the research study; the methods and means by which it is to be conducted; and the inconveniences and hazards that may reasonably be expected have been explained to me by

I have been given an opportunity to ask questions concerning this investigational study. Any such questions were answered to my full and complete satisfaction. Should any further questions arise concerning my rights I may contact

at

(Name, Address, and Phone Number of Hospital (Include Area Code))

I understand that I may at any time during the course of this study revoke my assent and withdraw from the study without further penalty or loss of benefits; however, I may be requested to undergo certain examination if, in the opinion of the attending physician, such examinations are necessary for my health and well-being. My refusal to participate will involve no penalty or loss of benefits to which I am otherwise entitled.

PART B - TO BE COMPLETED BY INVESTIGATOR

INSTRUCTIONS FOR ELEMENTS OF INFORMED CONSENT: *(Provide a detailed explanation in accordance with Appendix C, AR 40-38 or AR 70-25.)*

See Volunteer Agreement Affidavit Explanation.

You will receive a copy of the Volunteer Agreement Affidavit Explanation.

I do do not *(check one & initial)* consent to the inclusion of this form in my outpatient medical treatment record.

SIGNATURE OF VOLUNTEER	DATE	SIGNATURE OF LEGAL GUARDIAN <i>(if volunteer is a minor)</i>
PERMANENT ADDRESS OF VOLUNTEER	TYPED NAME OF WITNESS	
	SIGNATURE OF WITNESS	DATE

REVERSE OF DA FORM 5303-R, MAY 89

This form is affected by the Privacy Act of 1974

1. Authority: 10 USC 3012, 44 USC 3101 and 10 USC 1071-1087
2. Principal and Routine Purposes: To document participation in research conducted or sponsored by the U.S. Army Chemical Research, Development and Engineering Center. Personal information will be used for identification and location of participants.
3. Mandatory or Voluntary Disclosure: The furnishing of the SSN and home address is mandatory and necessary to provide identification, and to contact you if future information indicates that your health may be adversely affected. Failure to provide the information may preclude your participation in the research study.

PART A - PROTOCOL TESTING DATA (to be completed by investigator)

PROTOCOL: Log No. _____ Title: Determination of Laboratory Respirator Protection Level for Respiratory Protective Devices Submitted for NIOSH Certification

PRINCIPAL INVESTIGATOR: Last: Pappas First: Alex MI: G.

TEST ORGANIZATION: U.S. Army Edgewood CB Center Facility: Protection Factor Test Facility

Location: City: Aberdeen Proving Ground State: MD Zip: 21010-5424

TEST PERIOD: Start Date: _____ Completion Date: _____ LAB NOTEBOOK NO.:

CHALLENGE MATERIAL DATA (if applicable)

1. Name of material used (both active and inactive materials) Corn-Oil
2. Manufacturer: (Per Principal Investigator (P.I.)) Lot number: (Per P.I.) Expiration date: (Per P.I.)
3. Other pertinent information: (Allergic reactions to latex, butyl, silicone, butyl blends, natural rubber blends or other respirator integral materials should be known by the test subject and test subject should advise the principal investigator and his/her staff prior to LRPL value testing commencing.)

DATE(S) OF SUBJECT'S PARTICIPATION: _____ SUBJECT CODE:

EXTENT OF VOLUNTEER PARTICIPATION: Did volunteer complete the study? Yes___ No___ (if no, state reasons):

REMARKS:

PART B - VOLUNTEER INFORMATION (print clearly, using ink or ballpoint pen)

NAME: Last: _____ First: _____ Initial:

Social Security No.: _____ Sex: _____ Rank/Gr: _____ MOS:

HOME ADDRESS (permanent):

MILITARY ADDRESS:

Street: _____ Unit: _____

City: _____

City: _____

State: _____ Zip: _____

State: _____ Zip: _____

SMCCR Form 1068, 1 Mar 90, replaces SMCCR Form 1068, 1 Apr 89 which is obsolete. VOLUNTEER AGREEMENT AFFIDAVIT EXPLANATION

STUDY TITLE: Determination of Laboratory Respirator Protection Level (LRPL) for Respiratory Protective Devices Submitted for NIOSH Certification

LOCATION OF STUDY: U.S. Army Edgewood Chemical Biological Center
Building E5604
5183 Blackhawk Rd.
Aberdeen Proving Ground, MD 21010-5424

PRINCIPAL INVESTIGATOR: Alex G. Pappas
Materiel Evaluation Team
Phone: (410) 436 3338
agpappas@sbccom.apgea.army.mil

INSTRUCTIONS: You have been asked to take part in a study being conducted at the Edgewood Chemical Biological Center at Aberdeen Proving Ground, MD. It is very important for you to read and understand all of the procedures and general principles that apply to all individuals who participate in this study.

DESCRIPTION OF STUDY:

(1) Purpose

This study has been designed to evaluate the ability of the equipment to protect the user from airborne particles. The data obtained from this study will be used to determine whether or not the tested equipment meet LRPL standards set by the National Institute for Occupational Safety and Health (NIOSH) and the Soldier Biological Chemical Command (SBCCOM/RDECOM).

(2) Anticipated Duration of Your Participation

Your voluntary participation in this study is requested for a minimum of one day of testing. You may be given the opportunity to complete additional testing for this study on different occasions as more Respiratory Protective Devices (RPD) are identified for testing. Your future participation will be based on your availability and your willingness to complete additional RPD wear trials.

(3) Health Inquiry

When you first arrive at the test site the principal investigator will ask you about how you feel physically and will visually judge your present condition of health. If you report to have or appear to have a "cold" or if you do not otherwise feel well, you will be temporarily removed from the study and will not be allowed to participate in any testing until you have fully recovered. A health history questionnaire has also been provided for your signature as part of this Volunteer Agreement Affidavit Explanation to certify that you have been questioned regarding your current health status and relevant history of the medical criteria associated with this test. The principal investigator will explain all of the testing procedures of this study to you after

Procedure No. RB-APRS-ASRS-STP-CBRN-0352 Revision 0 Page 41 of 47
you have completed the health history questionnaire. You are encouraged to ask any questions that you may have about your participation in this study and about the study itself at any time. Once you have agreed to volunteer for this study, you will sign all of the required agreement forms.

A. Have you ever been treated by a physician for any of the following ailments? (Please circle your response)

Dizziness or fainting spells	Yes	No
Chronic respiratory illness	Yes	No
Asthma	Yes	No
Shortness of breath	Yes	No
Heart trouble	Yes	No
High or low blood pressure	Yes	No
Chest pain w/exercise	Yes	No
Diseases of the arteries	Yes	No
Diabetes	Yes	No
Elevated cholesterol	Yes	No

B. Have you taken medication or seen a physician for any of the following ailments within the last 15 days? (Please circle your response)

Dizziness or fainting spells	Yes	No
Chronic respiratory illness	Yes	No
Asthma	Yes	No
Shortness of breath	Yes	No
Heart trouble	Yes	No
High or low blood pressure	Yes	No
Chest pain w/exercise	Yes	No
Ear, nose, or throat trouble	Yes	No
Sinusitis	Yes	No
Susceptibility to skin reactions	Yes	No
History of allergic diseases	Yes	No
Upper respiratory tract infection	Yes	No
Swollen feet/ankles	Yes	No
Pain or cramps on legs	Yes	No
Painful joints	Yes	No

C. Have any of your immediate family members died from or been diagnosed with any of the following diseases? (Please circle your response and list relationship)

	Yes	No	Relationship
Heart trouble	Yes	No	_____
High or low blood pressure	Yes	No	_____
Diseases of the arteries	Yes	No	_____
Elevated cholesterol	Yes	No	_____

D. Please characterize your smoking history by checking the appropriate responses below.

- Never smoked
- Stopped more than 10 years ago
- Smoke up to 1 pack/day
- Smoke 1-2 packs/day
- Smoke 3+ packs/day
- Other:

What type of smoking? (circle all that apply) **cigarette** **cigar** **pipe**

E. Please characterize your current *regular* aerobic exercise habits (e.g., jogging, cycling) by checking the appropriate response below.

- | | Type of exercise |
|---|------------------|
| <input type="checkbox"/> Do not participate in regular aerobic exercise | _____ |
| <input type="checkbox"/> Do aerobic exercise 1-3 times a week | _____ |
| <input type="checkbox"/> Do aerobic exercise 4-5 times a week | _____ |
| <input type="checkbox"/> Do aerobic exercise 6-7 times a week | _____ |

F. Have you worn a respirator/mask before? Yes No

G. If so, did you have an adverse reaction before, while, or after wearing the respirator/mask? Yes No

H. Do you wear glasses or contacts? Yes No

(4) Testing Procedures

Before LRPL testing starts, Anthropometrical data will be taken from you. For example, face length and face width are common measurements, others may include neck circumference.. This data determines the size of equipment you require to be properly protected. You will then be trained on how to don and remove the equipment by either the principal investigator or other test personnel. The type of equipment used in this test at any one time, may include, but is not limited to:

- Air-Purifying Respirators (APR)
- Powered Air-Purifying Respirators (PAPR)
- Self-Contained Breathing Apparatus (SCBA) Open Circuit
- SCBA Closed Circuit
- Supplied Air Respirators
- Air-Purifying Escape Masks
- SCBA / APR Combination

The training is to accommodate you with the equipment so that you can operate it as it is intended. Once the training is complete, you will be asked to don the equipment and prepare to enter the chamber.

The challenge aerosol used in this test is comprised of a non-toxic corn oil mist, the same used in cooking and foodstuffs. A Laskin nozzle produces a coarse aerosol cloud, which is directed into an impaction plate to remove the larger particles and yield an aerosol in the desired size range. The concentrated aerosol from the generator is diluted with filtered ambient air to control the challenge aerosol concentration in the exposure chamber.

Once you have entered the chamber, a sample tube from your equipment will be attached to a laser photometer located outside of the chamber. This photometer, a 6-decade, 45-degree off-axis light-scattering laser photometer, sampling at a flow rate of 1 – 2 L/min, is used to quantify concentration of the challenge corn oil aerosol and the aerosol that penetrated the equipment. For a given particle size, the quantity of scattered light is proportional to the aerosol concentration. The photometer converted the quantity of scattered light to a voltage, which was then digitized and recorded by a computer. The data recorded is called a Protection Factor (PF), which is the ratio of the challenge concentration to the concentration that penetrated the equipment.

You will then be asked to complete the following one-minute exercises:

- 1) Normal Breathing
- 2) Deep Breathing
- 3) Move 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 Look Left and Right
- 9) Facial Expressions
- 10) Climb the Stairs
- 11) Normal Breathing

There may be more exercises added or substituted to the test such as rolling the walls and ceiling with a paint roller, bagging clothes and moving boxes from the floor to a table. Test personnel will communicate to you from the control room when to proceed to the next exercise.

Once the one-minute exercises are completed, you will exit the chamber and remove the equipment. The process of donning the equipment, entering the chamber, performing the exercises, exiting the chamber and removing the equipment is one complete trial. The process for a trial will be repeated as needed.

(4) *Possible Risks, Discomforts, and Inconveniences*

This study has been designed to include safeguards against any reasonably foreseeable risks of injury to you, the volunteer. The principal investigator will ensure that the test procedures are followed and that no changes will be allowed from the approved protocol. The following risks and discomforts could conceivably occur during the course of this study:

- (a) You may experience some minor discomfort due to the equipment. The equipment can be quickly and easily removed if your discomfort becomes so unbearable that you need to remove it.
- (b) The complete study may require a few hours of your time, depending on the type of equipment being tested.

(5) *Benefits*

Minor benefits include expert training in the proper use and fitting of this type of equipment.

(6) *Confidentiality of Your Records*

All records and medical information about you will be considered privileged and will be held in confidence. You will not be personally identified in any presentation or publication of the results of this study. However, complete confidentiality cannot be promised to volunteers who are military members because information bearing on your health may be required to be reported to appropriate medical or command authorities. It may be necessary for representatives of the Edgewood CB Center Human Use Committee to inspect the records of this study because of their role as approving officials. All records, including your name and social security number, will be stored for a minimum of 65 years following completion of this study.

(7) *Point of Contact*

The Human Use Committee Chairman may be contacted for any answers to pertinent questions about your rights as a volunteer during the study, and in the unlikely event of a research related injury. The commercial phone number for this office is (410) 436-2302. The DSN number is 584-2302.

(8) *Your Rights*

As a volunteer, your rights include the following:

- (a) Your participation is voluntary.
- (b) You may end your participation in this study, or in any part of this study, at any time.
- (c) You will not be penalized or lose any benefits that you are entitled to if you refuse to participate in any part of this study.
- (d) Once you have read this explanation, you are free to ask any questions that may help you to understand clearly the nature of this study.

(9) *Reasons for Termination without Your Consent*

- (a) The principal investigator may remove you from this study at any time if, in his opinion, you have shown behavioral or motivational problems that interfere with your ability to participate fully in this study.
- (b) Your participation will be limited if any of the testing equipment is unable to provide adequate measurements or fails.
- (c) You will not be allowed to participate in this study if some of your responses on the medical history questionnaire would suggest that your safety may be compromised during wear of a respirator.

IMPORTANT NOTICES

It is important for you to understand that this research investigation does **NOT**, directly or indirectly, expose you or any of the study personnel to any chemical, biological, or nuclear warfare agent or any other hazardous substance. This study contains no hidden experimental procedures.

This research project has been reviewed for both scientific and military importance to include medical and ethical concerns. As a volunteer, you will be authorized, under the direction of Army Regulation 70-25, all appropriate care for injury that occurs as a direct result of your participation in this study.

The complete study design is referred to as the "protocol" and a copy of this protocol will be provided to you upon request. Also, any significant new findings developed during the course of this study will be available to you if you so request.

IF THERE IS ANY PART OF THIS EXPLANATION THAT YOU **DO NOT** UNDERSTAND, ASK THE INVESTIGATOR **BEFORE** YOU SIGN BELOW.

VOLUNTEER'S NAME (please print)

PERMANENT ADDRESS

CITY/TOWN, STATE, ZIP CODE

I have received a copy of this consent form, have read the above explanation, and agree to participate in the investigational study described above.

SIGNATURE

DATE

I was present during the explanation referred to above as well as during the volunteer's opportunity to ask questions. I hereby witness the signature of the volunteer.

WITNESS SIGNATURE

DATE