National Institute for Occupational Safety and Health National Personal Protective Technology Laboratory P.O. Box 18070 Pittsburgh, PA 15236		
Procedure No. CET-APRS-STP-CBRN-0452	Revision: 1.1	Date: 22 December 2005

DETERMINATION OF LABORATORY RESPIRATOR PROTECTION LEVEL (LRPL) QUANTITATIVE, MEDIUM FLOW, DEEP PROBE, CORN OIL, FIT FACTOR PERFORMANCE TEST FOR CHEMICAL, BIOLOGICAL, RADIOLOGICAL AND NUCLEAR (CBRN) AIR-PURIFYING ESCAPE RESPIRATOR STANDARD TESTING PROCEDURE (STP)

1. PURPOSE:

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

1.2. The purpose of this STP is to describe the test conditions and procedures necessary to test and certify civilian manufacturer submitted CBRN Air-Purifying Escape Respirator (APER) certification applications for NIOSH approval. A CBRN APER is a complete system including a tight fitting hooded respiratory device including (1) the proper designations required by NIOSH and the manufacturer's unique components and (2) a compatible negative pressure air-filtering device that is installed per the manufacturer's current user's instructions. This STP is used to test CBRN APER against corn oil aerosol while worn by a human test subject breathing in a dynamic nine exercise specific sequence. Aerosol quantified instrumentation remotely senses internal and external corn oil concentrations via the attachment of tubing to the specific oral/nasal and 'under hood' ocular probes mounted in the tested APER. The requirement for this STP is to ensure that all CBRN APER, seeking NIOSH CBRN approval, have:

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

1.2.2. User's instructions for donning that are easily understood, applicable to all components, both visual and written, and current.

1.2.3. Achieved a pass or fail result based on completing 9 LRPL exercises as determined by appropriate pass criteria per class of respirator.

Approvals:	1st Level	2nd Level	3rd Level

1.2.4. Been evaluated on a complete test subject panel having facial sizes and shapes, neck sizes, and head sizes that approximate the distribution of facial sizes / shapes, neck sizes, and head sizes of the general applicable statement of standard user population. Quantities of required test subjects and sample respirators are described in Appendix B.

2. GENERAL:

2.1. This document describes the Determination of Laboratory Respirator Protection Level (LRPL) Quantitative, Medium-Flow, Deep Probe, Corn Oil, Protection Factor performance test for the CBRN APER 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 APER passes the specified test. The procedure is a separate test under the NIOSH/NPPTL Respirator Branch heading of CET-CBRN-ESCAPE-STP-0452. The procedure is designed to rigorously test the evaluated APER 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. This test is considered a human factors test that requires participation of human subjects to quantify the LRPL performance level required of the CBRN APER statement of standards. The successful completion of NIOSH/NPPPTL designated Live Agent Test (LAT) performance requirements, specific for the type of APER being considered for LRPL testing, must be demonstrated before LRPL testing commences on the submitted APER.

2.3. This STP shall be used to test several different types of CBRN APER for satisfactory Laboratory Respirator Protection Level performance. CBRN APER may include, but are not limited to, the following components: full facepiece, oral/nasal cup, or mouthpiece with nose clip.

3. TEST EQUIPMENT / TEST ITEMS/ HUMAN SUBJECTS

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

3.1.1. Corn oil - 99%. Commercial Product Name; Maise Oil, Maydol, Mazola Oil, Maize Oil. Corn oil utilized must comply with Chemical Abstract No. 8001-30-7 prior to test commencing. Material Safety Data Sheets (MSDS) for the type of corn oil used must be posted for review by all test subject and laboratory personnel in accordance with EPA Right to Know regulations, applicable OSHA HAZCOM requirements and this STP.

3.1.2. Environmental test chamber and plenum system or equivalent. The chamber shall be designed so that the individual(s) performing LRPL testing are visible at all times while in the chamber. The chamber design must meet local fire codes for enclosed spaces including an entry vestibule designed to allow safe entry and exit from the chamber with minimal disturbance to both aerosol concentration and uniformity. The vestibule shall be large enough to accommodate entry vestibule

door swing and eight test subjects while the main entry chamber door is closed. The test chamber shall be capable of maintaining spatial uniformity within ±10 percent in the vicinity of the respirator being tested. The challenge aerosol concentration shall not vary as a function of time more than ±10 percent over the duration of a single test (approximately 15 minutes). The aerosol challenge shall be characterized continually by a known quantitative system to verify that the aerosol is within specified parameters as detailed in section 3.1.5. An example is shown in Figure 1.

Figure 1. Environmental Test Chamber

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

Figure 2. Environmental Control System

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

Figure 3. Aerosol Measurement Systems

3.1.5. Aerosol Generator or equivalent. The Aerosol Generator shall be capable of maintaining 20 to 40 mg/m^3 corn oil challenge aerosol concentrations 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. The equipment shall be capable of operation with out using recycled air. An example of an Aerosol Generator system, the MSP Model 2045 High Output Aerosol Generator, is shown in Figure 4.

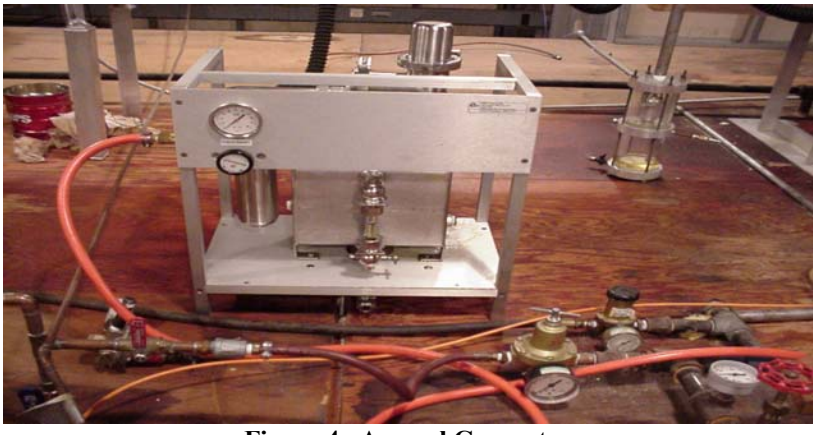

Figure 4. Aerosol Generator

3.1.6. Chamber Concentrations. The chamber aerosol concentration shall not vary as a function of time more that ± 10 percent over the duration of a single test (approximately 15 minutes). The test chamber shall be capable of maintaining spatial uniformity within ± 10 percent in the vicinity of the respirator being tested. An example of an instrument to verify spatial uniformity and chamber concentrations is the TSI DustTrak photometers (no figure available on the TSI DustTrak photometer).

3.1.7. Communications. A means of providing two-way communication between the test subject(s) and the test conductor(s) shall be provided. Non-verbal communication between test subjects inside test chamber and attending laboratory technicians is acceptable.

3.1.8. Facial/Neck Size Measurement; Calipers, Measurement Tapes, or equivalent. Calipers and measurement tapes shall be used to measure anthropometric variables for subject placement in the APER Laboratory Respirator Protection Level (LRPL) Test Panel (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. Measurement tape shall have millimeters as the smallest increment of measure. Figure 5. depicts examples of Facial/Neck Size Measurement Calipers. Figure 6. is an example of software available to manage the panel test measurements and placement of subjects.

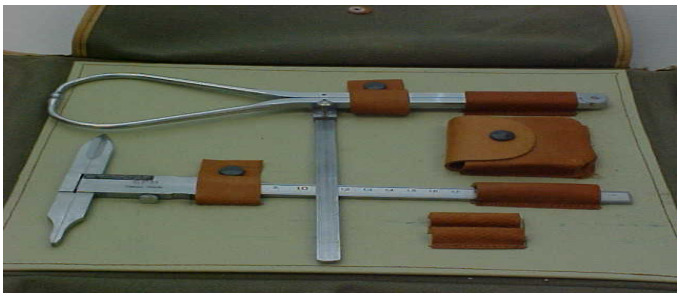

Figure 5. Facial/Neck Size Measurement Calipers

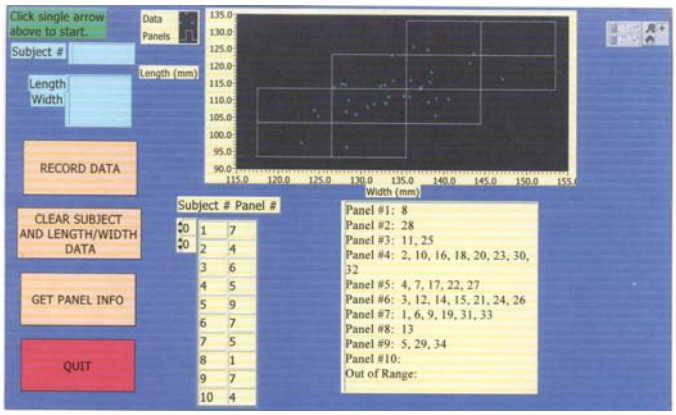

Figure 6. Sample LANL Panel Calibration Software

3.1.9. Tubing. Tygon tubing (1/4-inch i.d.) and connectors used to mate the APER probes to photometers.

3.1.10. APER Probes. The probes shall be of the shape defined by Liu [AIHAJ (45); 278-283, 1984] and shall not interfere with the fit or function of the respirator. Figure 7. depicts an exterior view of an APER probed in the oral/nasal zone of the APER oral/nasal cup.

3.1.11. Compressed Air Delivery System. A compressed air delivery system will be used to deliver make-up air to the hood as required for specific respirator designs. The compressed air delivery system must deliver air meeting the minimum grade requirements for Type I gaseous air set forth in the Compressed Gas Association (CGA) Commodity Specification for Air, G-7.1-1966 or later edition (Grade D or higher quality). The compressed air delivery system must be maintained and calibrated according to the equipment manufacturer's maintenance instructions. Inspection and calibration documentation tracking the compliance of the air quality to CGA G-7.1-1966 or later edition (Grade D or higher quality) must be maintained in the laboratory. Air quality maintenance checks are required to be performed in accordance with the equipment manufacturer's maintenance instructions and are required to be on hand, current, and capable of confirming compliance to the minimum air quality specified in this section.

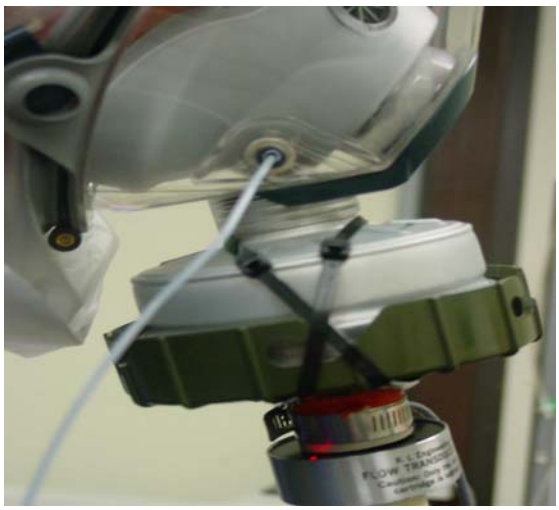

Figure 7. Sample Exterior View of Probed APER

3.2. Required CBRN APER Test Items:

3.2.1. Test APER. Each applicant shall provide the maximum number of APER of production quality, in the NIOSH agreed configuration, of each specified size configuration specified in Appendix B. The equivalent number of identical training aid systems is additionally required to be submitted. If no training aid system is submitted with the unit, the equivalent number of APER is additionally required to be submitted for training purposes. User's instructions for self-donning and system attachments or other hardware are required for each APER

submitted for test. Test factors such as weight of accessories, weight of critical components, type of head harness used and identical LAT configuration tested must be adhered to. Sixty-five (65) APERs are required if one universal size is tested, 69 APERs if two sizes (29 Small/Medium and 40 Medium/Large) are tested, and 78 APERs if three sizes (20 Small, 27 Medium and 31 Large). Additional size configurations are also possible; in these cases, NIOSH will determine the panel size, applicable anthropometric measurement ranges, and APER test quantity.

3.3. Human Factors:

3.3.1. Test Subjects. The minimum and maximum number of test subjects for each size configuration are specified in Appendix B. All procedures and requirements specified in the NIOSH Human Subject Review Board (HSRB) Protocol HSRB-03-NPPTL-04XP entitled, "Determination of Laboratory Respirator Protection Level (LRPL) for Respiratory Protective Devices (RPD) Submitted for NIOSH Certification" 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-03-NPPTL-04XP. The test subjects shall be required to complete a Health History Questionnaire as part of the Volunteer Agreement Affidavit Explanation contained in Protocol No, HSRB-03-NPPTL-04XP. Electronic caliper, manual caliper, and measuring tape measurements shall be used to determine facial/neck/head sizes for subject panel placement and assignment of APER size.

3.3.2. Test Administrator(s). Shall have successfully completed the CDC/ATSDR Scientific Ethics Training, the DHHS/NIH Human Participant Protections Education for Research Teams or an equivalent NIOSH sanctioned course. Note: The NIOSH Human Subject Review Board will determine if specific courses not stated above are equivalent.

4. TESTING REQUIREMENTS AND CONDITIONS:

4.1. Calibration. Prior to beginning any testing, all measuring equipment utilized for final measurements as part of this testing must have been calibrated within the preceding 12 months, or as specified by the equipment manufacturer, using a method traceable to the National Institute of Standards and Technology (NIST). Equipment calibration records shall be available for examination at each testing facility. Laboratory technicians will check calibration prior to the conduct of the testing. A statement that all test equipment is within calibration shall be attested by the lab technician on each NIOSH test report.

4.2. Safety. Normal laboratory safety practices must be observed. This includes safety precautions described in the current NIOSH Bruceton Research Center Laboratory Safety Manual or site-specific procedures that are applicable to health and safety requirements.

4.3. Certification Inventory. Test facility personnel will confirm that the model of APER submitted for LRPL testing is the same model and configuration as submitted under the NIOSH application for certification with the required accessories as defined by the

manufacturer and successfully live agent tested. Part number inspection, location and referencing must be accurate and complete before test begins. Any accessories that affect form, fit, function, or provide a protective quality shall be installed on the APER and subject to LRPL testing. Facility personnel are required to keep a certification inventory, when complete, prior to LRPL commencing. Individual manufacturer APER equipment stocks are required to be separated & covered between manufacturers.

4.4. Probing. Each APER shall be probed and verified functional prior to issue to test subjects by lab personnel for purposes of measuring concentrations of corn oil at the 'under the hood' ocular and oral/nasal zone in accordance with paragraph 3.1.10 of this STP. For those APER without oral/nasal cups defining the breathing zone, sampling probe must still extend into the oral/nasal zone per Para 3.1.10 of this STP. The LRPL test facility administrator or his staff probes the APER. The respirator manufacturer may elect to witness the probing with prior approval from NIOSH. As deemed necessary by NIOSH and the LRPL test facility, the effectiveness of the probing may be verified by a manufacturer's method prior to the actual LRPL corn-oil testing. The APER sampling locations are in the breathing zone and in the 'under the hood' ocular zone. The optimum sampling probe position for the breathing zone 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 'under the hood' ocular zone will also require a probe positioned similar to the oral/nasal zone probe, with the probe 1/4 inch from the bridge of the nose. The exact final position of the sample probes will depend upon the design of the APER being evaluated. Destructive probing techniques shall be used unless otherwise approved by NIOSH.

4.5. User's Instructions. Prior to conducting the test, the User's Instructions provided with the test equipment shall be reviewed by the test facility personnel and the test subjects. Test subjects will be taught by the principal investigator or a facility representative on the areas of manufacturer's size selection criteria, donning, fit check, doffing, and other fitting procedures for the APER, in order to represent any training prescribed or offered by the manufacture's instructions. Any clarifications or supplemental instructions provided by manufacturer representatives at the time of certification inventory, during the test or after the test must be NIOSH reviewed prior to incorporation into revised User's Instructions before final NIOSH approval is granted.

4.6. Self Donning. Each test subject shall perform an unassisted donning of the APER 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 APER until they are satisfied that they are wearing the APER in compliance with the manufacturer's User's Instructions prior to entering the chamber. Self-Donning relies on the clarity of the User's Instructions addressing, if applicable based on design, such issues as head harness pull-tab sequence, proper seating of oral/nasal cups, and proper orientation of other APER components.

4.7. Air Flow Sampling. Air shall be sampled out of the respirator oral/nasal zone and the 'under hood' ocular zone at a rate of 2.2 ± 0.2 Lpm in each zone. The method in which the sampling probe is installed shall not interfere with APER performance and shall

minimize sampling biases.

4.8. Make-Up Air: As deemed necessary based on respirator design, make-up air at a rate of 2.2 ± 0.2 Lpm will be returned to the respirator. The make-up air connection location will be at the top of the hood, approximating the crown of the wearer's head, with the exact final position dependent upon the design of the APER being evaluated to avoid kinking of the make-up air line. Make-up air must be of the applicable minimum grade requirements for Type I gaseous air set forth in the Compressed Gas Association (CGA) Commodity Specification for Air, G-7.1-1966 or later edition (Grade D or higher quality).

4.9. LRPL Exposure Chamber Conditions:

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

4.9.2. Relative Humidity Range = 50 $\pm$ 10 %

4.9.3. Corn Oil Challenge Concentration = 20-40 $\pm$ 2.0 mg/m^3

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

5. PROCEDURE:

Note: Review the manufacturer's operation and maintenance manuals of test equipment for calibration instructions, operational use, and maintenance procedures prior to commencing this STP.

5.1. General. This procedure describes the Laboratory Respirator Protection Level (LRPL) performance test for ensuring that the protection factor provided by the CBRN Air-Purifying Escape Respirator (APER) meets or exceeds the requirements defined in the Statement of Standard for CBRN APER. Refer to the current version of the APER Statement of Standard for further explanation of the LRPL requirement. This procedure describes the required human subject sample size, test equipment, data collection methods, human use protocol requirements, and the specific performance requirement for APER being tested.

5.2. Number of Test Samples.

5.2.1. Each applicant shall provide the maximum number of APER of production quality, in the NIOSH agreed configuration, and the equivalent number of identical training systems as described in Appendix B.

5.2.2. All CBRN APER shall be individually numbered with an indelible pen or tagged in a sequence that the number can be correlated to the NIOSH application number (TN), manufacturer, and administrative sequence number so it can be tracked throughout the LRPL.

5.2.3. The administrative sequence numbers are replicated in the test summary data sheets and indicate product performance per the stated requirement.

5.3. Test Equipment and Chamber Set-Up:

5.3.1. Test facility staff will install the sampling probe, in accordance with paragraph 4.4 of this STP, in each APER submitted under the applicable NIOSH TN and verify the integrity of probes before physical testing is began. A short length of tubing will then connect the sample probes in the APER to the aerosol detector unit.

5.3.2. In accordance with local operational standard procedures, add corn oil to the aerosol generators and allow 15 minutes for the chamber concentration to stabilize.

5.3.3. Electronic or manual calipers with equivalent accuracy to the Seritex model GPM 104, 0-200 mm length, or spreading measurement calipers, Seritex model GPM 106, 0 – 300 mm width, shall be used for facial length and width measurements. Measurement tape shall be used for head and neck circumference measurements. Measurement tape shall have millimeters as the smallest increment of measure.

5.3.4. Inadequate test probing examples are, but are not limited to: 1) probes that do not clearly enter the oral/nasal breathing zone or 'under hood' ocular zone, 2) penetrate just the eye lens without penetrating the oral/nasal cup, 3) penetrate through an APER molded seam, or 4) enter the oral/nasal cup but are blocked by internal respirator parts.

5.4. Conducting the LRPL Test:

5.4.1. Panels: Test subjects shall be selected to cover the applicable cells based on the component design of the APER and manufacturer sizing guidance. The APER Laboratory Respirator Protection Level (LRPL) Test Panel is referenced in Appendix A. The anthropometrical measurements to be taken are: 1) face length (Menton-Nasal Root Depression, also called Menton-Sellion), 2) face width (Bizygomatic diameter), 3) neck circumference: at the level of the infrathyroid landmark (Adam's apple) and measured perpendicular to the long axis of the neck, and 4) head circumference: the maximum circumference of the head just above the ridges of the eyebrows (supraorbital ridges) and the attachment of the ears. To measure head circumference, the subject looks straight ahead, the plane of the tape will be higher in the front than in the back and the sides should be parallel, and enough tension is exerted to compress the hair.

5.4.2. Size Assignment: Anthropometric sizing determines what size APER is issued to the test subject, if multiple sizes are available. For subjects which are of overlapping size assignment categories, for example Small and Medium, manufacturer procedures for evaluating respirator fit, if specified in the product's User's Instructions, will be performed to determine which size is assigned. These procedures may include, but are not limited to user seal checks or a qualitative / quantitative fit test. The best fitting size as determined by these

procedures will be assigned. Subjects that do not pass the fit criteria specified in the product's User's Instructions are not authorized to be used as subjects for the LRPL corn-oil test. All LRPL corn-oil passing or failing test results will be considered valid (unless otherwise determined by NIOSH through post-test failure analysis) for those subjects which have passed the fit criteria specified in the product's User's Instructions. The priority method of APER size assignment will be for a subject to simultaneously meet all 3 ranges of anthropometric criteria (that is, facial size, head circumference, and neck circumference) for a designated hood size in the APER Laboratory Respirator Protection Level (LRPL) Test Panel (Appendix A). For example, using Appendix A to assign a 'Small' size APER to a test subject, the subject must meet the size ranges for all of the 'Small' size criteria, those being: 'Face Length and Face Width'- Cell A, 'Head Circumference'-Cell B, and 'Neck Circumference- Cell C'. The secondary method of APER size assignment is to test cells consecutively (if the test subject can meet one or more, but not all, of the Cell requirements of a specific size APER). An example of consecutive testing is a subject who has a 'Small' face length and width and who tests these face criteria in Cell-A of the 'Small' size APER, but the subject also has a 'Medium' size neck circumference, Cell-F. Those test subjects that are determined to be on the border line between various size ranges of cells of a specific anthropometric criteria, must be re-measured. For those cases, were a test subject is rated for a dual size category (for example, Medium and Large), the use of expert sizing by test facility personnel is required to determine what size is initially tested. If test subjects fail their initially assigned size category twice, test facility personnel are authorized to resize the individual if panel test subjects availability is in demand.

5.4.3. Trials: Each LRPL subject shall perform a total of 2 trials (each trial consists of simultaneous evaluations of the breathing zone and the 'under the hood' zone). Each trial begins with a self-donning and consists of the nine LRPL exercises.

5.4.4. Training. Procedures for donning, doffing, trouble shooting, negative seal checks, head harness tightening, and accessory interfacing based on the manufacturer's NIOSH recognized User's Instructions shall be taught to test subjects by test facility personnel. Any clarifications or supplemental instructions provided by manufacturer representatives at the time of certification inventory, during the test or after the test must be NIOSH reviewed prior to incorporation into revised User's Instructions before final NIOSH approval is granted. Manufacturers may request the opportunity to observe LRPL testing of their equipment, with prior notification to NIOSH/NPPTL. The actual APER and training systems shall be assigned to clean-shaven test subjects by trained test facility personnel. An actual APER (not a device designed as a non-protective training system) will be used for the LRPL corn-oil chamber test. A training system or an additional actual APER used for training will be used for practice donning/doffing. After initial donning instruction and nine exercise demonstration, each test subject shall practice donning with the training system for 15 minutes under the guidance of test facility personnel. Following the donning training, each test subject shall practice wearing the training system continuously for 15 minutes.

5.4.5. Ready Line. After the test subjects have completed applicable administrative paperwork, have been trained, and performed practice donning/doffing, subjects will be issued the APER to be used in the LRPL chamber. 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.

5.4.6. Make-Up Air: As deemed necessary based on respirator design, make-up air at a rate of 2.2 ± 0.2 Lpm will be returned to the respirator. The make-up air connection location will be at the top of the hood, approximating the crown of the wearer's head, with the exact final position depend upon the design of the APER being evaluated to avoid kinking of the make-up air line. A two-way valve operated by control room personnel controls the flow of make-up air to either the respirator or to outside of the chamber. Make-up air will only flow into the respirator when the photometer is sampling from the ocular 'under hood' zone of the respirator.

5.4.7. Respirator and Sampling Line Purge: Following respirator connection to photometer sampling lines and the make-up air line, and prior to beginning the 9 test exercises, the photometers will continuously sample both the oral/nasal and ocular 'under hood' zones while the make-up air is flowing into the respirator. This purge procedure will last for up to 2 minutes while test control personnel monitor the photometer voltage and verify that is has stabilized.

5.4.8. 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. LRPL Exercises. The LRPL test consists of a set of nine standard exercises that use seven (7) basic US Department of Labor, Occupational Safety and Health Administration (OSHA) Quantitative Fit Test (QNFT) exercises plus two (2)* additional QNFT exercises generated from emergency response forums. They are one minute routines devised to stress the face seal and material integrity of the APER while it is worn by a human test subject. The appropriate number of test subjects (based on Appendix B) will successively don and wear the CBRN APER into the chamber. The exercise routine listed below shall be used to stress the face/neck seal and approximate field use conditions under controlled laboratory settings. During each trial of an LRPL test, each human subject will perform the following nine exercises for one minute each **:

5.5.1. 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 APER during any part of the LRPL active test, to include the APER sample line.

5.5.2. 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. 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 APER while the conducting the exercise.

5.5.4. 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.

5.5.5. 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.

5.5.6. 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 APER aggressively, for one minute or told to stop.

5.5.7. 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 APER. It is recommended that smiling and frowning be alternated during the one-minute exercise.

5.5.8. 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.

5.5.9. 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 APER during any part of the LRPL active test. Disconnect the sample line as instructed.

* One of two 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 nine (9), normal breathing.

5.6. Each trial consists of one donning, simultaneous sampling of the breathing zone and 'under hood' ocular zones, and one doffing. Test subjects will don the APER and enter the test chamber for testing. At the conclusion of this testing, test subjects will exit from the test chamber, return to the ready line and await further instructions for doffing the APER.

5.7. After a brief intermission (1-10 minutes) with the APER doffed, each test subject, will re-don the same APER and repeat Steps 5.4.6 through 5.6 to complete the second trial of testing.

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

5.9. If an APER is identified as a failure upon trial termination, test facility personnel will conduct failure assessment protocol of the APER in two phases. First phase is to inspect the APER while it is still donned on the test subject. Second phase is to inspect the APER when it is doffed. Post test failure analysis shall consist of inspection of the test subject's eye to eye lens positioning, head harness positioning, head harness strap twists, oral/nasal cup scrunched up on face, hair in the facial and/or neck 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 APER being improperly probed, reassign another like, but serviceable APER to the test subject and retest for two complete trials. If the APER 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 APER material or inadequate probe sealing areas are cause for reanalysis of the determined probe entry point. In cases, where the APER cannot be probed successfully by the test facility, manufacturer Quantitative Fit Test (QNFT) kits can be reviewed and considered for use, but only as a last resort.

6.0. PASS/FAIL CRITERIA

6.1. This test establishes the standard procedure for ensuring the following:
The criterion for conduct of this test is set forth in 42 CFR, Part 84, Subpart G, Section 84.63(a)(c)&(d); Federal Register, Volume 60, Number 110, June 8, 1995 and applicable RPD current statement of standards in final approved form.

(a) 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, I, K, and applicable portions of L, N and KK. All applicable manufacturer user's instructions that address seal enhancement kits and other critical seal components/tasks must be clearly depicted in final NIOSH approved documents and present during testing.

(b) 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.

(c) 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 Pass / Fail Requirement:

Each Air-Purifying Escape Respirator (APER) seeking a Chemical, Biological, Radiological and Nuclear (CBRN) protection rating will be self donned, worn and doffed by a voluntary human test subject in accordance with the applicant's User's Instructions for two independent trials on the same test subject in a controlled laboratory atmosphere containing non-toxic corn oil aerosol at 20-40 mg/m3, having a Mass Median Aerodynamic Diameter of 0.4 to 0.6 um and shall demonstrate a measured dual LPRL rating resulting in a final LRPL -E (LRPL Escape) value of PASS or FAIL for each trial. The first measured rating of the dual assessment is sampled in the breathing zone and is equal to 2,000.0 or greater for each trial. The second rating of the dual assessment is sampled in the 'under the hood' zone (ocular zone) and shall be an LRPL rating equal to 150.0 or greater. Each trial must meet both the fist rated breathing zone requirement and the second rated 'under the hood' ocular zone requirement for that trial to be considered a passing LRPL-E result as calculated in accordance with NIOSH Procedure No CET- CBRN-ESCAPE-STP-0452. Appendices A and B of NIOSH Procedure No CET- CBRN-ESCAPE-STP-0452 are used to determine test subject panel size and corresponding test subject anthropometric criteria. Should an LRPL failure be observed in either measured zone, the entire trial is considered a failure and entered as a failure of LRPL-E (LRPL Escape) for that trial. Should testing results show less than 95.0% of trials having passing LRPL-E results at any point in the testing, LRPL testing incident reports must be forwarded to NIOSH immediately along with recommendations for follow on testing corrections. NIOSH confirms re-test procedures and authorizes one additional run of test subjects that fills the entire anthropometric panel requirements be performed to increase the total number of trials; the total number of trials will be the sum of trials from the first and second run of subjects. An individual LRPL value is calculated quantitatively by evaluating a test subject properly wearing the respirator and conducting the following nine (9) exercises in this specified sequence: normal breathing, deep breathing, turn head side to side, move head up and down, reach for the floor and ceiling, rotate head side to side while on hands and knees, facial grimace, climb stairs at regular pace and normal breathing. Each respirator test subject shall not be subjected to any undue discomfort or encumbrance because of the fit, air flow

or other form, fit and function features of the respirator under test before, during or after the test period. For each size category in accordance with the applicant's User's Instructions, each cell corresponding to the anthropometric parameter corresponding to APER design will be tested. Cells can be either individually or simultaneously tested. An individual test subject must complete two test trials using the same APER; in the event that an individual test subject completes only one trial and does not complete the second trial, the LRPL data from the completed first trial will not be considered. Each candidate respirator is required to have a minimum of one respirator identified for LRPL training purposes at the time of certification testing. Training APERs are required to be administratively identified as different than actual certification APERs in support of efficient testing. All trials shall be considered in the Practical Performance Test (PPT) requirement criteria, PPT Standard Test Procedure No CET-CBRN-ESCAPE-STP-0456. A Practical Performance Test (PPT) failure occurring in any trial causes the LRPL test data for that trial to be invalid and the subject is disqualified from further LRPL testing.

7. RECORDS\TEST SHEETS

7.1. All test data will be recorded on the Laboratory Respirator Protection Level (LRPL) Test for CBRN Air-Purifying Escape Respirator (APER) test data sheets (Appendix C).

7.3. 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.

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

7.4.1. If the failure occurs on a new certification application, or extension of approval application, the Test Facility Manager (Principal Investigator or designee) will send a test report to the NIOSH Certification Evaluation and Testing (CET) Section Chief and prepare the hardware for return to the manufacturer.

7.4.2. 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.

7.4.3. If an APER fails the Pass / Fail criteria specified in Para 6.2 of this STP, ensure all measures are taken to ascertain the reason/cause for failure, conduct all post test inspections in accordance with Para 5.9 of this STP that support the accuracy of the reported failure and provide NIOSH with written Test Incident Reports (TIR), digital photos of assessment and recommendations as required.

Appendix A

APER Laboratory Respirator Protection Level (LRPL) Test Panel

	Small	Medium	Large
Face Length and Face Width	**Cell A** **Use LANL boxes 1, 2, 3, 4 (2 or 3 subjects each box, 2 trials per subject)** Subjects= 10 Trials= 20	**Cell D** **Use LANL boxes 3, 4, 5, 6, 7, 8; panel size 17 (2 or 3 subjects each box, 2 trials per subject)** Subjects= 17 Trials= 34	**Cell G** **Use LANL boxes 7, 8, 9, 10; panel size 11 (2 or 3 subjects each box, 2 trials per subject)** Subjects= 11 Trials= 22
Head Circumference	**Cell B** **N/A** Subjects= 0 Trials= 0	**Cell E** **N/A** Subjects= 0 Trials= 0	**Cell H** **570-603 mm** Subjects= 10 Trials= 20
Neck Circumference	**Cell C** **306-378 mm** Subjects= 10 Trials= 20	**Cell F** **355-403 mm** Subjects= 10 Trials= 20	**Cell I** **378-451 mm** Subjects= 10 Trials= 20

APPENDIX B

Sample Quantities for the APER Laboratory Respirator Protection Level Test

NOTE: Additional size configurations are also possible; in these cases, NIOSH will determine the panel size, applicable anthropometric measurement ranges, and APER test quantity.

1. **Manufacturers with a One-Size-Fits-All: minimum of 30 subjects, maximum 65 subjects, two trials each subject (min. 60, max. 130 data points.)**

   Sample Quantity to be Submitted→ One-Size-Fits-All:

   Manufacturer submits 65 actual APER plus 65 identical training aid systems or identical APER to be used for training.

   LRPL Cells to be Evaluated→ All LRPL cells, A-I; panel size. panel size – min. 30 subjects, 60 data points; max. 65 subjects, 130 data points.

   (Note: Precedence for subject testing is simultaneous cell evaluation of all cells of a specific size. Thirty subjects will be evaluated for neck circumference to cover cells C, F, and I. Twenty-five subjects will be evaluated for facial length and width to cover cells A, D, and G. Within LRPL cells A, D, and G, LANL boxes 1 through 10 will be applicable. Ten subjects will be evaluated for head circumference to cover cell H).

2. **Manufacturers with 2 APER Size Configurations (2 neck seal sizes and 2 oral nasal cup sizes): minimum of 30 subjects, maximum of 69 subjects, two trials each subject (min. 60, max. 138 data points. The minimum number of subjects, 30, is based on evaluating 30 subjects for the neck circumference criteria.**

   A. Sample Quantity to be Submitted → Small / Medium size

   (Small/Medium neck seal with a Small/Medium oral nasal cup)

   Manufacturer initially submits 29 actual APER plus 29 identical training aid systems or identical APER to be used for training. If additional units are needed to complete testing, the manufacturer will be contacted.

   LRPL Panel Cells A, B, C, D, E, F: panel size – min. 15 subjects, 30 data points; max. 29 subjects, 58 data points.

   (Note: Precedence for subject testing is simultaneous cell evaluation of all cells of a specific size. Fifteen subjects will be evaluated for neck circumference to cover cells C and F. Fourteen subjects will be evaluated for facial length and width to cover cells A and D. Within LRPL cells A and D, LANL boxes 1 through 6 will be applicable.

   B. Sample Quantity to be Submitted → Medium / Large size

   (Medium/Large neck seal with Medium/Large oral nasal cup)

   Manufacturer initially submits 40 actual APER plus 40 identical training aid systems or identical APER to be used for training. If additional units are needed to complete testing, the manufacturer will be contacted.

LRPL Panel Cells D, E, F, G, H, I: panel size – min. 15 subjects, 30 data points; max. 40 subjects, 80 data points.

(Note: Precedence for subject testing is simultaneous cell evaluation of all cells of a specific size. Fifteen subjects will be evaluated for neck circumference to cover cells F and I. Fifteen subjects will be evaluated for facial length and width to cover cells D and G. Within LRPL cells D and G, LANL boxes 5 through 10 will be applicable. Ten subjects will be evaluated for head circumference to cover cell H).

3. Manufacturers with 3 APER Sizes Configurations

(3 neck seal sizes and 3 oral nasal cup sizes): minimum of 38 subjects, maximum of 78 test subjects, two trails each subject (min. 76, max. 156 data points). The minimum number of subjects, 38, is based on evaluating 38 subjects for the facial length and width criteria.

A. Sample Quantity to be Submitted → Small size

(Small neck seal with Small oral nasal cup):

20 actual APER plus 20 identical training aid systems or identical APER to be used for training. If additional units are needed to complete testing, the manufacturer will be contacted.

LRPL Panel Cells A, B, C: panel size -- min. 10 subjects, 20 data points; max. 20 subjects, 40 data points.

(Note: Precedence for subject testing is simultaneous cell evaluation of all cells of a specific size. Ten subjects will be evaluated for neck circumference to cover cell C. Ten subjects will be evaluated for facial length and width to cover cell A. Within LRPL cell A, LANL boxes 1 through 4 will be applicable.)

B. Sample Quantity to be Submitted → Medium size:

(Medium neck seal with Medium oral nasal cup)

27 actual APER plus 27 identical training aid systems or identical APER to be used for training. If additional units are needed to complete testing, the manufacturer will be contacted.

LRPL Panel Cells D, E, F: panel size -- min. 17 subjects, 34 data points; max. 27 subjects, 54 data points.

(Note: Precedence for subject testing is simultaneous cell evaluation of all cells of a specific size. Ten subjects will be evaluated for neck circumference to cover cell F. Seventeen subjects will be evaluated for facial length and width to cover cell D. Within LRPL cell D, LANL boxes 3 through 8 will be applicable.)

C. Sample Quantity to be Submitted → Large size:

(Large neck seal with Large oral nasal cup)

31 actual APER plus 31 identical training aid systems or identical APER to be used for training. If additional units are needed to complete testing, the manufacturer will be contacted.

LRPL Panel Cells G, H, I: panel size -- min. 11 subjects, 22 data points; max. 31 subjects, 62 data points.

(Note: Precedence for subject testing is simultaneous cell evaluation of all cells of a specific size. Ten subjects will be evaluated for neck circumference to cover cell I. Ten subjects will be evaluated for head circumference to cover cell H. Eleven subjects will be evaluated for facial length and width to cover cell G. Within LRPL cells G, LANL boxes 7 through 10 will be applicable.)

NOTE: Some panel members may be the same individuals in a dual role filling the cell requirements of 2 or more APER size configurations. The data for each APER size are judged individually against the pass/fail criteria.

Appendix C

CBRN APER LRPL Test Data Sheet (Page 1 of 5)

National Institute for Occupational Safety and Health
Respirator Branch
Test Data Sheet No.: 0452

Task No.: **STP No.:** 0452

Manufacturer: **Reference No.:** 42 CFR 84.63 (a)(c)(d)

Test: Laboratory Respirator Protection Level Test for CBRN Air-Purifying Escape Respirators (APER)

Statement of Standard For Chemical, Biological, Radiological, and Nuclear (CBRN) Air-Purifying Escape Respirator

Test Date:

Model Number / Trade Name:

APER Actual Ready to Use Device Part Number:
APER Training Device Part Number:
Is this a retest under the same TN number?

If yes, what are the original test dates?

NIOSH Approval Numbers	

Breathing Zone Probe Location:

Under the Hood Zone Probe Location:

CBRN APER LRPL Test Data Sheet (Page 2 of 5)

Task No.: **STP No.:** 0452

Manufacturer: **Reference No.:** 42 CFR 84.63 (a)(c)(d)

Test: Laboratory Respirator Protection Level Test for CBRN Air-Purifying Escape Respirators (APER) Statement of Standard For Chemical, Biological, Radiological, and Nuclear (CBRN) Air-Purifying Escape Respirator

Temperature:
Relative Humidity:
Facepiece Size Quantity:

Key
LRPL BZ** LRPL 'breathing zone'
LRPL UH** LRPL 'under hood'
LRPL-E LRPL 'escape'

Test Subject No.	Test Subject Identification	Assigned Hood Size	LRPL Cell Letter(s)	LRPL BZ (Breathing Zone) Trial 1	LRPL UH ('Under Hood') Trial 1	LRPL-E* (Pass / Fail) Trial 1	LRPL BZ (Breathing Zone) Trial 2	LRPL UH ('Under Hood') Trial 2	LRPL-E* (Pass / Fail) Trial 2
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									
11									
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25									

*LRPL-E: Enter 'Pass' only if passing LRPL results are obtained in both LRPL BZ (breathing zone) and LRPL UH (under hood) zones. If a 'Fail' result is obtained in either of the 2 zones, record 'Fail'.

CBRN APER LRPL Test Data Sheet (Page 3 of 5)

Task No.: **STP No.:** 0452

Manufacturer: **Reference No.:** 42 CFR 84.63 (a)(c)(d)

Test: Laboratory Respirator Protection Level Test for CBRN Air-Purifying Escape Respirators (APER) — Statement of Standard For Chemical, Biological, Radiological, and Nuclear (CBRN) Air-Purifying Escape Respirator

Calculation of % 'Pass' LRPL-E trials

Number of 'Pass' trials from 'LRPL-E Trial 1' column here ?		Box 1P	
Number of 'Fail' trials from 'LRPL-E Trial 1' column here ?		Box 1F	
Number of 'Pass' trials from 'LRPL-E Trial 2' column here ?		Box 2P	
Number of 'Fail' trials from 'LRPL-E Trial 2' column here ?		Box 2F	
Add the number of trials in Box 1P and Box 2P here ?		Box A	Box A = Total 'Pass' LRPL-E trials
Add the number of trials in Box 1F and Box 2F here ?		Box B	Box B = Total 'Fail' LRPL-E trials
Add the numbers in Box A and Box B here ?		Box C	Box C = Total of 'Pass' and 'Fail' LRPL-E trials
% 'Pass' LRPL-E trials = (Box A ÷ Box C) X 100%. Enter result here ?		Box D	Box D = % 'Pass' LRPL-E trials

Overall Pass Percentage:		Overall Result:
= 95%	% 'Pass' LRPL-E trials	

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

Were the part numbers verified against the hardware? **Yes** **No**

CBRN APER LRPL Test Data Sheet (Page 4 of 5)

Task No.:		**STP No.:**	0452
Manufacturer:		**Reference No.:**	42 CFR 84.63 (a)(c)(d)
Test:	Laboratory Respirator Protection Level Test for CBRN Air-Purifying Escape Respirators (APER)		Statement of Standard For Chemical, Biological, Radiological, and Nuclear (CBRN) Air-Purifying Escape Respirator

Comments:

Signature:

Laboratory Technician

Date

Concurrence:

Laboratory Supervisor

CBRN APER LRPL Test Data Sheet (Page 5 of 5)

Task No.:		**STP No.:**	0452
Manufacturer:		**Reference No.:**	42 CFR 84.63 (a)(c)(d)
Test:	Laboratory Respirator Protection Level Test for CBRN Air-Purifying Escape Respirators (APER)		Statement of Standard For Chemical, Biological, Radiological, and Nuclear (CBRN) Air-Purifying Escape Respirator

LRPL Requirement:

Each Air-Purifying Escape Respirator (APER) seeking a Chemical, Biological, Radiological and Nuclear (CBRN) protection rating will be self donned, worn and doffed by a voluntary human test subject in accordance with the applicant's User Instructions for two independent trials on the same test subject in a controlled laboratory atmosphere containing non-toxic corn oil aerosol at 20-40 mg/m3, having a Mass Median Aerodynamic Diameter of 0.4 to 0.6 um and shall demonstrate a measured dual LPRL rating resulting in a final LRPL -E (LRPL Escape) value of PASS or FAIL for each trial. The first measured rating of the dual assessment is sampled in the breathing zone and is equal to 2,000.0 or greater for each trial. The second rating of the dual assessment is sampled in the 'under the hood' zone (ocular zone) and shall be an LRPL rating equal to 150.0 or greater. Each trial must meet both the fist rated breathing zone requirement and the second rated 'under the hood' ocular zone requirement for that trial to be considered a passing LRPL-E result as calculated in accordance with NIOSH Procedure No CET- CBRN-ESCAPE-STP-0452. Appendices A and B of NIOSH Procedure No CET- CBRN-ESCAPE-STP-0452 are used to determine test subject panel size and corresponding test subject anthropometric criteria. Should an LRPL failure be observed in either measured zone, the entire trial is considered a failure and entered as a failure of LRPL-E (LRPL Escape) for that trial. Should testing results show less than 95.0% of trials having passing LRPL-E results at any point in the testing, LRPL testing incident reports must be forwarded to NIOSH immediately along with recommendations for follow on testing corrections. NIOSH confirms re-test procedures and authorizes one additional run of test subjects that fills the entire anthropometric panel requirements be performed to increase the total number of trials; the total number of trials will be the sum of trials from the first and second run of subjects. An individual LRPL value is calculated quantitatively by evaluating a test subject properly wearing the respirator and conducting the following nine (9) exercises in this specified sequence: normal breathing, deep breathing, turn head side to side, move head up and down, reach for the floor and ceiling, rotate head side to side while on hands and knees, facial grimace, climb stairs at regular pace and normal breathing. Each respirator test subject shall not be subjected to any undue discomfort or encumbrance because of the fit, air flow or other form, fit and function features of the respirator under test before, during or after the test period. For each size category in accordance with the applicant's User Instructions, each cell corresponding to the anthropometric parameter corresponding to APER design will be tested. Cells can be either individually or simultaneously tested. An individual test subject must complete two test trials using the same APER; in the event that an individual test subject completes only one trial and does not complete the second trial, the LRPL data from the completed first trial will not be considered. Each candidate respirator is required to have a minimum of one respirator identified for LRPL training purposes at the time of certification testing. Training APERs are required to be administratively identified as different than actual certification APERs in support of efficient testing. All trials shall be considered in the Practical Performance Test (PPT) requirement criteria, PPT Standard Test Procedure No CET-CBRN-ESCAPE-STP-0456. A Practical Performance Test (PPT) failure occurring in any trial causes the LRPL test data for that trial to be invalid and the subject is disqualified from further LRPL testing.

Revision History

Revision	Date	Reason for Revision
0	23 September 2004	Historic document
1.1	22 December 2005	Update header and format No changes to method