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National Personal Protective Technology Laboratory
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Procedure No. TEB-CBRN-APR-STP-0553

Revision: 2.0

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DETERMINATION OF LABORATORY RESPIRATORY PROTECTION LEVEL
(LRPL) VALUES FOR CBRN LOOSE-FITTING POWERED AIR-PURIFYING
RESPIRATOR (PAPR), STANDARD TESTING PROCEDURE (STP)

1. PURPOSE

The document establishes the procedure for ensuring that the respirator is designed and constructed to fit persons with various facial shapes and sizes using the NIOSH Bivariate Panel (referred to as the NIOSH Panel). This is accomplished by determining the laboratory respirator protection level (LRPL) values provided by powered air-purifying respirator (PAPR), loose fitting facepiece configurations. These configurations submitted for a new approval or extension of approval must meet the minimum certification standards set forth in this Standard Testing Procedure (STP) as prescribed in 42 CFR Part 84 and the Statement of Standard for Chemical, Biological, Radiological and Nuclear (CBRN) Powered Air-Purifying Respirator (PAPR).

2. GENERAL

This STP describes the determination of the laboratory respirator protection level (LRPL) for human subjects wearing a CBRN PAPR loose-fitting facepiece 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.

3. EQUIPMENT / MATERIAL

- 3.1. TSI Rear Light Scattering Laser Photometer, model 8587A, or equivalent. Concentration Range 1.0 $\mu\text{g}/\text{m}^3$ to $>200 \text{ mg}/\text{m}^3$. Dynamic Range LRPL values to 100,000. As shown in Figure 1.
- 3.2. NIOSH Dynamic Fit Software. The software is used to record the data collected by the laser photometer for each respirator and convert this data to LRPL values per exercise. The individual LRPL values are then converted to an overall LRPL factor for each trial.
- 3.3. Aerosol Generator, MSP Model 2045 High Output Aerosol Generator or equivalent. The aerosol generator is capable of maintaining 5 to $100 \text{ mg}/\text{m}^3$ of corn oil challenge aerosol concentrations for the required test duration with a Mass Median Aerodynamic Diameter (MMAD) of 0.4 to $0.6 \mu\text{m}$ in the test chamber. The geometric standard deviation must be less than 2.0. As shown in Figure 2.
- 3.4. TSI Model 8530, DustTrak II Aerosol Monitor, or equivalent. Range 0.001 to $100 \text{ mg}/\text{m}^3$ (Calibrated to ISO 12103-1, A1 test dust). Resolution $\pm 0.1\%$ of reading or $\pm 0.001 \text{ mg}/\text{m}^3$, whichever is greater. As shown in Figure 3.
- 3.5. TSI Model 8038 PortaCount Pro+ Respirator Fit Tester, or equivalent. As shown in

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Figure 4.

- 3.6. Corn Oil - 99% Pure. CAS Number 8001-30-7. Commercial product names are Maise/Maize Oil, Maydol and Mazola Oil.
- 3.7. Scanning Mobility Particle Sizer (SMPS), TSI Model 3936 series. SMPS is made by combining the TSI model 3080 Electronic Classifier, TSI Model 3775 Condensation Particle Counter and Long Differential Mobility Analyzer (DMA). For determining the particle size and distribution of the chamber. As shown in Figure 5.
- 3.8. Environmental test chamber. 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 include an entry vestibule designed to allow safe entry and exit from the chamber with minimal disturbance to both aerosol concentration and uniformity. An example of a charged corn oil chamber is provided in Figure 6.
- 3.9. Chamber Communications. Electronic audio communications (chamber loudspeaker) from laboratory technicians to test subjects to ensure test subjects can clearly hear when to start and stop the test exercise regimen.
- 3.10. 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. As shown in Figure 7.
- 3.11. 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 8 is an interior view of a sample probed respirator in the oral-nasal region of the nose cup. Figure 9 is an exterior view of a sample probed respirator showing the metal interface for tubing and penetration through the lens and nose cup. Figure 10 and 11 are photographs of the probes used. There are two rubbers washers, one metal washer and one nut.
- 3.12. Human Test Subjects
 - 3.12.1. Human test subjects are required for this test. The number of subjects needed is based on the respirator design described in the application. See Attachments C, D and E. Manual caliper instruments are used to determine facial sizes for subject panel representation in the NIOSH Panel.

4. TESTING REQUIREMENTS AND CONDITIONS

- 4.1. Prior to beginning any testing, confirm that all measuring equipment employed has been calibrated in accordance with the testing laboratory's calibration procedure and schedule. All measuring equipment utilized for this testing must have been calibrated using a method traceable to recognized international standards when available.

5. PROCEDURE

5.1. Respirator Set-up

- 5.1.1 Each facepiece shall be probed prior to the facepiece being issued to test subjects. The test facility administrator or his staff destructively probes all submitted respirators uniformly.
- 5.1.2 The respirator sampling probe location shall terminate in the oral/nasal region. The optimum sampling probe position is approximately from the skin at the point of quadrilateral symmetry of the mouth and nose, i.e., midway between the nose and upper lip (approximately 1/4 inch for hoods with nose cups). 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 little to no impact on the designed function of the facepiece, nose cup or faceblank area that the probe is penetrating. When probing submitted respirators, test administrator should not attach the probe through material seams since the seam penetration can cause leakage. 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 nose cup.
- 5.1.3 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 nose cup function is restricted by probe, testing laboratory may consider alternate equivalent probe locations.
- 5.1.4 In cases where the respirator cannot be probed successfully by the test facility, kits with adapters for quantitative fit testing from the manufacturer can be reviewed and considered for use, but only as a last resort.
- 5.1.5 Accessories may be provided and attached to the CBRN PAPR facepieces submitted for testing. NPPTL will determine what accessories will be tested.

5.2. Human Subject and Respirator Selection

- 5.2.1 Manual caliper facial measurements shall be used to determine facial size and panel placement prior to each test subject donning a respirator. Anthropometric measurements are shown in Attachment A.
- 5.2.2 Test subjects shall be selected to cover all the cells within the panels referenced in Attachment B. Each LRPL test shall consist of two trials. A minimum of 50, 68, or 76 pass/fail data points shall be collected from two trials by test subjects of each facepiece size of each respirator submitted to NIOSH, as prescribed in Attachments C, D, and E.
- 5.2.3 If an approval holder or applicant submits a respirator design to fit a sub-

population of users, the approval holder or applicant should provide NIOSH with information on the expected size distribution based on the NIOSH Panel. This information will be considered for the NIOSH LRPL testing.

5.3. Chamber Set-up

- 5.3.1. Turn on air handling unit with sufficient airflow to maintain the proper corn oil concentration.
- 5.3.2. Turn on vacuum pump for laser photometers.
- 5.3.3. Turn on mixing fans to 6.1 volts to produce an even concentration distribution throughout the chamber.
- 5.3.4. Turn on air compressor for corn oil generators to maintain the proper corn oil concentration. Corn Oil Challenge Concentration = 30 to 40 mg/m³.
- 5.3.5. Turn on laser photometers and warm up for 30 minutes.
- 5.3.6. Turn on SMPS and warm up for 15 minutes.
- 5.3.7. Turn on DustTrak.
- 5.3.8. Allow 30 minutes for the chamber concentration to stabilize.
- 5.3.9. Use the DustTrak to monitor the chamber concentration.
- 5.3.10. Adjust the air pressure at the generators regulator to establish the corn oil concentration of 30 to 40 mg/m³.
- 5.3.11. Use the SMPS according to the manual to determine the particle size. The correct size should be 0.4 to 0.6 µm with a geometric standard deviation of less than 2.0.

5.4. Conducting the LRPL Test

- 5.4.1. The manufacturer's User Instructions (UI) provided with the test equipment shall be reviewed by all test facility personnel.
- 5.4.2. Test subject training will be conducted by test facility personnel based on the UI. The training shall address procedures for donning, doffing, trouble shooting, user seal checks, head harness tightening, and accessory interfacing must be taught to test subjects by test facility administrator.
 - 5.4.2.1. Expert donning is not allowed in the conduct of this test.
 - 5.4.2.2. Each test subject shall perform an unassisted donning of the respirator.

- 5.4.2.3. Self-donning under supervision of the test administrator is permitted to make sure the appropriate adjustments to the facepiece are being performed until the test administrator is satisfied that they are wearing the respirator in compliance with the manufacturer's UI.
- 5.4.2.4. Each test subject shall practice donning and doffing the respirator until they feel comfortable with the donning of the respirator.
- 5.4.2.5. After the practice donning and doffing is complete, the test subject shall don the respirator again and continue to wear it for five minutes before proceeding to the PortaCount fit testing.
- 5.4.2.6. The PortaCount test should be performed with the blower off.
- 5.4.3 Test subjects enter the corn oil chamber and are instructed to attach their sample line tubing to their assigned photometer. Chamber concentration is monitored during the conduct of each individual LRPL test.
- 5.4.4 Information for each test subject will be recorded in the NIOSH Dynamic Fit software program. Test Administrator will start the software program and relay the information of time to start the test, exercise and timing of the exercise being performed.
- 5.4.5 The LRPL trial consists of a set of eleven one-minute standard exercises. 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. Subjects should not touch any portion of the respirator during any part of the LRPL active test. Test Administrator will give verbal commands to stop and start each exercise.
- 5.4.5.1 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.
- 5.4.5.2 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.
- 5.4.5.3 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 and return to the forward-facing position to exhale. Caution subjects not to hit the shoulder with any part of the respirator during the conduct of the exercise.

- 5.4.5.4 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. Return to the neutral, forward-facing position to exhale. Slowly move down past the horizontal level start point to the end point where the chin just touches the chest.
- 5.4.5.5 Recite the “Rainbow Reading Passage”: The subject shall talk out loud while reading a copy of the passage entitled Rainbow Passage. Subject will keep reading the passage until told to stop.
- 5.4.5.6 Sight a mock rifle: While normal breathing, pick up the mock rifle. Test subjects shoulder the mock rifle in the favored shooting posture shoulder position. Bend the head while 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. 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.
- 5.4.5.7 Reach for the floor and ceiling: While in normal breathing, standing, feet shoulder width apart and at arm’s 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, exhales, and extends 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.
- 5.4.5.8 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. Position on hands and knees 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. Exhale once reaching the neutral, forward facing position. 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.
- 5.4.5.9 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.
- 5.4.5.10 Climb the Stairs at Regular Pace: Test subjects pair off in twos, while in normal breathing, one test subject of the pair waits 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 waits. Continue the cycle until one minute expires or told to stop. A similar procedure is used even if one subject is testing—i.e., delay between each stair cycle. Return to the floor standing position. Ensure sample lines are not restricting movement during the climb.

5.4.5.11 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.

- 5.4.6 Instruct the subjects to disconnect from the photometer. Exit the chamber. Inform the subject(s) to return to the ready line and await further instructions for doffing the respirator or leaving the respirator donned. 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 instructed to doff.
- 5.4.7 The overall calculated LRPL value for each individual will be recorded by the NIOSH Dynamic Fit software and written on the test data sheet as shown in Attachment F.
- 5.4.8 All comments and observations by test subjects, which are voluntary, will be written on the test data sheet.
- 5.4.9 After a brief intermission (1-10 minutes), each test subject will re-don the same respirator facepiece and repeat steps, beginning with 5.4.5, to complete the second trial for the test.
- 5.4.10 If a respirator is identified as a failure upon trial termination, the Test Administrator 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 distorted 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 respirator to the test subject and retest for two complete trials.

5.5. Data Analysis

- 5.5.1. The overall LRPL value will be collected for each trial run and written into the test data sheet.

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5.5.2. The Test Administrator will record for each test subject the following:

5.5.2.1. Subject ID number; facepiece size worn; NIOSH Panel cell, any relevant comments noted during the trial.

6. PASS/FAIL CRITERIA

6.1. The overall LRPL value for each respirator shall be equal to or greater than 10,000 LRPL factor for 95 % of the trials evaluated.

7. RECORDS/TEST SHEETS

7.1. All test data will be recorded on the Laboratory Respirator Protection Level Test for CBRN LRPL test data sheets.

8. ATTACHMENTS

8.1. Attachment A: Anthropometric Measurements

8.2. Attachment B: NIOSH Bivariate Panel

8.3. Attachment C: NIOSH Panel, One Size

8.4. Attachment D: NIOSH Panel, Two Sizes

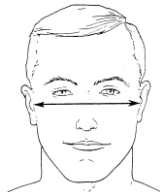
8.5. Attachment E: NIOSH Panel, Three or more Size(s)

8.6. Attachment F: CBRN LRPL Data Sheet

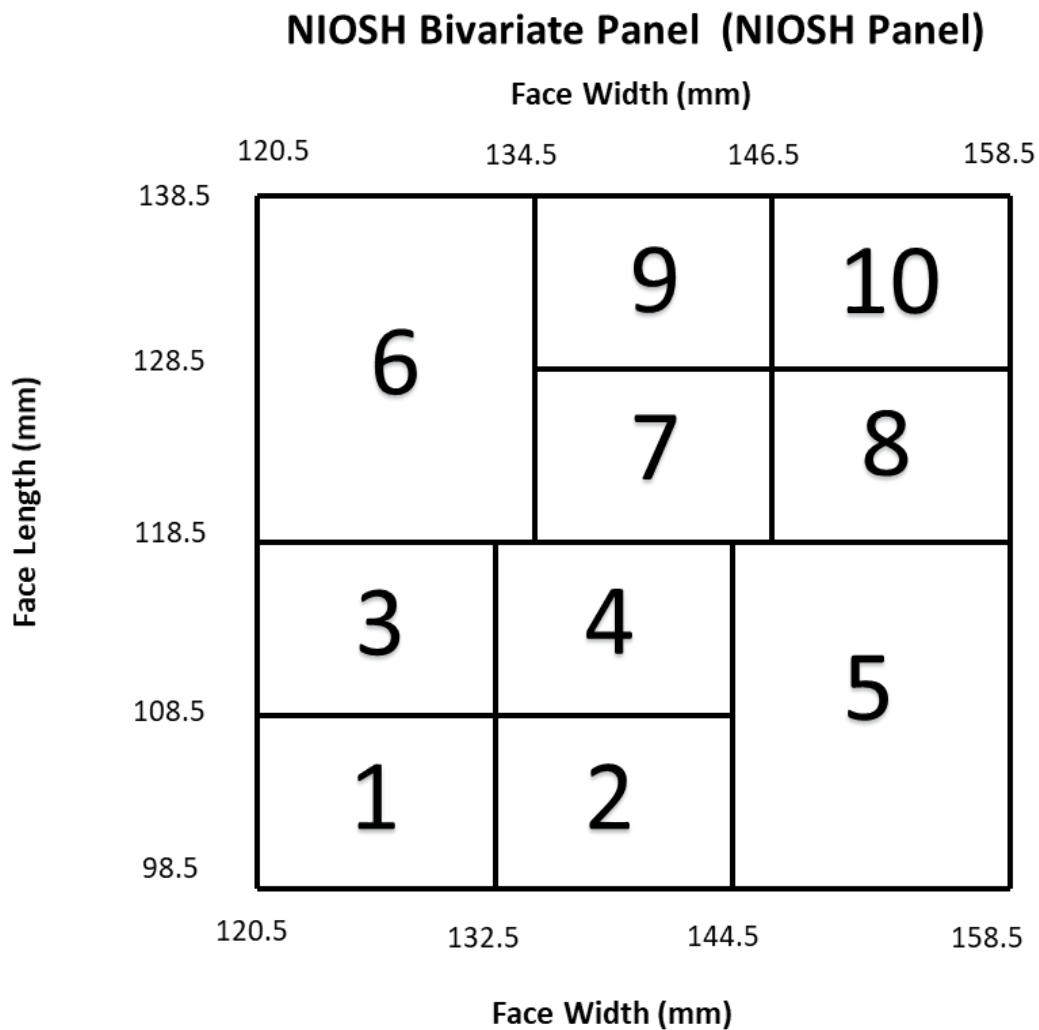
8.7. Attachment G: Laboratory Respirator Protection Level Calculations

8.8. Attachment H: Figures

8.1 Attachment A: Anthropometric Measurements

Description	Definition	Diagram
Bizygomatic Breadth	Maximum horizontal breadth of the face as measured with a spreading caliper between the zygomatic arches.	
Menton–Sellion Length	Distance as measured with a sliding caliper in the midsagittal plane between the menton landmark and the sellion landmark.	

8.2 Attachment B: NIOSH Bivariate Panel (NIOSH Panel)



8.3 Attachment C: NIOSH Panel test subject selection to be used for LRPL testing, One Size

CBRN APR or SCBA facepiece designed and manufactured in one unique size: **25 test subjects**, two replicates each, for a total 50 data points.

25 Member CBRN Panel – Facepiece manufactured in one unique size		
NIOSH Panel Cell	Number of test subjects	
1	2 subjects	An additional six subjects will be selected from Cells 2, 3, 4, 7, and 8. No more than four subjects permitted from any one NIOSH Panel Cell.
2	2 subjects	
3	2 subjects	
4	2 subjects	
5	2 subjects	
6	2 subjects	
7	2 subjects	
8	2 subjects	
9	2 subjects	
10	1 subject	

8.4 Attachment D: NIOSH Panel test subject selection to be used for LRPL testing, Two Sizes

CBRN APR or SCBA facepiece designed and manufactured in two unique sizes: 29 test subjects, two replicates each, for a total of 58 data points.

29-Member CBRN Panel - CBRN APR or SCBA facepiece manufactured in two unique sizes*		
NIOSH Panel - cell number	Number of test subjects	
1	14-15 subjects from Cells 1-6 (at least one from each cell and no more than four from any one cell for a total of 14-15 subjects)	
2		
3		
4		
5	Smaller Size	14-15 subjects from Cells 5-10 (at least one from each cell and no more than four from any one cell for a total of 14-15 subjects)
6		
7		
8		
9		
10		
		Larger Size

*For those panel cell sizes that overlap across two facepiece size distributions (i.e., panel cells 5 and 6), the test subjects will be provided with either the smaller size or larger size respirator. If the minimum fit (as described above) is not achieved using the PortaCount fit test for the first size tested, the test subject can be tested in the alternate size offered at the discretion of the Test Administrator.

8.5 Attachment E: NIOSH Panel test subject selection to be used for LRPL testing, Three Sizes or more

CBRN APR or SCBA facepiece designed and manufactured in three unique sizes: 38-member panel, two replicates each, for a total of 76 data points.

38 Member CBRN Panel - CBRN APR or SCBA facepiece manufactured in three (or more)* unique sizes			
NIOSH Panel cell number	Number of test subjects		
1	10 subjects from Cells 1-4 (at least one from each cell and no more than four from any one cell for a total of 10 subjects)		
2			
3			
4			
5	Smaller size	17 subjects from Cells 3-8 (at least one from each cell and no more than four from any one cell for a total of 17 subjects)	
6			
7			
8			
9			
10			
		Medium size	11 subjects from Cells 7-10 (at least one from each cell and no more than four from any one cell for a total of 11 subjects)
			Larger size

*For those panel cell sizes that overlap across three facepiece size distributions (i.e., panel cells 3 - 8), the test subjects will be provided with either the smaller size or larger size respirator. If the minimum fit (as described above) is not achieved using the PortaCount fit test for the first size tested, the test subject can be tested in one of the alternate sizes offered at the discretion of the Test Administrator.

Note: Three size distributions of small, medium, and large are annotated by smaller, medium, and larger sizes. For those submissions that contain extra small, use Cell 1 as an extra small (XSML) where the test subject must achieve a pass. For those submissions that contain extra-large, use Cell 10 as an extra-large (XL) where the test subject must achieve a pass.

[illegible]

Total Pass / Fail Results			
LRPL		Practical Performance (Modified LRPL Test)	
Passes		Passes	
Failures		Failures	
Overall results			

Comments

Was all equipment verified to be in calibration throughout the testing: ☐ yes ☐ no
Were all the part numbers verified against the hardware: ☐ yes ☐ no

Test Administrator Signature: _____ Date: _____

Concurrence: _____ Date: _____

8.7 Attachment G: Laboratory Respirator Protection Level Calculations

The respirator system's performance is numerically quantified in terms of a LRPL value. The LRPL value is calculated by determining the ration of challenge aerosol concentration to the in-mask aerosol concentration as qualified by integrating the peak voltage output from the photometer over a time interval. A LRPL value is calculated for each individual exercise (LRPL_i):

$$LRPL_i = \frac{\text{Challenge Concentration}}{\text{In-mask Concentration}}$$

Each LRPL_i for that trial are then used to calculate an overall LRPL value for the subject (LRPL_o) as follows where *n* is the number of exercises. The LRPL_o is affected most by the smallest LRPL_i. Under the conditions of the test and the sensitivity of the photometers, the maximum LRPL_o that can be reported is 100,000. The LRPL_o values obtained are used to evaluate the system against the appropriate LRPL requirements.

$$LRPL_o = \frac{\text{Number of Exercises}}{\sum \left(\frac{1}{\text{Fit Factor e1}} + \frac{1}{\text{Fit Factor e2}} + \frac{1}{\text{Fit Factor e3}} + \dots + \frac{1}{\text{Fit Factor e11}} \right)}$$

Example: A five exercise LRPL test has been conducted. Here are the calculations for the LRPL_o based on the LRPL_i values for each exercise. LRPL₁ = 100,000; LRPL₂ = 10,000; LRPL₃ = 25,000; LRPL₄ = 75,000; LRPL₅ = 100,000; n = 5.

$$LRPL_o = \frac{5}{\sum \left(\frac{1}{100,000} + \frac{1}{10,000} + \frac{1}{25,000} + \frac{1}{75,000} + \frac{1}{100,000} \right)}$$

$$LRPL_o = 28,846 PF_o = 5 \left(\left(\frac{1}{100,000} \right) + \left(\frac{1}{10,000} \right) + \left(\frac{1}{25,000} \right) + \left(\frac{1}{75,000} \right) + \left(\frac{1}{100,000} \right) \right)^{-1}$$

$$PF_o = 28846$$

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Attachment H: Figures

Figure 1: TSI Laser Photometer

Figure 2: Aerosol Generator

Figure 3: DustTrak II Aerosol Monitor

Figure 4: TSI PortaCount

Figure 5: Scanning Mobility Particle Sizer

Figure 6: Charged Test Chamber

Figure 7: Facial Size Measurement Calipers

Figure 8: Interior View of a Probed Sample Respirator

Figure 9: Exterior View of a Probed Sample Respirator

Figure 10: View of Sample Probe – Various lengths

Figure 11: Sample Probe View Set Up as – Double (left) and Single (right)



Figure 1: Laser Photometer, Model 8587A



Figure 2: Aerosol Generator



Figure 3: DustTrak II Aerosol Monitor



Figure 4: TSI PortaCount Model 8038



Figure 5: Scanning Mobility Particle Sizer



Figure 6: Charged Test Chamber



Figure 7: Facial Size Measurement Calipers



Figure 8: Interior View of a Probed Sample Respirator



Figure 9: Exterior View of a Probed Sample Respirator



Figure 10: View of Sample Probe – Various lengths



Figure 11: Sample Probe View Set Up as – Double (left) and Single (right)

Revision History

Revision	Date	Reason for Revision
0.0	17 November 2006	Original Issue
1.0	10 June 2008	Significant changes – While the basic method of conducting the test is essentially the same as in the previous revision, non-essential language has been removed, and instructions specific to having the test performed by a third-party laboratory have been deleted.
2.0	20 October 2021	Changes throughout the document to incorporate a new anthropometric panel referred to as the NIOSH Panel. General revisions to reflect the use of the PortaCount fit tester.