



National Institute for Occupational Safety and Health  
National Personal Protective Technology Laboratory  
P.O. Box 18070  
Pittsburgh, PA 15236

Procedure No. TEB-CBRN-APR-STP-0553

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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 test establishes the procedure for ensuring that the respirator is designed and constructed to fit persons with various facial shapes and sizes as specified by the Los Alamos National Laboratory (LANL) panel. This is accomplished by determining the respiratory protection factors provided by PAPR, loose fitting 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), and the Statement of Standard for Chemical, Biological, Radiological and Nuclear (CBRN) Powered Air-Purifying Respirator (PAPR).

2. GENERAL

- 2.1. This document describes the determination of 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.
- 2.2. LRPL testing is completed using a team of personnel, a facility test administrator and their staff of two to six personnel. Through out this STP, the term "test administrator" will be used and it will imply the test administrator or their staff unless otherwise stated.

3. EQUIPMENT / MATERIAL / REFERENCES

- 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

Approvals:			
First Level	Second Level	Third Level	Fourth Level

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 8520, Dustrak Aerosol Monitor, or equivalent. Range 0.001 to 100 mg/m<sup>3</sup> (Calibrated to ISO 12103-1, A1 test dust). Resolution  $\pm 0.1\%$  of reading or  $\pm 0.001$  mg/m<sup>3</sup>, whichever is greater. As shown in figure 3.
- 3.5. Corn Oil - 99% Pure. CAS Number 8001-30-7. Commercial product names are Maise/Maize Oil, Maydol and Mazola Oil.
- 3.6. 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 4.
- 3.7. 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 5.
- 3.8. 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.
- 3.9. 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 6.
- 3.10. 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 is an interior view of a sample probed respirator in the oral-nasal region of the nose cup. Figure 8 is an exterior view of a sample probed respirator showing the metal interface for tubing and penetration through the lens and nose cup. Figure 9 and 10 are photographs of the probes used. There are two rubbers washers, one metal washer and one nut.
- 3.11. Human Test Subjects
  - 3.11.1. 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 course.
  - 3.11.2. At least twenty-five (25) human test subjects are required for this test. More subjects may be needed as necessary, based on the application specifics. 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. Manual caliper instruments are used to determine facial head sizes for subject panel placement and assignment of APR sizes.

#### 4. TESTING REQUIREMENTS AND CONDITIONS:

- 4.1. Prior to beginning any testing, all measuring equipment to be used must have 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 the National Institute of Standards and Technology (NIST) when available.
- 4.2. Any laboratory using this procedure to supply certification test data as a contractor to NIOSH will be subject to the provisions of the NIOSH Supplier Qualification Program (SQP). This program is based on the tenets of *ISO/IEC 17025, the NIOSH Manual of Analytical Methods* and other NIOSH guidelines. An initial complete quality system audit and follow on audits are requirements of the program. Additional details of the Program and its requirements can be obtained directly from the Institute. \*  
\*Note 4.2 does not apply to Pretest data from applicants as required under 42 CFR part 84.64.
- 4.3. Precision and accuracy (P&A) must be determined for each instrument in accordance with laboratory procedures and NIOSH/NPPTL guidance. Sound practice requires, under *NIOSH Manual of Analytical Methods*, demonstrating a tolerance range of expected data performance of a plus or minus 25% of a 95% confidence interval of the stated standard requirement. NIOSH/NPPTL P&A tolerance can be higher but not lower.

#### 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. 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 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 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 nosecup.

- 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 nosecup 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 fir 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.
- 5.2.2. Test subjects shall be selected to cover all the cells within the panels referenced in Appendix A and B. Each LRPL test shall consist of 2 trials. A minimum of 50 data points shall be collected from two trials by test subjects of each facepiece size of each respirator submitted to NIOSH, as prescribed in Appendix A and B.

## 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 5.5 volts.
- 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/m<sup>3</sup>.
- 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/m<sup>3</sup>.
- 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 Users Instructions (UI) provided with the test equipment shall be reviewed by all test facility personnel. Test subjects will be taught by the test facility administrator on the areas of manufacturer's size selection, donning, positive and negative user seal checks, doffing and other donning procedures related to the accessories as specified by the UI.
- 5.4.2. Test subject training will be conducted by test facility personnel based on the manufacturer's users instructions. Procedures for doffing, trouble shooting, negative user seal checks, head harness tightening and accessory interfacing must be taught to test subjects by test facility administrator. Each test subject shall perform an unassisted donning of the respirator. Self donning under supervision of test administrator is permitted to make the appropriate adjustments to the facepiece until they are satisfied that they are wearing the respirator in compliance with the manufacturer's user instructions. Expert donning is not allowed in the conduct of this test.
  - 5.4.2.1. After verifying the fit of the respirator using the user instructions, each test subject shall practice donning and wear the respirator for a maximum of 15 minutes for each activity. Instruction period will be a minimum of 10 minutes and a maximum of 30 minutes.
- 5.4.3. Subjects will be assigned to a specific photometer and moved to the ready line in groups of four or less based on the number of photometer test input lines. Test administrator will verify that the blower is running before subjects enter the chamber.
- 5.4.4. Test subjects entering and leaving the corn oil-charged chamber must enter into the vestibule first. Once the outside door is closed, the interior door is opened to allow subjects in the chamber. Once subjects are in the chamber they will be instructed to attach their sample line tubing to their assigned photometer. Chamber concentration is required to be monitored continuously during the entire

conduct of each individual LRPL test.

- 5.4.5. 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.
- 5.4.6. 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.
  - 5.4.6.1. 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.
  - 5.4.6.2. 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.
  - 5.4.6.3. 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. Caution subjects not to hit the shoulder with any part of the respirator during the conduct of the exercise.
  - 5.4.6.4. 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.
  - 5.4.6.5. 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.
  - 5.4.6.6. 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.

- 5.4.6.7. Reach for the floor and ceiling: 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.
- 5.4.6.8. 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 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.
- 5.4.6.9. 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.
- 5.4.6.10. Climb the Stairs At Regular Pace: Test subjects pair off in twos, while in normal breathing, one test subject of the a 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 minuet expires or told to stop. Return to the floor standing position. Ensure sample lines are not restricting movement during the climb.
- 5.4.6.11. 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.
- 5.4.7. Instruct the subjects to disconnect from the photometer. Exit the chamber using the vestibule room. Inform the subjects 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.

- 5.4.8. 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.
- 5.4.9. All comments and observations by test subjects, which are voluntary, will be written on the test data sheet.
- 5.4.10. After a brief intermission (1-10 minutes), each test subject will re-don the same respirator facepiece and repeat steps to complete the 2<sup>nd</sup> 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.
- 5.4.11. If a respirator is identified as a failure upon trial termination, 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. 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 consistently failing or suddenly failing 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.

## 5.5. Data Analysis

- 5.5.1. The overall LRPL factor will be collected for each trail run and written into the test data sheet.
- 5.5.2. The test administrator will record for each test subject the following:
  - 5.5.2.1. Subject ID number; facepiece size worn; LANL cell, any relevant comments noted during the trail.

## 6. PASS/FAIL CRITERIA

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

## 7. RECORDS\TEST SHEETS

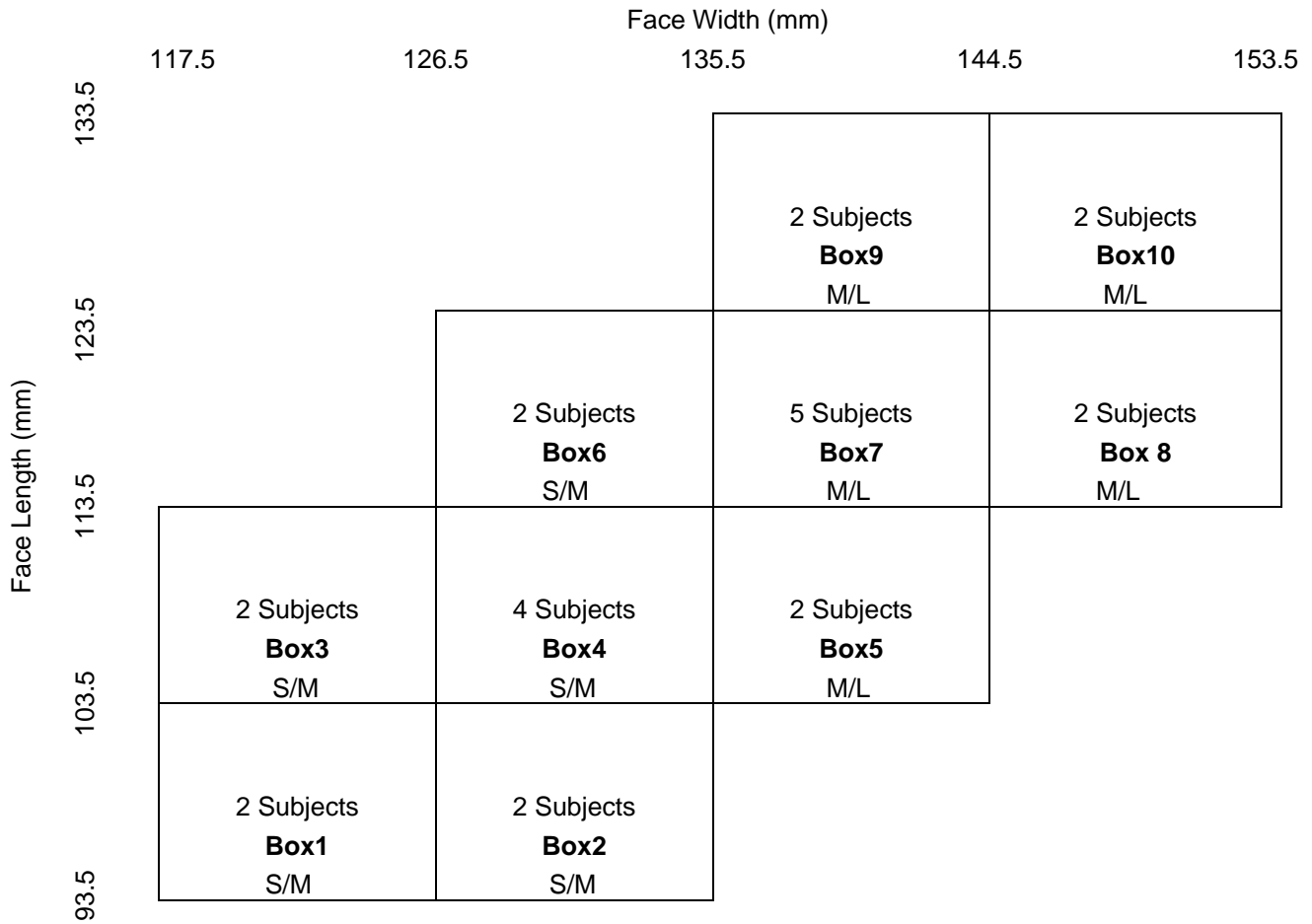
- 7.1. All test data will be recorded on the Laboratory Respirator Protection Level Test for CBRN LRPL test data sheets.



8. ATTACHMENTS

- 8.1. Attachment A: LANL Panel, One Size
- 8.2. Attachment B: LANL Panel, Two Size
- 8.3. Attachment C: LANL Panel, Three or more Size(s)
- 8.4. Attachment D: Test Panels Used for the Laboratory Respirator Protection Level Tests
- 8.5. Attachment E: CBRN LRPL Data Sheet
- 8.6. Attachment F: Protection Factor Calculations
- 8.7. Attachment G: Figures

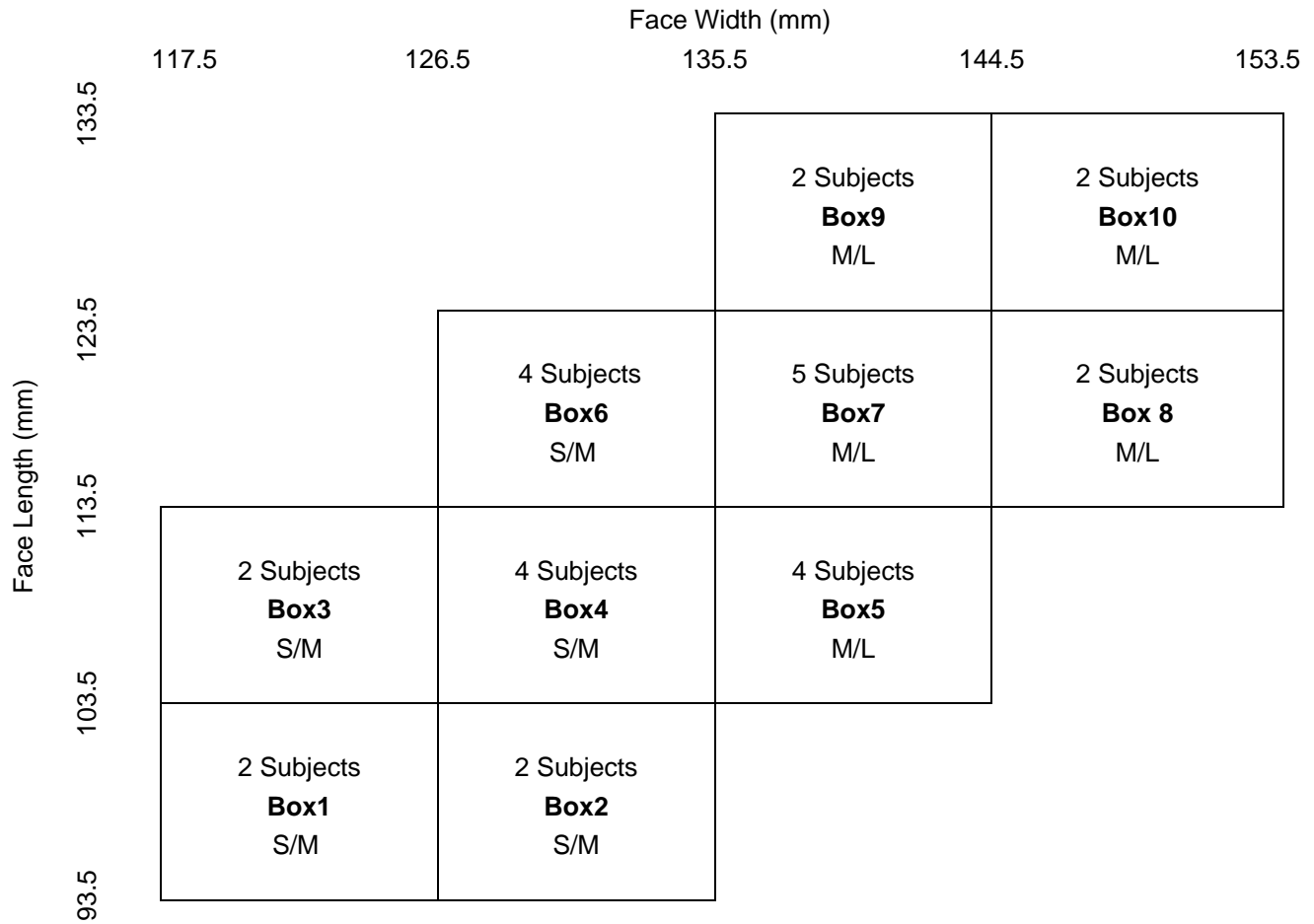
**Attachment A: LANL Panel, One Size**



**25 Member Panel for Testing of a One Size CBRN PAPR**

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.

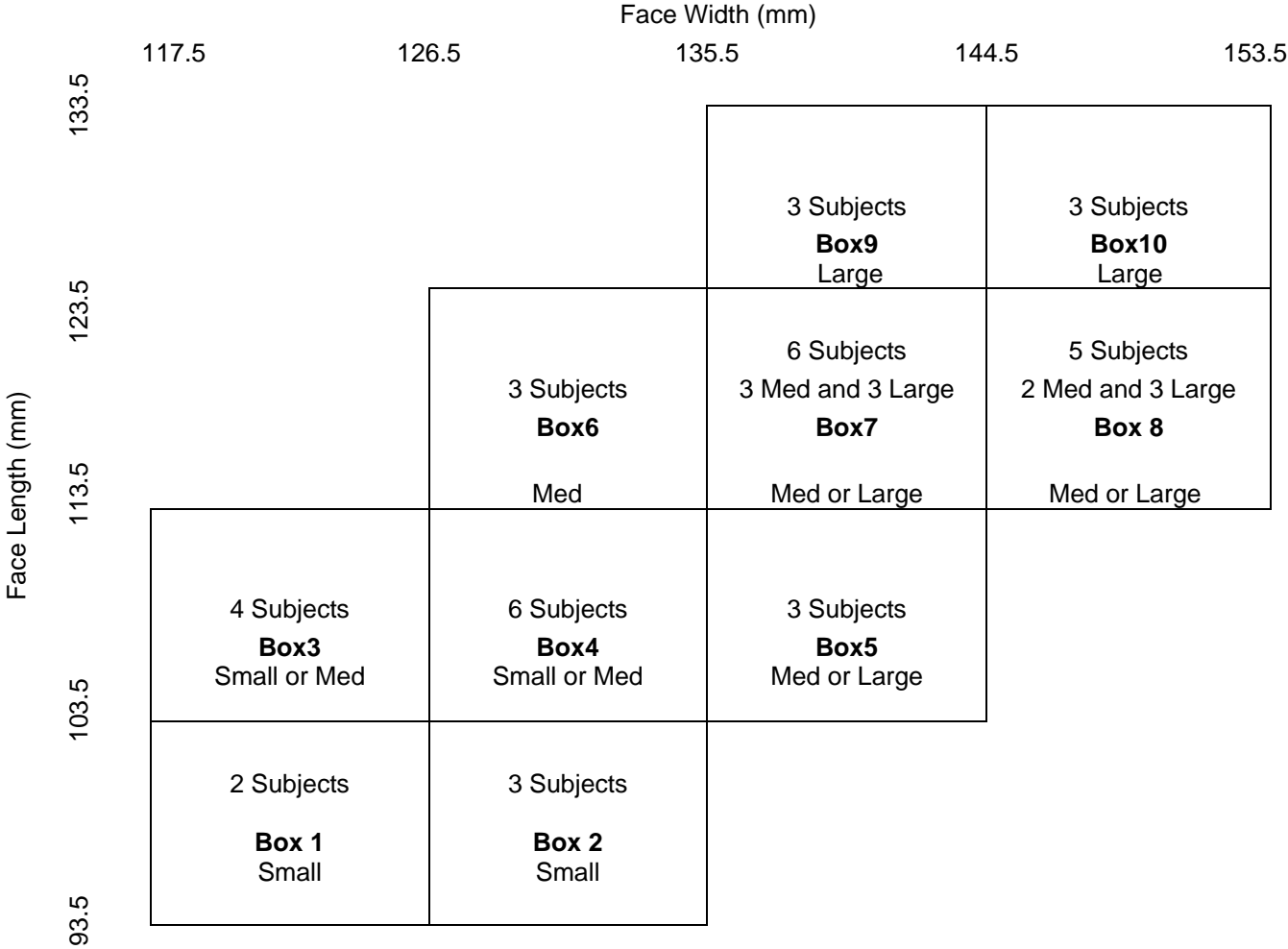
**Attachment B: LANL Panel, Two Sizes**



**29 Member Panel for Testing of a Two Size CBRN PAPR**

Note: For the purpose of testing available human test subjects. 2 size distribution of medium and large or small and medium is annotated by S/M or M/L.

**Attachment C: LANL Panel, Three Sizes or more**



**38 Member Panel Distribution for a Three Size CBRN PAPER**

Note: For the purpose of testing available human test subjects. 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).

**Attachment D: 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)**





Total Pass / Fail Results			
LRPL		Modified LRPL	
Pass		Pass	
Fail		Fail	
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: \_\_\_\_\_



### Attachment F: Protection Factor Calculations

The respirator system's performance is numerically quantified in terms of a PF value. The PF 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 PF is calculated for each individual exercise (PF<sub>i</sub>):

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

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

$$PF_o = n \left( \sum_{i=1}^n \frac{1}{PF_i} \right)^{-1}$$

Example: A five exercise PF test has been conducted. Here are the calculations for the PF<sub>o</sub> based on the PF<sub>i</sub> values for each exercise. PF<sub>1</sub> = 100,000 ; PF<sub>2</sub> = 10,000 ; PF<sub>3</sub> = 25,000 ; PF<sub>4</sub> = 75,000 ; PF<sub>5</sub> = 100,000 ; n = 5

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

$$PF_o = 28846$$

**Attachment G: Figures**

Figure 1: TSI Laser Photometer

Figure 2: Aerosol Generator

Figure 3: Dustrack Aerosol Monitor

Figure 4: Scanning Mobility Particle Sizer

Figure 5: Charged Test Chamber

Figure 6: Facial Size Measurement Calipers

Figure 7: Interior View of a Probed Sample Respirator

Figure 8: Exterior View of a Probed Sample Respirator

Figure 9: Front View of Sample Probe

Figure 10: Side View of Sample Probe



Figure 1: Laser Photometer, Model 8587A



Figure 2: Aerosol Generator



Figure 3: Dustrack Aerosol Monitor



Figure 4: Scanning Mobility Particle Sizer



Figure 5: Charger Test Chamber



Figure 6: Facial Size Measurement Calipers





Figure 7: Interior View of a Sample Respirator Probed



Figure 8: Exterior View of a Probed Sample Respirator

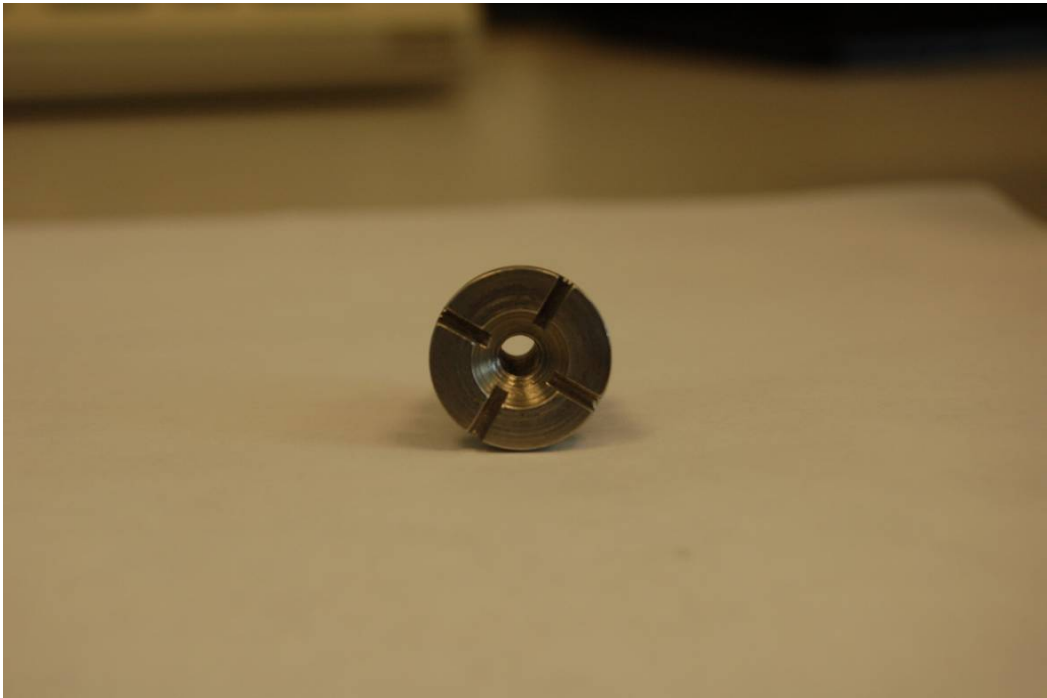


Figure 9: Front View of Sample Probe

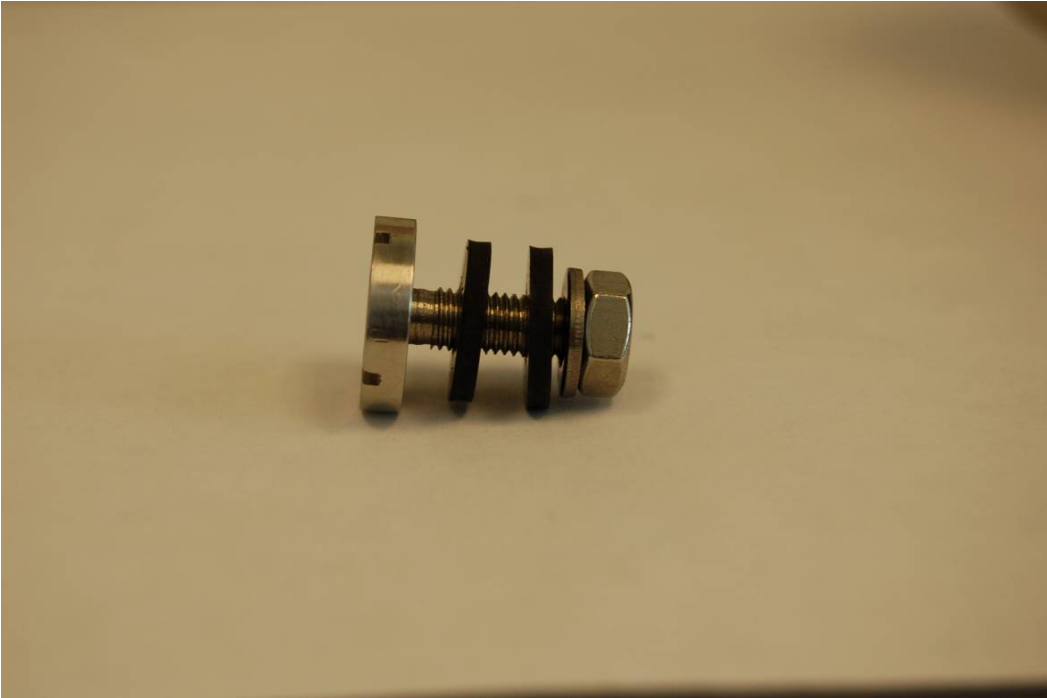


Figure 10: Side View of Sample Probe

### Revision History

<b>Revision</b>	<b>Date</b>	<b>Reason for Revision</b>
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.