National Institute for Occupational Safety and Health National Personal Protective Technology Laboratory 626 Cochrans Mill Road Pittsburgh, PA 15236		
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DETERMINATION OF RESPIRATOR FIT, QUANTITATIVELY USING CORN OIL AEROSOL, FOR POWERED AIR-PURIFYING RESPIRATORS WITH LOOSE-FITTING RESPIRATORY INLET COVERINGS, STANDARD TESTING PROCEDURE (STP)

1. PURPOSE

This procedure establishes the method by which a generated corn oil aerosol is used for determining if powered, air-purifying respirators (PAPRs) supplied with loose fitting respiratory inlet coverings meet the facepiece-fit requirements at 42 CFR Part 84, Subpart K, Section 84.176(b).

2. GENERAL

This STP describes the Determination of Respirator Fit, Quantitatively Using Corn Oil Aerosol, For Powered Air-Purifying Respirators With Loose-Fitting Respiratory Inlet Coverings test procedure in sufficient detail that a person knowledgeable in the appropriate technical field can select equipment with the necessary resolution, conduct the test, and determine whether or not the evaluated product passes the test.

3. EQUIPMENT/MATERIAL

3.1. TSI Rear Light Scattering Laser Photometer, model 8587A, or equivalent with concentration range 1.0 $\mu g/m^3$ to >200 mg/m^3. See Figure 1.

3.2. NIOSH Dynamic Fit Software. (The software is used to monitor the particle count both inside and outside the respirator, calculate a fit factor for each exercise and the average fit factor for the trial in real time.)

3.3. Aerosol Generator, MSP Model 2045 High Output Aerosol Generator or equivalent - The aerosol generator is required to be capable of maintaining 5 to 100 mg/m^3 of corn oil challenge aerosol concentrations with a Mass Median Aerodynamic Diameter (MMAD) of 0.4 to 0.6 µm for the specified test duration in the test chamber. See Figure 2.

3.4. TSI model 8530, DustTrak II Aerosol Monitor, or equivalent - Range 0.001 to 400 mg/m^3 (Calibrated to ISO 12103-1, A1 test dust), and resolution ±0.1% of reading or ±0.001 mg/m^3, whichever is greater – See 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 composed of the TSI model 3080 Electronic Classifier, TSI model 3775 Condensation Particle Counter and Long Differential Mobility Analyzer (DMA). See Figure 4.

3.7. Environmental test chamber - The chamber shall be designed so that the individual(s) performing fit factor 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 the aerosol concentration and the concentration uniformity. An example of a charged corn oil chamber is illustrated in Figure 5.

3.8. Chamber Communications - Electronic audio communications (chamber loudspeaker) are employed to transmit a real-time voice signal from laboratory technicians to test subjects to ensure that test subjects can clearly hear when to start and stop the test exercise regimen or receive safety information.

3.9. Facial Size Measurement Calipers - 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. These are shown in Figure 6 and Figure 7.

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 8 and Figure 9 are photographs of the probes used. Each probe bulkhead fitting is sealed using two rubber washers, one metal washer and one nut.

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.

4.2. General respiratory inlet covering fit requirements for PAPRs -

4.2.1. The fit test shall be performed using a panel of test subjects of various facial sizes measured in accordance with the NIOSH Bivariate Panel (NIOSH Panel). The measured face length and face width are used to designate the subject's NIOSH Panel cell number, as illustrated in Figure 10.

4.2.1.1. Face Width is the Bizygomatic Breadth measurement (Figure 9), using the spreading measurement calipers.

4.2.1.2. Face Length is the Menton-Sellion measurement (Figure 9), using the sliding measurement calipers.

4.2.2. Any PAPR part which must be removed to perform the respiratory inlet covering fit test shall be replaceable without special tools and without disturbing the facepiece on the wearer's face.

4.2.3. The respirator, including the respiratory inlet covering, shall be adjusted

according to the manufacturer's user instructions, prior to entering the chamber; however, upon entry into the test chamber neither the respirator, nor the respiratory inlet covering shall not be re-adjusted.

4.3. Test subject selection

4.3.1. For PAPRs with up to three sizes of loose-fitting respiratory inlet coverings, the test will be conducted employing 18 individual test subjects which represent the NIOSH Panel (Appendix 8.5). See Table 1 for the suggested test subject distribution in relation to the NIOSH Panel (NIOSH is allowing flexibility in the use of subjects from well-populated panel cells. NIOSH will attempt to test using a panel that contains at least one subject from each cell, but when subjects from all cells are unavailable they may be supplanted by adding subjects from more populated cells; however, no more than four subjects from any one cell may contribute to the overall test panel composition for any respirator under evaluation.)

Table 1: Recommended test subject distribution to be used for fit testing in relation to the NIOSH Panel

NIOSH Panel – Cell Number	Number of Test Subjects
1	1
2	1
3	2
4	4
5	1
6	1
7	4
8	2
9	1
10	1

4.3.1.1. For PAPRs supplied with respiratory inlet coverings in only one size - a subject failing to achieve a pass in their initial trial is considered to be a face-size failure. (no alternate size to try)

4.3.1.2. For PAPRs supplied with loose-fitting, respiratory inlet coverings in two sizes -

4.3.1.2.1. Subjects from panel cells 1-4 and cell 6 shall be tested first wearing the smaller size inlet covering. If the subject does not achieve a trial pass in the smaller size inlet covering, the subject can be tested again (second trial) wearing the larger size inlet covering.

4.3.1.2.2. Subjects from panel cells 7-10 and cell 5 shall be tested first wearing the larger size inlet covering. If the subject does not achieve a trial pass in the larger size inlet covering, the

subject can be tested again (second trial) wearing the smaller size inlet covering.

4.3.1.2.3. A subject failing to achieve a trial pass in either of the sizes available for testing is considered to be a face-size failure.

4.3.1.3. For PAPRs supplied with loose-fitting, respiratory inlet coverings in three sizes -

4.3.1.3.1. Subjects from panel cells 1 and 2 shall be tested wearing the smaller size initially.

4.3.1.3.2. Subjects from panel cells 3-7 shall be tested wearing the regular/medium size initially.

4.3.1.3.3. Subjects from panel cells 8, 9, and 10 shall be tested wearing the larger size initially.

4.3.1.3.4. If a subject does not achieve a trial pass in the first inlet covering size evaluated, the subject will be retested in the next available size (second trial). A subject failing in the smaller size inlet covering, can try the medium size (second trial), and then larger size (third trial) inlet covering. A subject failing to achieve a trial pass in the medium size inlet covering can try the smaller and larger size inlet coverings. A subject failing in the larger size inlet covering can try the medium, then the smaller size inlet covering. A subject failing to achieve a trial pass in any of the sizes available for testing is considered a face-size failure.

4.3.1.3.5. The test administrator may determine whether or not third trials are needed for test completion. For a subject failing to achieve a trial pass in the small or medium size inlet covering, trying the large size may not be necessary since the large size may be obviously too big for the subject. For a subject failing to achieve a trial pass in the large and medium size inlet covering, trying the small size may not be necessary since the small size may be obviously too small for the subject.

5. PROCEDURE

5.1. Chamber Set-up

5.1.1. Turn on air handling unit with sufficient airflow to maintain the proper corn oil concentration.

5.1.2. Turn on vacuum pump for laser photometers

5.1.3. Turn on mixing fans to 6.1 volts.

5.1.4. Turn on air compressor for corn oil generators to maintain the proper corn oil concentration. Corn Oil Challenge Concentration = 30 to 40 mg/m^3.

5.1.5. Turn on laser photometers.

5.1.6. Turn on SMPS and warm up for 15 minutes.

5.1.7. Turn on DustTrak.

5.1.8. Allow 30 minutes for the chamber concentration to stabilize.

5.1.9. Use the DustTrak to monitor the chamber concentration.

5.1.10. Adjust the air pressure at the generators regulator to establish the corn oil concentration of 30 to 40 mg/m^3.

5.1.11. 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.

5.2. Conducting the Corn Oil Test

5.2.1. The Users Instructions (UI) provided with the test samples 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, doffing and procedures related to the accessories as specified by the UI.

5.2.2. Test subject training will be conducted by test facility personnel based on the manufacturer's users' instructions. Each test subject shall perform an unassisted donning of the respirator. Self-donning under supervision of the test administrator is permitted to make the appropriate adjustments to the respiratory inlet covering until they are satisfied that they are wearing the respirator in compliance with the manufacturer's users' instructions. Expert donning is not allowed in the conduct of this test.

5.2.3. Subjects will be assigned to a specific photometer and moved to the chamber in groups of four or less based on the number of photometers.

5.2.4. Test subjects entering and leaving the corn oil-charged chamber must enter 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 duration of each individual (face-size trial) Corn Oil test.

5.2.5. 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.

5.2.6. A fit factor test consists of a set of four two-minute standard exercises. During the test, each human subject will perform the following four exercises for two minutes each in the below listed sequence. Subjects should not touch any portion of the respirator during any part of the testing exercises. Test administrator will give verbal commands to stop and start each exercise.

5.2.6.1. Two (2) minutes nodding up and down and turning head side to side.

5.2.6.2. Two (2) minutes callisthenic arm movements.

5.2.6.3. Two (2) minutes running in place.

5.2.6.4. Two (2) minutes pumping with tire pump.

5.2.7. Instruct the subjects to disconnect sample line from the photometer. Exit the chamber using the vestibule room. Inform the subject to return to the ready line and await further instructions for doffing the respirator or leaving the respirator donned. Subjects that are being reviewed for test failure protocol will remain with respirator donned until instructed to doff.

5.2.8. An overall pass/fail statement for each individual will be recorded by the NIOSH Dynamic Fit software and written on the test data sheet as shown in attachment 8.1.

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

5.2.10. 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, probe loose, 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. If the respirator has a serviceable probe but continues to fail, log it as a Corn Oil 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 face blank material or inadequate probe sealing areas are cause for reanalysis of the determined probe entry point.

6. PASS/FAIL CRITERIA

6.1. The requirement for passing this test is set forth in 42 CFR Part 84, Subpart K, Section 84.176(b).

6.2. The number of face-size failures will not exceed four.

6.3. If an overall pass is achieved, but three subjects report the same issue about the comfort of the facepiece, the test will be considered a failure.

6.4. Fit factor for loose-fitting PAPR -

6.4.1. For each face-size trial, an overall average fit factor of 500 must be achieved.

6.4.2. A minimum average fit factor of 500 must be achieved during each of the subject exercises which comprise a single face-size trial.

7. RECORDS/TEST SHEETS

7.1. All test data collected will be recorded on the appropriate Determination of Quantitative Corn Oil Fit Test data sheet.

8. ATTACHMENTS

8.1. Example Data Sheet - PAPR Fit Corn Oil Test Data Sheet – Page 1

8.2. Example Data Sheet - PAPR Fit Corn Oil Test Data Sheet – Page 2

8.3. Photographs

8.3.1. Figure 1. Photograph of Laser Photometer

8.3.2. Figure 2. Photograph of Aerosol Generator

8.3.3. Figure 3. Photograph of DustTrak II Aerosol Monitor

8.3.4. Figure 4. Photograph of Scanning Mobility Particle Sizer

8.3.5. Figure 5. Photograph of Charged Test Chamber

8.3.6. Figure 6. Photograph of Sliding Calipers

8.3.7. Figure 7. Photograph of Spreading Calipers

8.3.8. Figure 8. Photograph of Front View of Sample Probe

8.3.9. Figure 9. Photograph of Side View of Sample Probe

8.4. Figure 9. Anthropometric Measurements

8.5. Figure 10. Diagram, NIOSH Panel

8.1. Example Data Sheet – Page 1

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

Task Number: TN-XXXXX
Test: PAPR Fit Testing (Cornoil)
Manufacturer: Company Name
Item Tested:
Minimum Fit Factor:

Reference No.: CFR 84.176(b)
STP No.:

Subject	Face Size	Facepiece	Result	
			Trial 1	Trial 2

Overall Result: _____

Test Operator: _____ **Date:** _____
Engineering Technician

Comments:

Was all equipment verified to be in calibration throughout testing?

Test Operator Signature: _____

8.2. Example Data Sheet – Page 2

Fit Testing Report

Name	GAGEPak #		Calibration Due
TSI Photometer			
TSI Photometer			

8.3. Photographs

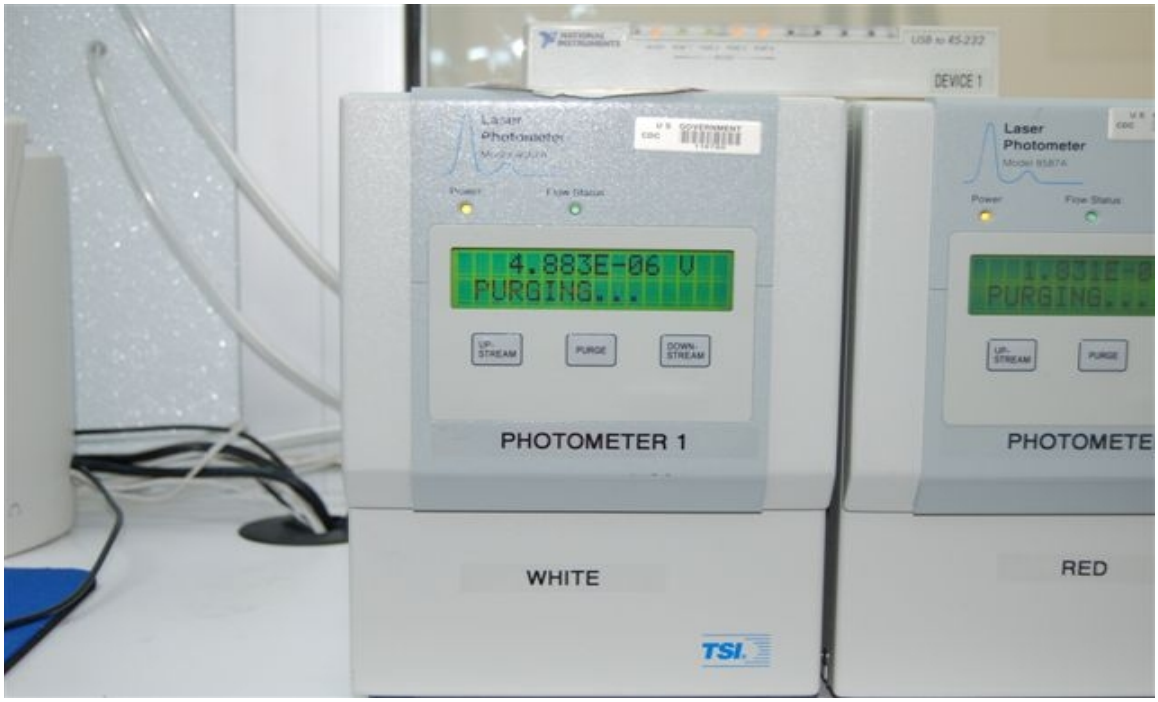


Figure 1: Laser Photometer, Model 8587A

Figure 2: Aerosol Generator

8.3. Photographs

Figure 3: DustTrak II Aerosol Monitor

Figure 4: Scanning Mobility Particle Sizer

8.3. Photographs

Figure 5: Charged Test Chamber

Figure 6: Sliding Calipers

8.3. Photographs

Figure 7: Spreading Calipers

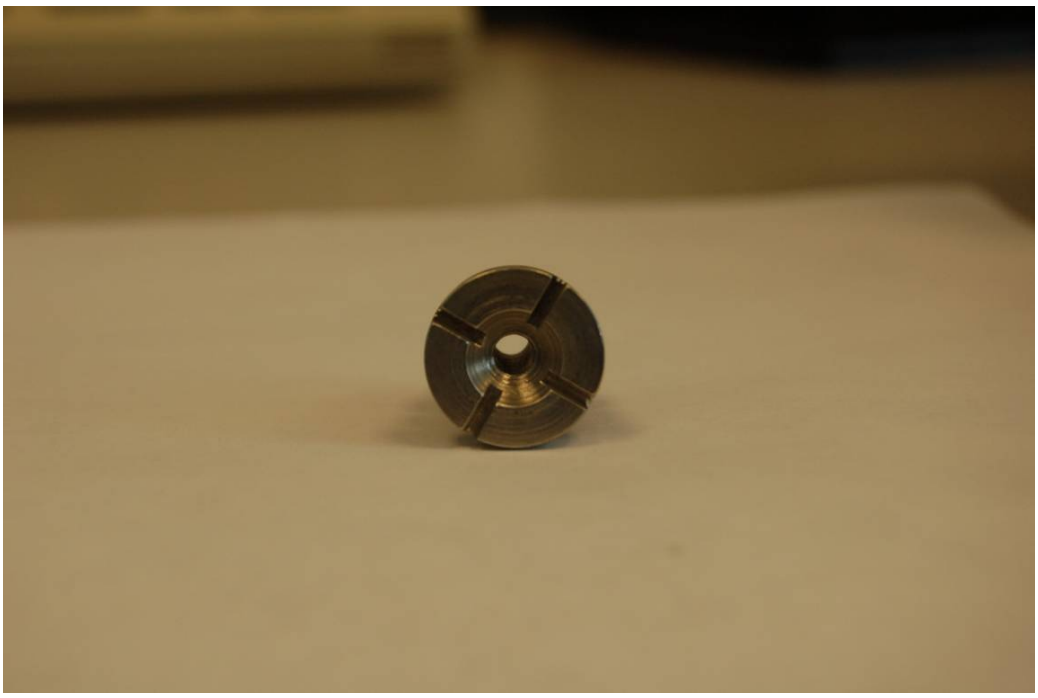


Figure 8: Front View of Sample Probe

8.3 Photographs

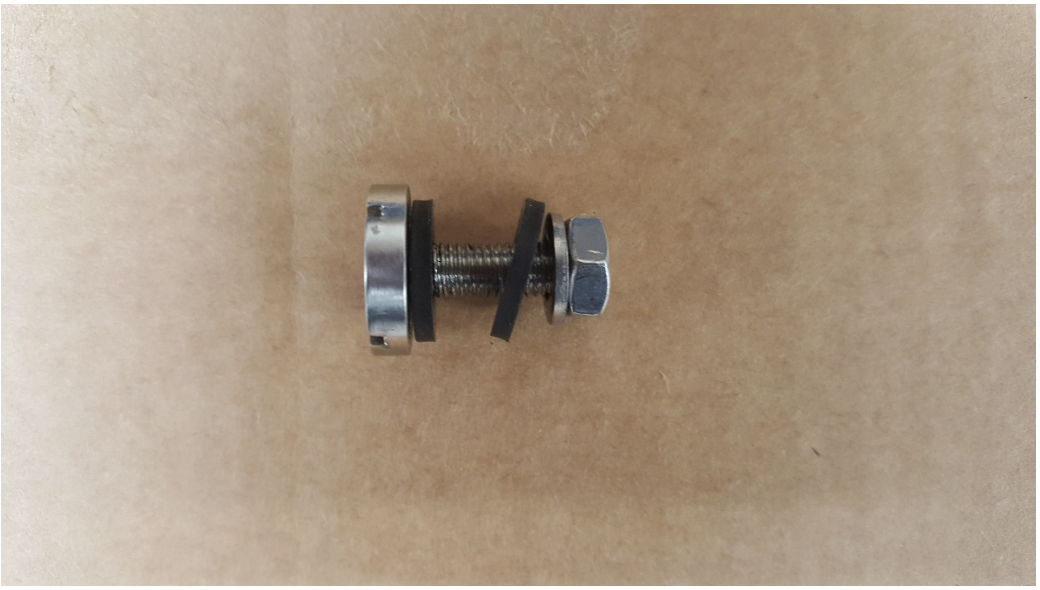


Figure 9. Side View of Sample Probe

8.4. Anthropometric Measurements

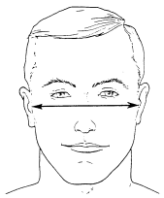
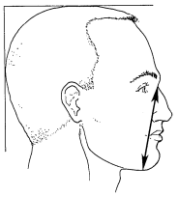
Description	Definition	Diagram
Bizygomatic Breadth	Maximum horizontal breadth of the face as measured with a spreading caliper between the zygomatic arches.	
Menton–Sellion Length	Distance as measured with a sliding caliper in the midsagittal plane between the menton landmark and the sellion landmark.	

Figure 9: Anthropometric Measurements

8.5. NIOSH Panel

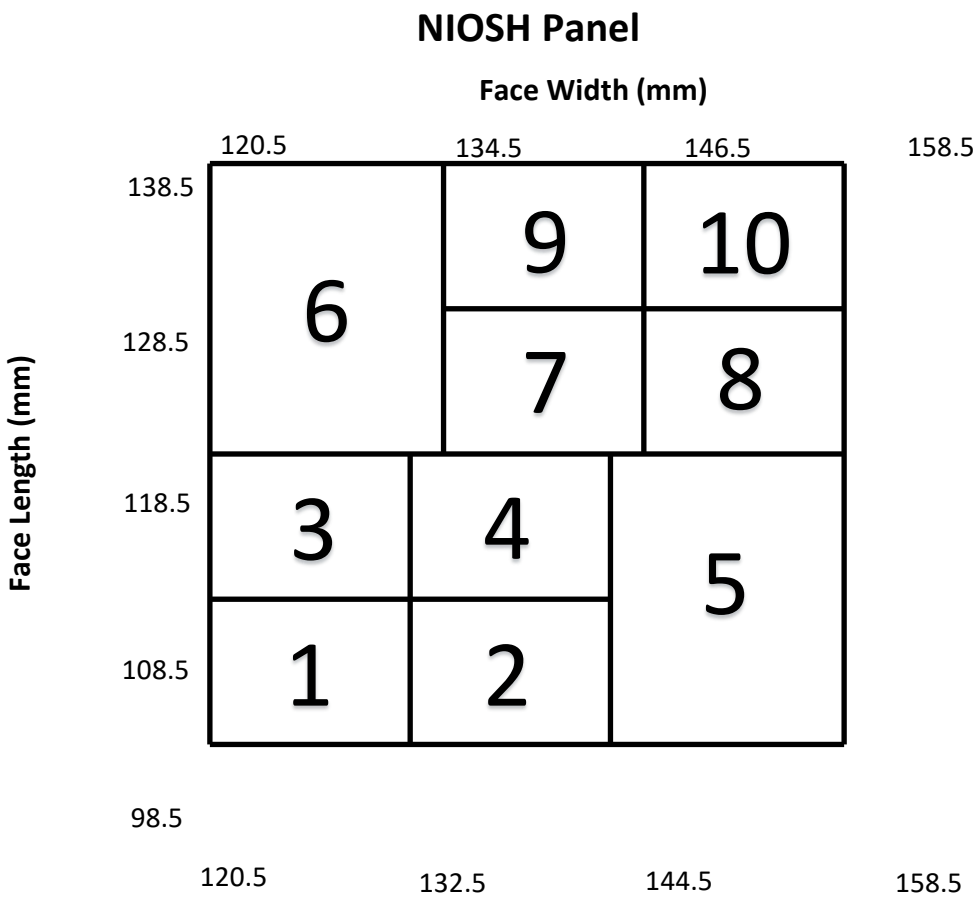


Figure 10: NIOSH Bivariate Panel (NIOSH PANEL)

Revision History

Revision	Date	Reason for Revision
0.0	18 March 2020	Original release