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National Personal Protective Technology Laboratory
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| Date: January 31, 2007 | NOTE: The Respirator Branch maintains an updated index of current procedures. |
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# Total Inward Leakage Test for Half-mask Air-purifying Particulate Respirators

1. Purpose

   1.1. This procedure establishes test method for quantifying the Total Inward Leakage (TIL) for half-mask respirators under 42CFR Part84, Subpart K, including those having elastomeric and filtering facepieces. The purpose of the test is to (1) ensure that a half-mask respirators are capable of providing a minimum level of protection as measured by total inward leakage, over the range of facial sizes for which the facepieces were designed to fit and (2) ensure that the User's Instructions describe how to achieve that fit. The respirators will be tested on 35 human subjects, having facial sizes designated by the respirator manufacturer for the specific facepiece, from a NIOSH panel having facial sizes and shapes that approximate the distribution of sizes and shapes of the working population of the United States.

2. General

   2.1. This procedure describes the TIL test for respirators using a Condensation Nuclei Counter (CNC) in an ambient atmosphere, in sufficient detail that a person knowledgeable in fit testing procedures can conduct the test, determine the level of protection afforded by the respirator and make a pass/fail determination based on specific requirements.

3. Equipment/ Materials

   3.1. The following is a list of equipment necessary to conduct the test:

| Approvals: | 1st Level | 2nd Level | 3rd Level | 4th Level |
|---|---|---|---|---|
| | | | | |


3.1.1. PortaCount® Plus with Companion™, CNC fit test apparatus and associated facepiece adapters and calibration equipment

3.1.2. One or more TSI particle generators.

3.1.3. Thirty-five of each size and style of non-cleanable respirator to be evaluated or three of each size and style of cleanable respirators.

3.2. Test Subjects

3.2.1. Thirty-five test subjects meeting the requirements of NIOSH Human Test Subject Review Board (HSRB) approved protocol. Refer to HSRB-04-NPPTL-02XP ", and having facial dimensions falling within the requirements of the test panel for the size of the respirator to be tested. See Appendix A.

3.2.2. All test subjects shall also have facial characteristics which result in being included within the Principal Components Analysis Panel, which excludes extreme facial features. See Appendix B.

4. Testing Requirements and conditions

4.1. At a minimum, all measuring equipment utilized for this testing must have been calibrated within the preceding 12 months using a method traceable to the National Institute of Standards and Technology (NIST), or more frequently if specified by the equipment manufacturer. Equipment calibration records shall be available for examination at each testing facility. Prior to beginning any testing, a statement that all test equipment is within calibration shall be attested by the lab technician on each test report.

4.2. Prior to conducting the test, the Users Instructions provided by the manufacturer shall be reviewed to verify that the instructions for facepiece size selection are easily understood, easily followed, and practical. Test subjects will familiarize themselves with the manufacturer's selection, donning and fitting procedures for

the respirator.

4.3. The manufacturer's User Instructions for size selection shall be followed to determine consistency with NIOSH Panel cells for facial measurements.

4.4. Each respirator shall be probed for purposes of measuring concentrations of aerosol inside the facepiece. The optimum sampling probe position is approximately 1/4 inch from the skin at the point of quadrilateral symmetry of the mouth and nose, i.e. midway between the nose and upper lip. The exact position(s) of the sample probe(s) will depend upon the design of the mask being evaluated.

4.5. A short length of PortaCount tubing will then connect the sample probe(s) in the mask to the aerosol detector unit. The method in which the sampling probe(s) is used shall not interfere with respirator performance and shall minimize sampling biases.

5. Procedure

5.1. Turn on, calibrate equipment and measure the particle count in the ambient atmosphere. The ambient atmosphere must contain at least 500 particles per cc of air.

5.2. Each subject shall be allowed to read the test activity sheet and then complete the daily pre-test questionnaire and be dismissed for cause. See appendix C & D.

5.3. Each test subject shall not be permitted to eat or smoke for at least 30 minutes before the start of the test or between re-donnings.

5.4. Each test subject shall perform an assisted donning of the respirator facepiece in accordance with the manufacturer's User's Instructions.

5.5. Each test subject will be permitted time to make the appropriate adjustments to the facepiece until they are satisfied that they are wearing the facepiece in compliance with the manufacturer's User Instructions.

5.6. Each test subject shall perform a user seal check in accordance with the manufacturer's User's Instructions. Any test subject not being able to successfully perform a user seal check shall be allowed to continue the test, but the fact that a seal check could not be performed shall be noted..

5.7. Each test subject shall wear the respirator facepiece for approximately 5 minutes before beginning the test.

5.8. The actual TIL value shall be recorded in accordance with the PortaCount instructions, except as noted herein, for each test subject while performing the following sequence of exercises for 30 seconds each.

Normal Breathing

Deep Breathing

Turn Head Side to Side while pausing for two normal inhalations at each side

Move Head Up and Down while pausing for two normal inhalations in the head up position and in the head down position

Recite the Rainbow Passage

Reach for the Floor and Ceiling while pausing for two normal inhalations in the arms-up position and in the arms-down position

Grimace (not included in the TIL determination)

Normal Breathing

5.7 The subject shall doff the respirator, wait at least 1 minute, then re-don the respirator and repeat the procedure. The procedure shall be repeated until three individual donnings and tests are completed.

5.8 All test subjects' comments shall be noted on the test data sheet.

6. Recording

6.1. The actual TIL values shall be recorded in accordance with the software instructions.

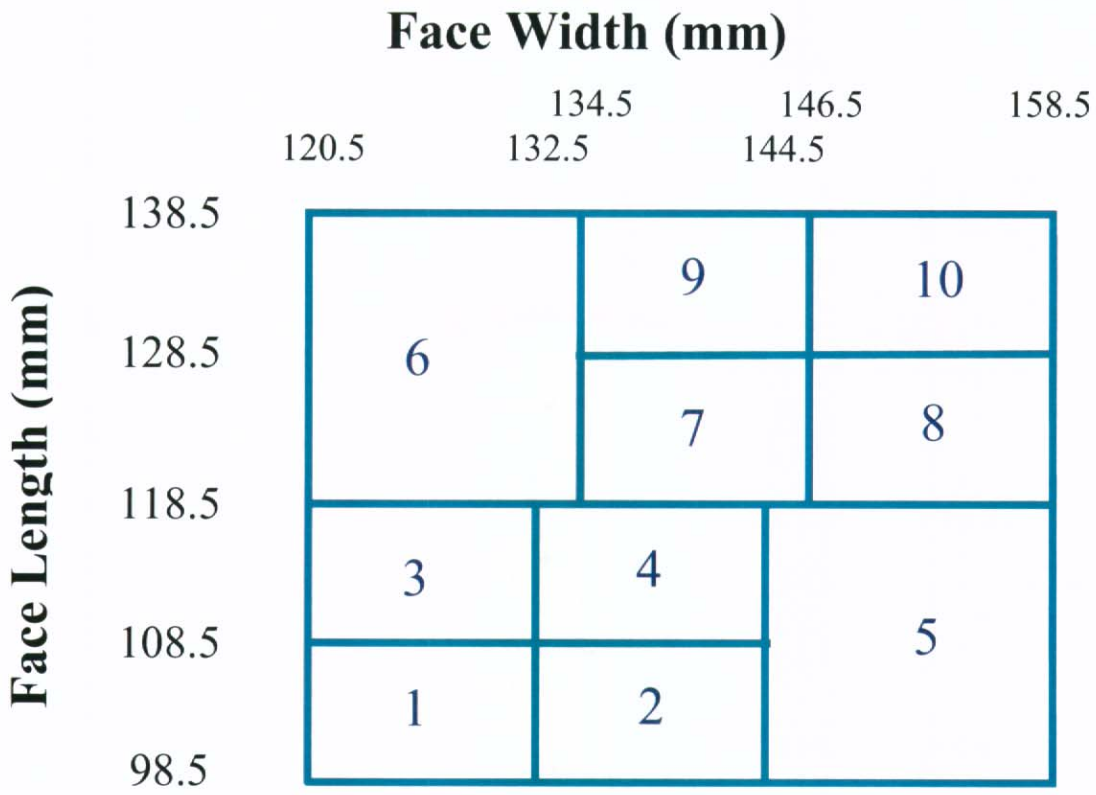
6.2. All respirator, test subject and test administrator identifiers shall be recorded.

7. Pass/Fail Criteria

7.1.1. Pass/failure criteria is given in 42CRF Part 84, §84.xxx .

**Appendix A**

**NIOSH - NPPTL RESPIRATOR TIL PANEL**



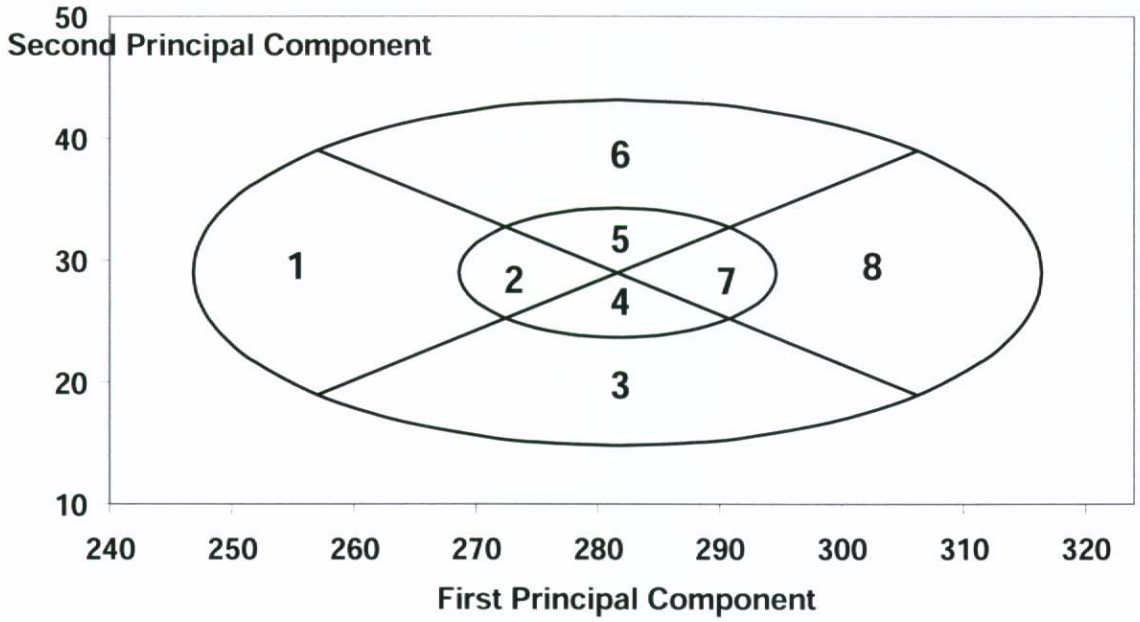

Panel Use

For the purpose of measuring the TIL, each respirator, regardless of size designation, will be tested on 35 test subjects chosen from the panel boxes matching the respirator sizing as described in instructions for use accompanying the respirator.

**Appendix B**

**PCA Panel**

The fit test panel based on Principal Component Analysis (PCA) is shown in Figure 1. This panel covers 95.2% of the male and 97.6% of the female civilian workforce. The layout of cells is different from the bivariate panel. The limit of this panel is based on an ellipse in which more than 95% of the population is included. The inner ellipse includes about one-third of the population. The rationale for the rest of the PCA configuration is to have uniform distributions for each cell. Thus, two lines were used to divide the two ellipses into four quadrants resulting in 8 cells.




**PCA Panel Diagram**

To use the PCA panel, the 10 face dimensions need to be first measured as described in below. The first and second principal components (PC1 and PC2) are then calculated as follows.

PC1 = 0.343264*(minimum frontal breadth) + 0.426498*(face width) + 0.372717*(bigonial breadth) + 0.329648*(menton sellion length) + 0.363474*(interpupillary distance) + 0.372241*(head breadth) + 0.113578*(nose protrusion) + 0.301125*(nose breadth) + 0.202311*(nasal root breadth) + 0.193650*(subnasale-sellion length)

PC2 = - 0.152951*(minimum frontal breadth) - 0.039087*(face width) - 0.093279*(bigonial breadth) + 0.359799*(menton sellion length) - 0.173099*(interpupillary distance) + 0.013306*(head breadth) + 0.551842*(nose protrusion) - 0.210833*(nose breadth) - 0.341235*(nasal root breadth) + 0.584261*(subnasale-sellion length)

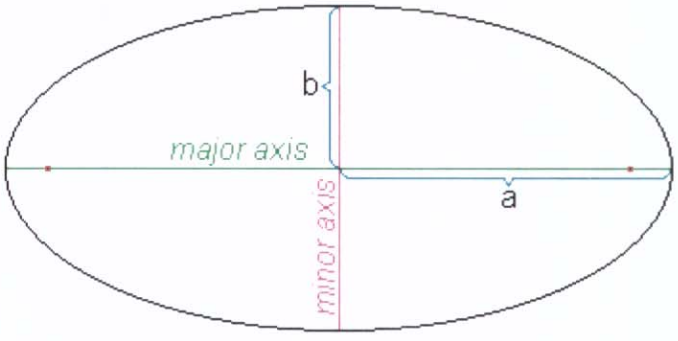
The following algorithm is be used to determine which cell the subject is in.

x = PC1 - 281.6217618
y = PC2 - 28.9865054
slope = 5.5847930/13.6991108 = 0.4076756
a = 2.54 * 13.6991108
b = 2.54 * 5.5847930
c = 0.95 * 13.6991108
d = 0.95 * 5.5847930

$$r_1 = \sqrt{x^2/a^2 + y^2/b^2}$$

$$r_2 = \sqrt{x^2/c^2 + y^2/d^2}$$

where x and y are new coordinates for translating the origin of PC1 and PC2 from their mean values (281.6217618 for PC1 and 28.9865054 for PC2) to zero;
slope is the slope value for the two lines dividing the ellipse into 8 cells;
a is a constant for the length of the semimajor axis for the outer ellipse (see the illustration below);
b is the constant for the length of the semiminor axis for the outer ellipse (see the illustration below);
c is a constant for the length of the semimajor axis for the inner ellipse;
d is the constant for the length of the semiminor axis for the inner ellipse;
$r_1$ and $r_2$ are calculated values to determine where a particular data point or a subject is, e.g., the data point is outside the outer ellipse when $r_1 > 1$ or on the outer ellipse when $r_1 = 1$ or inside the outer ellipse when $r_1 < 1$.




Use the x, y and r1 values and the algorithm below to determine if the subject is in cells 1-4:
if $x \geq 0$ and $y \geq 0$ and $r_1 \leq 1$ and $abs(y)/abs(x) \leq$ slope then cell = 8
if $x \geq 0$ and $y < 0$ and $r_1 \leq 1$ and $abs(y)/abs(x) <$ slope then cell = 8
if $x \geq 0$ and $y < 0$ and $r_1 \leq 1$ and $abs(y)/abs(x) \geq$ slope then cell = 3
if $x < 0$ and $y < 0$ and $r_1 \leq 1$ and $abs(y)/abs(x) >$ slope then cell = 3
if $x < 0$ and $y < 0$ and $r_1 \leq 1$ and $abs(y)/abs(x) \leq$ slope then cell = 1
if $x < 0$ and $y \geq 0$ and $r_1 \leq 1$ and $abs(y)/abs(x) <$ slope then cell = 1
if $x < 0$ and $y \geq 0$ and $r_1 \leq 1$ and $abs(y)/abs(x) \geq$ slope then cell = 6

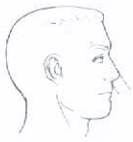
if $x \geq 0$ and $y \geq 0$ and $r_1 \leq 1$ and abs(y)/abs(x) > slope then cell = 6

If the $r_2$ value is less than or equal to 1, use the following algorithm to adjust the cell number:
if cell = 1 and $r_2 \leq 1$ then cell = 7
if cell = 2 and $r_2 \leq 1$ then cell = 4
if cell = 3 and $r_2 \leq 1$ then cell = 2
if cell = 4 and $r_2 \leq 1$ then cell = 5

. Description, definition and diagram of measurements

| Description | Definition | Diagram |
|---|---|---|
| Bigonial Breadth | Straight-line distance measured with a spreading caliper between the right and left gonion landmarks on the corners of the jaw. |  |
| Bizygomatic Breadth | Maximum horizontal breadth of the face as measured with a spreading caliper between the zygomatic arches. |  |
| Head Breadth | Maximum horizontal breadth of the head as measured with a spreading caliper above the level of the ears |  |
| Interpupillary Distance | Distance as measured with a pupillometer at the center of the right and the center of the left pupil |  |
| Menton-Sellion Length | Distance as measured with a sliding caliper in the midsagittal plane between the menton landmark and the sellion landmark |  |

Appendix. Description, definition and diagram of measurements (continued)

| Dimension | Description | Diagram |
|---|---|---|
| Minimum Frontal Breadth | Straight-line distance as measured with a spreading caliper between the right and left frontotemporale landmarks |  |
| Nasal Root Breadth | Horizontal breadth of nose as measured with a sliding caliper at the sellion landmark and a depth equal to one-half the distance from the bridge of the nose to the eyes |  |
| Nose Breadth | Straight-line distance as measured with a sliding caliper between the right and left alare landmarks |  |
| Nose Protrusion | Straight-line distance as measured with a sliding caliper between the pronasale landmark and the subnasale landmark |  |
| Subnasale-Sellion Length | Straight-line distance as measured with a sliding caliper between the subnasale landmark and the sellion landmark |  |

Appendix c

## Activity Sheet

Before beginning the test you will be asked to read the respirator user's instructions, put on a respirator and wear it for approximately 5 minutes to become familiar with the sensation of wearing the respirator

During the test you will be standing and will be asked to perform the following sequence of exercises for about 30 seconds each.

Normal Breathing

Deep Breathing

Turn Head Side to Side while pausing for two normal inhalations at each side

Move Head Up and Down while pausing for two normal inhalations in the head up position and in the head down position

Read and recite the Rainbow Passage

Reach for the Floor and Ceiling while pausing for two normal inhalations in the arms-up position and in the arms-down position

Grimace

Normal Breathing

You will then remove the respirator, rest for several minutes and then perform the test sequence twice more for a series of three tests.

Appendix D

## Pre-test Questionnaire

### Total Inward Leakage (TIL) Test

Name:_____ Date: _____

Emergency Contact: _____ Phone: _____

1. Do you feel well today? ..... ☒Yes ☐No

2. Have you had a cold or flu within the last two weeks? ..... ☐Yes ☒No
   If yes, how long has it been since you recovered from the cold or flu? ..... _____ Days

3. Have you eaten today? ..... ☒Yes ☐No

4. Have you had at least 8 ounces of fluid in the last four hours? ..... ☒Yes ☐No

5. Have you started or stopped taking any medications (or changed Doses) since your last physical exam with your physician? ..... ☐Yes ☒No

6. Take a few minutes to review the activity sheet for the test that you will be performing today. Is there any reason why performing the tasks described may be unsafe? ..... ☐Yes ☒No

7. Have you had an illness or injury that requires you to see a doctor or go to the hospital for treatment since your last physical exam with our physician? ..... ☐Yes ☒No

8. Have you experienced any of the following conditions since your last physical exam with our physician? ..... ☐Yes ☒No

- Shortness of breath
- Wheezing
- Pregnancy (or possibility of)
- Pain or tightness in your chest
- Irregular heartbeat
- High or low blood pressure
- Fainting or dizzy spells
- Any other lung or heart problems
- Unusual, severe headaches
- Extremity numbness or tingling
- Pain or discomfort in your legs when walking
- A seizure

Your Signature: _____ Date: _____

Technician's Name: _____

[√]Yes **Do not test** [√]Yes **Consult with physician before proceeding**