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National Personal Protective Technology Laboratory  
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Procedure No. RCT-APR-STP-0005-05a-06

Revision: 3.0

Date: 20 December 2018

DETERMINATION OF QUALITATIVE ISOAMYL ACETATE (IAA)  
FACEPIECE FIT, AIR-PURIFYING RESPIRATORS  
STANDARD TESTING PROCEDURE (STP)

1. PURPOSE

This test establishes the procedure for ensuring that the level of protection provided by the Isoamyl Acetate facepiece fit test requirements on air-purifying respirators submitted for Approval or Extension of Approval meet the minimum certification standards set forth in 42 CFR Part 84, Subpart G, Section 84.63(a)(c), Subpart I, Section 84.124, and Subpart L, Section 84.205, Subpart KK, Section 84.1135 Volume 60, Number 110, June 8, 1995.

2. GENERAL

This STP describes the Determination of Qualitative Isoamyl Acetate (IAA) Facepiece Fit Test Air-Purifying Respirators test 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 product passes the test.

3. EQUIPMENT/MATERIAL

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

- 3.1.1. Large viewable chamber with interlocking double doors and exhaust system, approximately 9.7' x 12.2' x 8' in size.
- 3.1.2. Tire pump
- 3.1.3. Isoamyl acetate, 99%.
- 3.1.4. Tiered wick.
- 3.1.5. Graduated cylinder, 100 ml.
- 3.1.6. Sliding measurement calipers, Seritex model GPM 104, 0-200 mm length, as shown in Attachment 8.2.
- 3.1.7. Spreading measurement calipers, Seritex model GPM 106, 0-300 mm width, as shown in Attachment 8.3.
- 3.1.8. Facepiece, mouthpiece, hood, or helmet equipped with a cartridge or canister with organic vapor protection.

#### 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 International System of Units (SI) when available.
- 4.2. General facepiece fit test requirements for gas mask, chemical cartridge, mouthpiece, and powered air-purifying respirators.
  - 4.2.1. The fit test shall be performed using a panel of test subjects of various facial sizes measured according to the NIOSH Bivariate Panel (NIOSH Panel) requirements. The measured face length and face width are used to designate the subject's NIOSH Panel cell number, as illustrated in Attachment 8.5.
    - 4.2.1.1. Face Width is the Bizygomatic Breadth measurement (Attachment 8.4), using the spreading measurement calipers.
    - 4.2.1.2. Face Length is the Menton-Sellion measurement (Attachment 8.4), using the sliding measurement calipers.
  - 4.2.2. Prior to fit testing, test subjects shall be subjected to the odor threshold screening as follows:
    - 4.2.2.1. Prepare a stock solution by adding 1 ml isoamyl acetate to 800 ml of distilled water and shake for 30 seconds. This solution is stable for two days.
    - 4.2.2.2. To a 1 liter volumetric add 0.4 ml stock solution to 500 ml distilled water. To an identical volumetric add 500 ml distilled water. Mark both samples with an identifying marker known only to the test operator. The solutions must be made fresh daily.
    - 4.2.2.3. The following instructions shall be typed on a card and placed on the table in front of the two test jars (i.e. 1 and 2): "The purpose of this test is to determine if you can smell banana oil at a low concentration. The two bottles in front of you contain water. One of these bottles also contains a small amount of banana oil. Be sure the covers are on tight, and then shake each bottle for two seconds. Unscrew the lid of each bottle, one at a time, and sniff at the mouth of the bottle. Indicate to the test operator which bottle contains banana oil."
    - 4.2.2.4. If the test subject correctly identifies the jar containing the odor test solution, the subject shall continue with the fit testing.
    - 4.2.2.5. The screening shall be conducted in an isoamyl acetate free environment.

- 4.2.3. Any gas mask, chemical cartridge, powered air purifying, or mouthbit respirator part which must be removed to perform the facepiece or mouthpiece fit test shall be replaceable without special tools and without disturbing the facepiece or mouthpiece fit.
  - 4.2.4. Each wearer shall enter the chamber containing 100 ppm isoamyl acetate for half-mask respirators and 500 ppm for full facepieces, mouthpieces, hoods, and helmets.
  - 4.2.5. The respirator or mouthpiece may be adjusted, according to the manufacturer's user instructions, prior to entering the chamber, if necessary; however, upon entry into the test chamber the facepiece or mouthpiece shall not be adjusted.
  - 4.2.6. If a respirator comes in multiple sizes, a test subject may only achieve a pass in one size, except when testing an extra-small or extra-large facepiece, in accordance with 4.3.2.
  - 4.2.7. If a test subject is unable to achieve a user seal check after three donning attempts, it is considered a failed trial; however, if the facepiece model comes in multiple sizes they may attempt to don an alternate size.
  - 4.2.8. If a test subject is able to achieve the required user seal checks; but, prior to starting the test, the subject detects the IAA, the subject shall be removed to an IAA-free atmosphere and permitted to don the respirator again. After two attempts the trial is considered a failure. However, if the facepiece model comes in multiple sizes they may attempt to don an alternate size.
- 4.3. Test subject selection
- 4.3.1. For respirators designed and manufactured in one, two or three unique facepiece sizes, the fit test will be conducted with 18 individual test subjects using 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 at least one subject from each cell, but no more than four subjects may be tested per cell).

Table 1: Suggested test subject distribution to be used for Isoamyl Acetate 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. Respirators designed and constructed in one unique size, a subject failing to achieve a pass is considered a failure.

4.3.1.2. Respirators designed and constructed in two unique sizes.

4.3.1.2.1. Subjects in panel cells 1-4 and cell 6 shall be tested first wearing the smaller sized respirator. If the subject does not pass in the smaller sized respirator, the subject can be tested again wearing the larger sized respirator.

4.3.1.2.2. Subjects in panel cells 7-10 and cell 5 shall be tested first wearing the larger sized respirator. If the subject does not pass in the larger sized respirator, the subject can be tested again wearing the smaller sized respirator.

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

4.3.1.3. Respirators designed and constructed in three unique sizes.

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

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

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

4.3.1.3.4. If a subject does not pass in the first respirator size, the subject will be retested in the next available size. A subject failing in the smaller sized respirator, can try the medium, and then larger sized respirator. A subject failing in the medium

sized respirator can try the smaller and larger sized respirators. A subject failing in the larger sized respirator can try the medium, then the smaller sized respirator. A subject failing to achieve a pass in any of the sizes available for testing is considered a failure. The test administrator may determine whether or not the third trial is worthy of completion. If the subject failed to achieve a pass in the small and medium sized respirator, trying the large may not be necessary since the large may be too big for the subject. If the subject failed to achieve a pass in the large and medium sized respirator, trying the small may not be necessary since the small may be too small for the subject.

- 4.3.2. For respirators designed and manufactured in four or five unique face piece sizes, the panel fit test will be conducted on 21 and 24 member panels, respectively, using the NIOSH Panel (Appendix 8.5). No more than four subjects may be tested per cell. Four individual test failures will be allowed; the number of test failures is not increased with the increased number of test subjects.
  - 4.3.2.2. Subjects in panel cells 1 and 2 shall be tested wearing the small size first.
  - 4.3.2.3. Subjects in panel cells 3-7 shall be tested wearing the regular/medium size first.
  - 4.3.2.4. Subjects in panel cells 8, 9, and 10 shall be tested wearing the large size first.
  - 4.3.2.5. For each additional size facepiece, such as an extra-small (XS) or extra-large (XL), there will be an additional 3 subjects tested.
    - 4.3.2.5.1. Testing an additional size designated as extra-small shall include testing an additional three subjects from panel cells 1-3 and must include one positive test utilizing a subject from panel cell 1. If three subjects from cell 1 are unable to pass the XS, the project will be denied.
    - 4.3.2.5.2. Testing an additional size designated as extra-large shall include testing an additional three subjects from panel cells 5-10 and must include one positive test utilizing a subject from panel cell 10. If three subjects from cell 10 are unable to pass the XL, the project will be denied.
  - 4.3.2.6. If a subject does not pass in the first respirator size, the subject will be retested in the next available size, reference 4.3.1.3.4 if more detail is required.

## 5. PROCEDURE

- 5.1. Follow individual instruction manuals if any, for set up, calibration, and maintenance of equipment used in this procedure prior to beginning any testing. Malfunctioning equipment must be repaired or replaced and properly set up and calibrated before starting all tests.
- 5.2. Determine the amount of isoamyl acetate required to produce the concentration desired according to the size and volume of the test chamber using the following formula.


$$C = \frac{V \otimes \frac{22.4}{MW} \frac{T}{273} \frac{760}{P} \times 10^6}{V_t}$$

Where: V = volume in ml of isoamyl acetate required in ml  
 C = concentration in ppm of isoamyl acetate desired in chamber  
 MW = molecular weight of isoamyl acetate  
 T = chamber temperature in degrees Kelvin  
 P = chamber pressure (760 mm Hg)  
 ⊗ = density of isoamyl acetate in g/ml  
 V<sub>t</sub> = volume of chamber in liters

- 5.2.1. For the NIOSH test chamber: using the graduated cylinder, distribute onto the tiered wick 16 ml isoamyl acetate for halfmask respirators or 80 ml isoamyl acetate for full facepiece, hoods, helmets and mouthbit respirators.
- 5.3. Allow 20 minutes for equalization of the concentration in the chamber.
- 5.4. In an isoamyl acetate free environment, allow the test subject to read the manufacturers donning instructions and perform positive or negative user seal check procedures.
- 5.5. The test subject will don the respirator and perform a user seal check per the manufacturer's user instructions. If the test subject cannot obtain a successful user seal check, he/she will not be sent into the chamber. Upon obtaining a successful user seal check, the subject will enter the chamber.
- 5.6. For all IAA fit tests, the test subject shall enter the test chamber and remain in the test chamber for 8 minutes while performing the following activities:
  - 5.6.1. Two (2) minutes nodding up and down, and turning head side to side.
  - 5.6.2. Two (2) minutes callisthenic arm movements.
  - 5.6.3. Two (2) minutes running in place.
  - 5.6.4. Two (2) minutes pumping with tire pump.

- 5.7. The test subject must not detect the odor of IAA when they enter the chamber and perform the required exercises. If on initial entry into the IAA chamber, the subject immediately (before the required exercises begin) detects the odor of IAA, the subject will immediately exit the chamber, adjust the respirator, perform a second user seal check, and if successful, re-enter the chamber.
  - 5.8. Upon completion of the above activities the test subject will exit the chamber and verbally notify the test operator as to the performance of the respirator with any remarks pertinent to the fit or performance of the respirator.
  - 5.9. If the subject detects the banana type odor of isoamyl acetate during any exercise they will indicate a thumbs down motion and will be removed from the chamber. Once removed, a user seal check will be performed and the facepiece harness or tension mechanism will be checked for their tightness.
6. PASS/FAIL CRITERIA
- 6.1. The criteria for passing this test is set forth in 42 CFR Part 84, Subpart G, Section 84.63(a)(c), Subpart I, Section 84.124, Subpart L, Section 84.205, and Subpart KK, Section 84.1135 and Section 84.1142.
  - 6.2. The number of test 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.
7. RECORDS/TEST SHEETS
- 7.1. All test data collected will be recorded on the appropriate Determination of Qualitative Isoamyl Acetate (IAA) Facepiece Fit IAA Test data sheet.
8. ATTACHMENTS
- 8.1. Facepiece Fit IAA Test Data Sheet.
  - 8.2. Sliding Calipers
  - 8.3. Spreading Calipers
  - 8.4. Anthropometric Measurements
  - 8.5. NIOSH Panel

**Attachment 8.1: Facepiece Fit IAA Test Data Sheet**

<b>National Institute for Occupational Safety and Health</b> <b>Respirator Branch</b> <b>Test Data Sheet</b>																																									
<b>Task Number:</b> TN-NNNNN	<b>Reference No.:</b> CFR Reference number																																								
<b>Test:</b> Facepiece Fit IAA Test	<b>STP No.:</b> 5, 5.1 or 6																																								
<b>Manufacturer:</b>																																									
<b>Item Tested:</b> Facepiece with OV Cartridge																																									
<b>Concentration = XXX ppm isoamyl acetate vapor</b>																																									
<table border="1"> <thead> <tr> <th>Subject</th> <th>Face size</th> <th>Result</th> </tr> </thead> <tbody> <tr><td>A</td><td>1</td><td>PASS</td></tr> <tr><td>B</td><td>2</td><td>PASS</td></tr> <tr><td>C</td><td>4</td><td>PASS</td></tr> <tr><td>D</td><td>3</td><td>PASS</td></tr> <tr><td>E</td><td>10</td><td>PASS</td></tr> <tr><td>F</td><td>8</td><td>PASS</td></tr> <tr><td>G</td><td>7</td><td>PASS</td></tr> <tr><td>H</td><td>9</td><td>PASS</td></tr> <tr><td>I</td><td>5</td><td>PASS</td></tr> <tr><td>J</td><td>6</td><td>PASS</td></tr> <tr><td>K</td><td>4</td><td>PASS</td></tr> <tr><td>L</td><td>7</td><td>PASS</td></tr> </tbody> </table>			Subject	Face size	Result	A	1	PASS	B	2	PASS	C	4	PASS	D	3	PASS	E	10	PASS	F	8	PASS	G	7	PASS	H	9	PASS	I	5	PASS	J	6	PASS	K	4	PASS	L	7	PASS
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<b>Engineering Technician</b>																																									



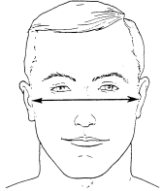

**Attachment 8.2: Sliding Calipers**



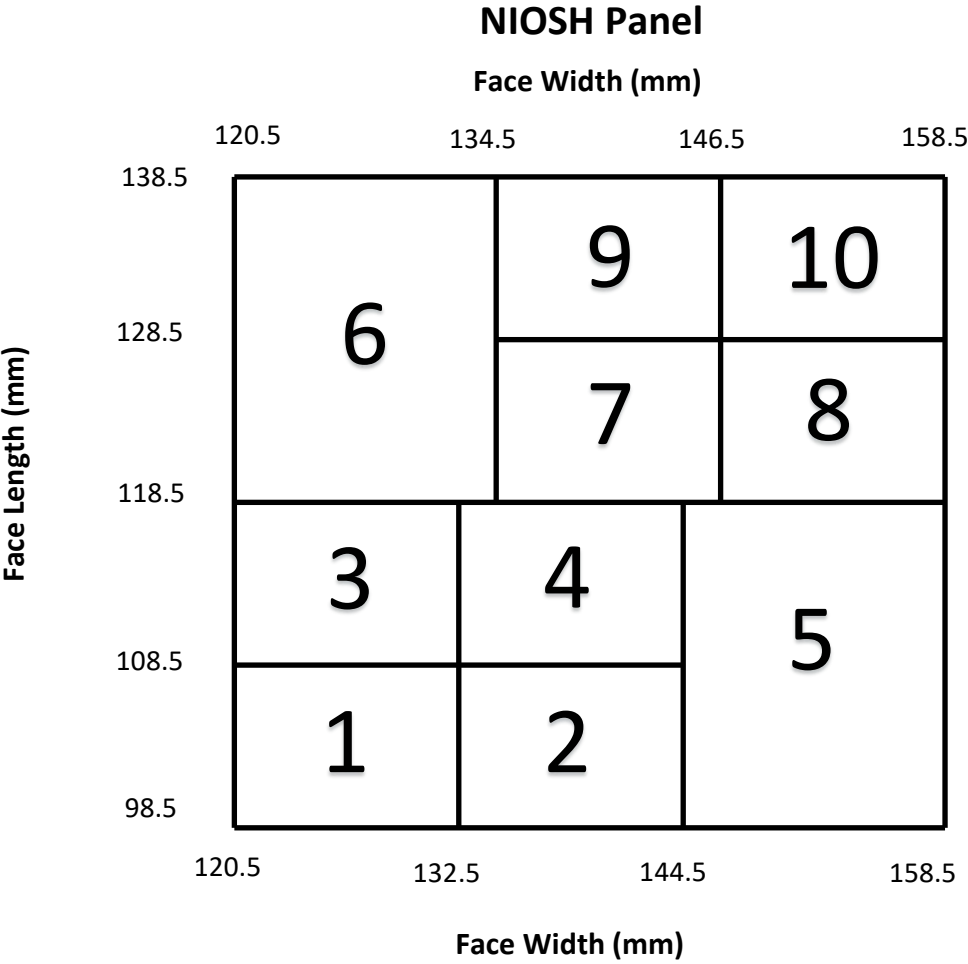
**Attachment 8.3: Spreading Calipers**



**Attachment 8.4: Anthropometric Measurements**

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

**Attachment 8.5: NIOSH Bivariate Panel (NIOSH PANEL)**



### Revision History

Revision	Date	Reason for Revision
	February 1996	NIOSH has reduced the IDLH for isoamyl acetate in the Pocket Guide to Chemical Hazards from 3000 ppm to 1000 ppm. This resulted in the NIOSH STP being run at the IDLH concentration contrary to good work practices, and OSHA standards which stipulate the “concentrations during the test shall not exceed an OSHA permissible exposure limit, the ACGIH threshold limit values, or any known recommended exposure limit, when there is no OSHA PEL or ACGIH TLV, and not create a health or physical hazard for the test subject or operator.” In the face of these facts, the test concentration was reduced to the OSHA PEL and NIOSH REL of 500 ppm with commitment to revisit the appropriateness of the test, and of isoamyl acetate as the test agent of choice in future regulation change modules.
1.0	16 January 2002	Historic document
1.1	3 June 2005	Update header and format to reflect lab move from Morgantown, WV No changes to method
2.0	20 March 2008	Correct errors in sections 4.3.3.2 and 5.2 and update to reflect new file naming procedures and changes announced in Letter to All Manufacturers dated 18 May 2005.
3.0	20 December 2018	Changes throughout the document to incorporate a new anthropometric panel referred to as the NIOSH Panel.