National Institute for Occupational Safety and Health National Personal Protective Technology Laboratory P.O. Box 18070 Pittsburgh, PA 15236		
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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, Extension of Approval, or examined during Certified Product Audits, meet the minimum certification standards set forth in 42 CFR Part 84, Subpart G, Section 84.63(a)(c)(d), Subpart I, Section 84.124, Subpart L, Section 84.205, and Subpart KK, Section 84.1141 and Section 84.1142; 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 with 28 liter container.

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, 0-50 mm depth.

3.1.7. Spreading measurement calipers, Seritex model GPM 106, 0-300 mm width.

Approvals:			
First Level	Second Level	Third Level	Fourth Level

3.1.8. Facepiece, mouthpiece, hood, or helmet equipped with organic vapor cartridge.

3.1.9. Ten test subjects meeting requirements of the NIOSH Human Subject Review Board (HSRB) approved Protocol. Refer to HSRB-81-DSR-03, "Protocol for the Testing of Respiratory Protective Devices" for the proper consent form and complete details on the use of human test subjects in respirator certification testing.

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 manufacturer's calibration procedure and schedule. 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).

4.2. Normal laboratory safety practices must be observed. This includes safety precautions described in the current ALOSH Facility Laboratory Safety Manual.

4.2.1. Safety glasses, lab coats, and hard-toe shoes must be worn at all times.

4.2.2. Work benches must be maintained free of clutter and non-essential test equipment.

4.2.3. When handling any glass laboratory equipment, lab technicians and personnel must wear special gloves which protect against lacerations or punctures.

4.3. General facepiece fit test requirements for gas mask, chemical cartridge, mouthpiece, and powered, air-purifying respirators.

4.3.1. The fit test shall be performed using a panel of test subjects of various facial sizes, determined through measurement according to the March 1974, "Selection of Respirator Test Panels Representative of U.S. Adult Facial Sizes" published by the Los Alamos Scientific Laboratory.

4.3.2. The test subjects shall be subjected to initial and annual physicals along with supplemental facial measurements. The facial measurements shall be used to determine facial size.

4.3.3. Prior to the fit testing, test subjects that have passed the physical requirement examination shall also be subjected to the odor threshold screening evaluation as follows.

4.3.3.1. 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 one week.

4.3.3.2. 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.

4.3.3.3. The solutions are to be prepared in an area separate from the screening and testing area.

4.3.3.4. 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."

4.3.3.5. If the test subject correctly identifies the jar containing the odor test solution, the subject shall continue with the fit testing.

4.3.4. 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.

4.3.5. Each wearer shall enter the chamber containing 100 ppm isoamyl acetate for halfmask respirators and 500 ppm for full facepiece, mouthpieces, hoods, and helmets.

4.3.6. The facepiece or mouthpiece may be adjusted, if necessary, in the test chamber before starting the test.

4.4. For respirators submitted by the applicant where a single facepiece is not intended to fit everyone (i.e. not intended to fit a full panel consisting of sizes 1 through 10), the following face sizes shall be selected:

4.4.1. Small facepiece- panel face sizes 1, 2, 3, 4; panel size 6 (1 or 2 for each size to total 6)

4.4.2. Medium facepiece- panel face sizes 3, 4, 5, 6, 7, 8; panel size 6 (1 for each size to total 6)

4.4.3. Large facepiece- panel face sizes 7, 8, 9, 10; panel size 6 (1 or 2 for each size to total 6)

4.4.4. Small/Medium facepiece- panel face sizes 1, 2, 3, 4, 5, 6; panel size 6 (1 for each size to total 6)

4.4.5. Medium/Large facepiece- panel face sizes- 5, 6, 7, 8, 9, 10; panel size 6 (1 for

each size to total 6)

4.5. For respirators submitted by the applicant where a single facepiece (one size fits all) is intended to fit everyone, the following face sizes shall be selected: Panel face sizes 1 through 10 (1 for each size to total 10).

4.6. For hoods and helmets- the same face size criteria used for facepieces will apply to hoods and helmets, the reason being that head size is generally proportional with face size.

4.7. For mouthpiece type respirators- panel size of six test subjects from sizes 1, 2, 5, 6, 9, 10. The reason being there is less difference in the sizes of mouth (not relatively, but in absolute terms).

4.8. **Please refer to Material Safety Data Sheets for the proper protection and care in handling, storing, and disposing of the chemicals used in this procedure.**

5. PROCEDURE

Note: Reference Section 3 for equipment, model numbers and manufacturers. For calibration purposes use those described in the manufacturer's operation and maintenance manuals.

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.

$$C = \frac{V \Delta \; \frac{22.4}{MW} \; \frac{T}{273} \; \frac{760}{P} \; x10^{6}}{V_t}$$

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)
Δ= density of isoamyl acetate in g/ml
V_t= volume of chamber in liters

5.2.1. For the NIOSH test chamber: using the graduated cylinder, distribute onto the tiered wick 17.4 ml isoamyl acetate for halfmask respirators or 87 ml isoamyl acetate for full facepiece, hoods, helmets and mouthbit respirators.

5.3. Allow 30-60 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/or 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's 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. Up to three different test subjects of a specified size will have the opportunity to obtain a successful user seal check before the project is denied. The test subjects of the specified size will be observed to try to insure that there is no unique characteristic of all three that would create an unfair disadvantage for the respirator. For example, three test subjects would not be chosen who all have a very shallow nose bridge.

5.6. For all fit tests except high efficiency powered air purifying respirators (HE PAPR), 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 and turning head.

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 into a 28 liter container.

5.7. For high efficiency powered air purifying respirators (HE PAPR), the applicant must provide a charcoal-filled canister or cartridge of a size and resistance similar to the high efficiency filter (CFR 84.1142). The test subject shall enter the test chamber and remain in the test chamber for 5 minutes while performing the following activities:

5.7.1. Two (2) minutes walking, nodding and turning head.

5.7.2. Three (3) minutes exercising and running in place.

5.8. 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. If the subject again detects the odor of IAA, the respirator will be denied on the basis that the user seal check process is inadequate to determine fit or the respirator is unable to maintain a fit.

5.9. 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 a “yes” or “no” if they detect the banana type odor of isoamyl acetate, and any other remarks pertinent to the fit or performance of the respirator.

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)(d), Subpart I, Section 84.124, Subpart L, Section 84.205, and Subpart KK, Section 84.1141 and Section 84.1142.

6.2. Whenever less than a full panel (one of each size 1 thru 10) is used to evaluate a single size of any multiple size facepiece, no failures will be allowed. These respirators are designed to fit a specific facial size range (such as small) and are expected to fit all subjects of that size range. For overlapping panel face sizes (size 3, 4, 7 and 8) a subject need only pass wearing a respirator in one or the other size. Test subjects in the overlapping groups need not pass the test in both sizes; however, all panel face sizes for a specified respirator size must be accounted for during the test as follows:

6.2.1. The test subject will don the respirator and perform a user seal check per the manufacturer's User's 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. Up to three different test subjects of a specified size will have the opportunity to obtain a successful user seal check before the project is denied. The test subjects of the specified size will be observed to try to insure that there is no unique characteristic of all three that would create an unfair disadvantage for the respirator. For example, three test subjects would not be chosen who all have a very shallow nose bridge.

6.2.2. 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. If the subject again detects the odor of IAA, the respirator will be denied on the basis that the user seal check process is inadequate to determine fit or the respirator is unable to maintain a fit.

6.3. A full panel of sizes 1 through 10 is used to evaluate a one-size-fits-all respirator. All panel face sizes must be accounted for during the test as stated in 6.2.1 and 6.2.2 above. One failure where the test subject detects the odor of IAA during the exercises will be permitted; however, an additional test using a different test subject of the same size must be performed with passing results. If two or more failures occur, the project will be denied.

7. RECORDS/TEST SHEETS

7.1. All test data collected will be recorded on the DETERMINATION OF QUALITATIVE ISOAMYL ACETATE (IAA) FACEPIECE FIT test data sheet.

7.2. All videotapes and photographs of the actual test being performed, or of the tested equipment shall be maintained in the task file as part of the permanent record.

7.3. All equipment failing any portion of this test will be handled as follows:

7.3.1. If the failure occurs on a new certification application, or extension of approval application, send a test report to the RCT Leader and prepare the hardware for return to the manufacturer.

7.3.2. If the failure occurs on hardware examined under an Off-the-Shelf Audit the hardware will be examined by a technician and the RCT Leader for cause. All equipment failing any portion of this test may be sent to the manufacturer for examination and then returned to NIOSH. However, the hardware tested shall be held at the testing laboratory until authorized for release by the RCT Leader, or his designee, following the standard operating procedures outlined in Procedure for Scheduling, and Processing Post-Certification Product Audits, RB-SOP-0005-00.

8. ATTACHMENTS

8.1. Data Sheet.

8.2. Los Alamos Full Facepiece Test Panel Size.

8.3. Los Alamos Halfmask Test Panel Size.

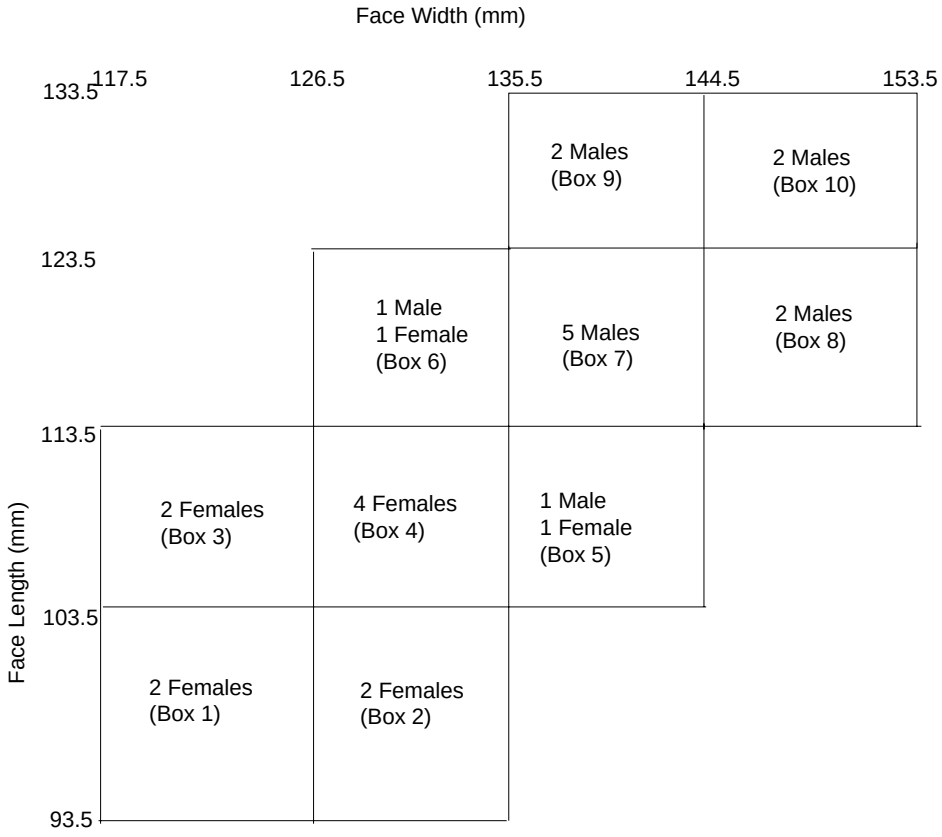
RESPIRATOR BRANCH

QUALITATIVE ISO/AMYL ACETATE FIT TEST DATA SHEET
(Ref. STP 005,005a,006)

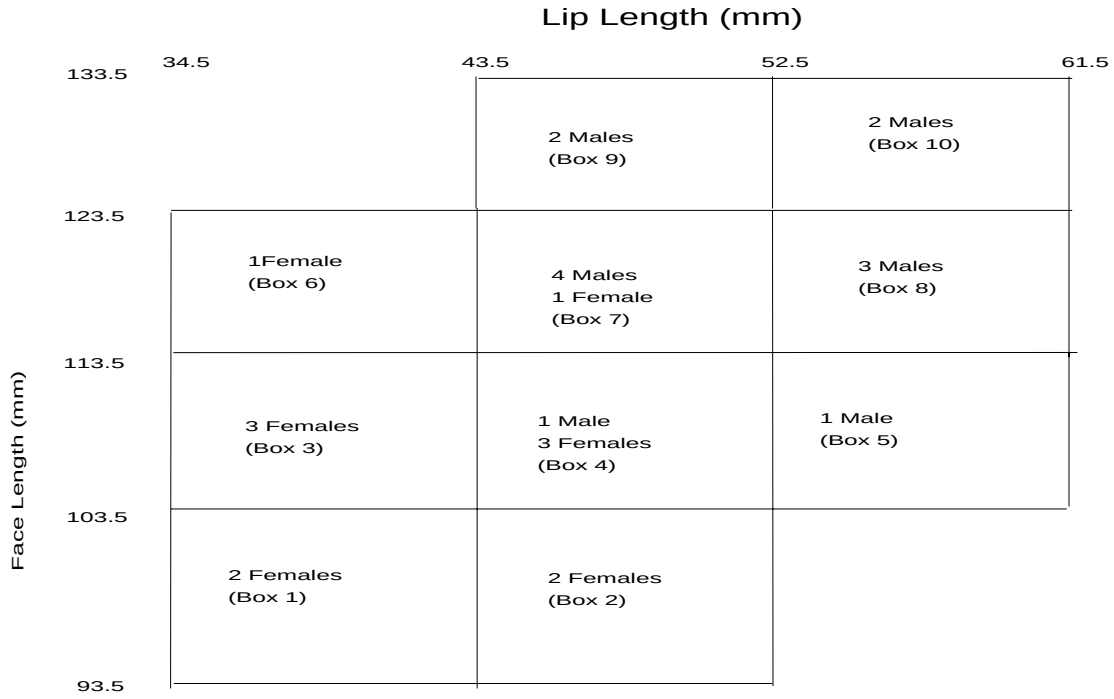
Task Number: TN-_____ Concentration:
Manufacturer: _____ Item Tested:

SUBJECT ID #	FACESIZE	REMARKS	RESULTS

Test Operator: _____ Date:
Overall Results:



Los Alamos
Scientific Laboratory Male-and-Female
25 Member Panel for Testing of Full-Face Masks



Los Alamos
Scientific Laboratory Male-and-Female
25 Member Panel for Testing of Half-Masks.

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.