DETERMINATION OF RESPIRATOR FIT, QUANTITATIVELY USING CORN OIL AEROSOL, FOR POWERED AIR-PURIFYING RESPIRATORS WITH LOOSE- OR TIGHT-FITTING RESPIRATORY INLET COVERINGS, STANDARD TESTING PROCEDURE

1. PURPOSE

This document establishes the procedure by which a generated corn oil aerosol is used for determining if powered air-purifying respirators (PAPRs) incorporating loose- or tight-fitting respiratory inlet coverings submitted for Approval, Extension of Approval, or examined during Certified Product Audits meet the minimum certification standard set forth in 42 CFR Part 84, Subpart K, Section 84.176.

2. GENERAL

This standard testing procedure (STP) describes the named procedure in sufficient detail that a person knowledgeable in the appropriate technical field can select equipment with the necessary resolution, conduct the test, determine whether or not the product passes the test, and create a record of those results, reporting the measurements obtained in a preestablished, standard format.

3. EQUIPMENT/MATERIALS

3.1. Rear Light Scattering Laser Photometer: TSI Inc., model 8587A, or equivalent. Concentration range is 1.0 micrograms per cubic meter ($\mu g/m^3$) to >200 milligrams per cubic meter (mg/m^3).

3.2. NIOSH Dynamic Fit Software: Custom software developed in the LabVIEW environment, or equivalent. Software is available from NIOSH or Data Science Automation.

3.3. Aerosol Generator: MSP, model 2045 High Output Aerosol Generator, or equivalent. 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 micrometers (µm).

3.4. Aerosol Monitor: TSI Inc., DustTrak II Aerosol Monitor model 8530, or equivalent. Detection range of 0.001 to 400 mg/m^3 with resolution of ± 0.1 percent (%) of reading or ± 0.001 mg/m^3, whichever is greater.

3.5. Corn Oil, 99% pure. CAS Number 8001-30-7. Commercial product names are Maise/Maize Oil, Maydol, and Mazola Oil, or equivalent.

3.6. Scanning Mobility Particle Sizer (SMPS): TSI Inc., with models 3082 Electrostatic Classifier (EC), 3081A Long Differential Mobility Analyzer (DMA), 3752 High-Concentration Condensation Particle Counter (CPC), and 3088 Advanced Aerosol Neutralizer, or equivalent.

3.7. Aerosol Test Chamber: The chamber shall be designed and constructed so that the test participants have ample space for unobstructed movement during the test and are visible

at all times while in the chamber. The chamber shall have an air handling unit to provide a consistent and uniform aerosol concentration and fresh air, and may include mixing fans. The chamber design should 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. All tubing shall be conductive and tubing lengths and bends should be minimized.

3.8. Chamber Communications: Generic brand and model. Electronic audio communications (i.e., loudspeaker) for real-time voice communication from test administrator to test participants.

3.9. Tire Pump: Generic brand and model. Hand operated floor style tire pump that is approximately 20 inches (in.) tall with an approximately 15 in. stroke.

3.10. Face Size Sliding Measurement Caliper: Seritex, model GPM 104, or equivalent. With range of 0-200 millimeters (mm).

3.11. Face Size Spreading Measurement Caliper: Seritex, model GPM 106, or equivalent. With range of 0-300 mm.

3.12. Facepiece Direct Probe: Custom probe developed by NIOSH, or equivalent. The basis of design was first described by Liu [AIHAJ (45); 278-283, 1984]. The design shall not interfere with the fit or function of the PAPR. The probe is a bulkhead fitting and provides a tight seal using two rubber washers, one metal washer, and one nut. See Attachment A.

4. TESTING REQUIREMENTS AND CONDITIONS

4.1. Prior to beginning any testing, all measuring equipment to be used shall have been calibrated in accordance with the testing laboratory's calibration procedure and schedule. All measuring equipment utilized for this testing should have been calibrated using a method traceable to the National Institute of Standards and Technology (NIST), when available.

4.2. General fit test requirements for PAPRs

4.2.1. The fit test shall be performed using a group of test participants of various face sizes. Face size is determined from the NIOSH Bivariate Panel (NIOSH Panel) as illustrated in Attachment B. The measured face width and face length of each test participant are used to designate the test participant's NIOSH Panel cell number.

4.2.1.1. Face Width is the Bizygomatic Breadth measurement (Attachment C), using the spreading measurement calipers.

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

4.2.2. The PAPR shall be adjusted according to the applicant's User Instructions (UI) prior to entering the chamber. Upon entry into the test chamber, the inlet covering shall not be re-adjusted.

4.2.3. If a PAPR is supplied with multiple inlet covering sizes, to achieve a test participant pass, each test participant is required to achieve a success in any one size, except when testing an extra-small or extra-large inlet covering, in accordance with 4.3.3.1.4.

4.2.4. For tight-fitting PAPR:

4.2.4.1. Any PAPR part which must be removed to perform the user seal check shall be replaceable without special tools and without disturbing the inlet covering on the test participant's face.

4.2.4.2. If the test participant is unable to achieve a user seal check after three donning attempts, it will be deemed a trial failure. If the applicant has provided the PAPR in multiple sizes, the test participant may attempt to don an alternate size inlet covering.

4.3. Test participant selection and testing panel composition requirements

4.3.1. NIOSH is allowing flexibility in the selection of test participants. NIOSH will attempt to select a panel that contains at least one face size representative from each panel cell. No more than four test participants may be from any single panel cell. See Table 1 for the suggested face size distribution in relation to the NIOSH Panel (Attachment B).

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

NIOSH Panel – Cell Number	Number of Face Size Representatives
1	1
2	1
3	2
4	4
5	1
6	1
7	4
8	2
9	1
10	1

4.3.2. For PAPRs designed and manufactured with one, two, or three inlet covering sizes, the fit test will be conducted with 18 test participants which are selected to represent the NIOSH Panel (Attachment B).

4.3.2.1. For PAPRs designed and manufactured in one unique inlet covering size, a test participant failing to achieve a trial pass is deemed a test participant failure.

4.3.2.2. For PAPRs designed and manufactured in two unique inlet covering sizes:

4.3.2.2.1. Test participants from panel cells 1-4 and cell 6 shall be tested wearing the smaller size inlet covering initially.

4.3.2.2.2. Test participants from panel cells 7-10 and cell 5 shall be tested wearing the larger size inlet covering initially.

4.3.2.2.3. If a test participant does not achieve a trial pass in the first inlet covering size evaluated, the test participant may be asked to conduct additional trials in the alternate size.

4.3.2.2.4. The outcome of a test participant failing to achieve at least one trial pass with either of the available inlet covering size options is deemed a test participant failure.

4.3.2.3. For PAPRs designed and manufactured in three unique inlet covering sizes:

4.3.2.3.1. Test participants from panel cells 1 and 2 shall be tested wearing the smaller size initially.

4.3.2.3.2. Test participants from panel cells 3-7 shall be tested wearing the regular/medium size initially.

4.3.2.3.3. Test participants from panel cells 8-10 shall be tested wearing the larger size initially.

4.3.2.3.4. If a test participant does not achieve a trial pass in the first inlet covering size evaluated, the test participant may be asked to conduct additional trials in the next available size(s). For example:

A test participant failing to achieve a trial pass in the smaller sized inlet covering may then proceed to trials with the medium size and, if necessary, the larger size inlet covering.

A test participant failing to achieve a trial pass in the medium sized inlet covering may then proceed to trials with the smaller size and, if necessary, the larger size inlet coverings.

A test participant failing to achieve a trial pass in the larger size inlet covering may then proceed to trials with the medium size and, if necessary, the smaller sized inlet covering.

The test administrator may have discretion with additional size trials. Additional size trials may not be necessary if the available inlet covering size is obviously inappropriate for the test participant.

4.3.2.3.5. The outcome of a test participant failing to achieve at least one trial pass with any of the available inlet covering size options is deemed a test participant failure.

4.3.3. For PAPRs designed and manufactured with four or five unique inlet covering sizes, the fit-test will be conducted with 21- or 24- test participants, respectively, representing the NIOSH Panel (Attachment B).

4.3.3.1. For PAPRs designed and manufactured in four or five unique inlet covering sizes:

4.3.3.1.1. Test participants from panel cells 1 and 2 shall be tested wearing the small size initially.

4.3.3.1.2. Test participants from panel cells 3-7 shall be tested wearing the regular/medium size initially.

4.3.3.1.3. Test participants from panel cells 8-10 shall be tested wearing the large size initially.

4.3.3.1.4. For each additional size inlet covering, such as an extra-small (XS) or extra-large (XL), three (3) additional test participants shall be required.

4.3.3.1.4.1. Testing an additional size designated as extra-small shall include testing an additional three test participants from panel cells 1-3. At least one test participant must be from panel cell 1.

4.3.3.1.4.2. Testing an additional size designated as extra-large shall include testing an additional three test participants from panel cells 5-10. At least one test participant must be from panel cell 10.

4.3.3.1.5. If a test participant does not achieve a trial pass in the first inlet covering size evaluated, the test participant may be asked to conduct additional trials in the next available size(s). See section 4.3.2.3.4 for further guidance.

4.3.3.1.6. The outcome of a test participant failing to achieve at least one trial pass with any of the available inlet covering size options is deemed a test participant failure.

5. PROCEDURE

NOTE: Reference Section 3 for equipment, model numbers, and manufacturers. Equipment should be operated and calibrated in accordance with the manufacturer's operation and maintenance manual(s), or the laboratory's quality management system.

5.1. Aerosol Test Chamber Set-up

5.1.1. Power on photometers, SMPS, and aerosol monitor and allow to warm up following the manufacturer's instructions.

5.1.2. Power on chamber air handling unit (exhaust), aerosol generators, and chamber mixing fans.

5.1.2.1. Adjust mixing fans to create an even distribution of aerosol particles throughout the chamber, while avoiding high airflows and turbulent air.

5.1.2.2. Adjust chamber air handling unit speed and aerosol generator pressure to balance the chamber flow and establish a corn oil challenge concentration. Corn oil challenge concentration is measured by the aerosol monitor.

5.1.2.2.1. Establish a corn oil challenge concentration of 30 to 40 mg/m^3.

5.1.3. Allow a minimum of 30 minutes for the aerosol test chamber corn oil challenge concentration to stabilize.

5.1.4. Use the SMPS to measure the aerosol particle size.

5.1.4.1. The size required is 0.4 to 0.6 μm with a geometric standard deviation of less than 2.0 MMAD.

5.1.5. Use the aerosol monitor to periodically measure the aerosol test chamber corn oil challenge concentration prior to and during each trial. Adjust concentration if necessary.

5.2. Donning of the PAPR

5.2.1. The inlet covering shall be minimally modified for the installation of the facepiece direct probe. The installation shall not interfere with the fit or function of the PAPR. The probe should be positioned in the oral/nasal region of the PAPR. Each probe is sealed against in the inlet covering using two rubber washers, one metal washer, and one nut.

5.2.2. The UI provided by the applicant shall be reviewed by the test administrator and test participant. Test participant training will be conducted by the test administrator per the applicant's UI. Test participants will be instructed, when applicable, on the applicant's size selection, donning, head-harness tightening, suspension adjustment, positive and negative pressure user seal checks, doffing, and accessory interfacing as specified by the UI.

5.2.3. Each test participant shall perform an unassisted donning of the PAPR. Donning shall be supervised by the test administrator.

5.2.3.1. The test administrator is permitted to make the appropriate adjustments to the inlet covering until the test administrator is satisfied that the test

participant is wearing the PAPR in compliance with the applicant's UI.

5.2.3.2. Expert donning is not allowed. The test administrator or other parties are not allowed to put the PAPR on the test participant.

5.2.4. Test participants will don the PAPR and it will be set to the lowest user-selectable speed setting.

5.3. Conducting the Corn Oil Test

5.3.1. Test participants shall enter the aerosol test chamber through the enclosed vestibule area to minimize disruptions to the aerosol challenge concentration. Only one door may be open at a time. Once the test participant is in the chamber, they will be instructed to attach their sample line tubing to an assigned photometer.

5.3.2. The photometer will measure the corn oil challenge concentration in the chamber at the start of each trial.

5.3.3. The photometer will continuously measure the corn oil breakthrough concentration in the oral/nasal region of the PAPR during the trial.

5.3.4. The NIOSH Dynamic Fit software will be used to record raw data from the photometer and continuously generate a fit factor throughout each exercise and trial. The fit factor value is updated approximately once per second. The fit factor calculation is described in Attachment D.

5.3.5. A trial consists of a set of four two-minute standard exercises. During the trial, each test participant will perform the following four exercises, for two minutes each, in the sequence listed below. The test administrator will give verbal commands to stop and start each exercise.

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

Two (2) minutes calisthenic arm movements.

Two (2) minutes running in place.

Two (2) minutes pumping with tire pump.

5.3.5.1. Test participants should not touch any portion of the PAPR during any part of the testing exercises.

5.3.6. The test administrator will identify a pass/fail result for each test participant exercise and trial.

5.3.7. After the completion of a trial, test participants will be instructed to disconnect the sample line from the photometer and exit the chamber through the vestibule area.

5.3.7.1. For trials identified as passing, the test participant may be instructed to doff the PAPR.

5.3.7.2. For trials identified as failing, the test administrator shall conduct a failure analysis to confirm or reject the failing result. The test participant may be instructed to leave the PAPR donned. If necessary, the test administrator will examine the PAPR in the donned configuration. The test administrator will instruct the test participant to doff the PAPR when their review is complete.

5.3.8. Comments and observations by test participants are voluntary. All pertinent comments and observations shall be recorded by the test administrator. Care must be taken to ensure test participant comments are understood and accurately recorded.

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.

6.2. For tight-fitting full facepiece PAPR, to achieve a test participant pass:

6.2.1. The fit factor must meet or exceed 500 throughout the entire trial.

6.3. For tight-fitting half mask PAPR, to achieve a test participant pass:

6.3.1. The fit factor must meet or exceed 100 throughout the entire trial.

6.4. For loose-fitting inlet covering PAPR, to achieve a test participant pass:

6.4.1. The fit factor must meet or exceed 500 throughout the entire trial.

6.5. The number of test participant failures may not exceed four. The outcome of five or more test participant failures is deemed an overall test failure.

6.6. Special considerations for PAPR with an extra-small inlet covering:

6.6.1. The outcome of no test participants from panel cell 1 passing in accordance with 4.3.3.1.4.1 is deemed an overall test failure.

6.6.2. The outcome of three (3) test participants from panel cell 1 failing in accordance with 4.3.3.1.4.1 is deemed an overall test failure.

6.7. Special considerations for PAPR with an extra-large inlet covering:

6.7.1. The outcome of no test participants from panel cell 10 passing in accordance with 4.3.3.1.4.2 is deemed an overall test failure.

6.7.2. The outcome of three (3) test participants from panel cell 10 failing in accordance with 4.3.3.1.4.2 is deemed an overall test failure.

6.8. If an overall pass is achieved, but three test participants report the same issue about the comfort of the PAPR, the outcome is deemed an overall test failure.

7. RECORDS/TEST SHEETS

7.1. All test data collected will be recorded on the appropriate fit test data sheet (Attachment E).

8. LIST OF ABBREVIATIONS AND ACRONYMS

Table 2: List of Abbreviations and Acronyms Used Within This Document

Abbreviation or Acronym	Definition
NIOSH	National Institute for Occupational Safety and Health
NPPTL	National Personal Protective Technology Laboratory
PAPR	powered air-purifying respirator
STP	standard testing procedure
CFR	Code of Federal Regulations
$\mu g/m^3$	micrograms per cubic meter
mg/m^3	milligrams per cubic meter
MMAD	Mass Median Aerodynamic Diameter
µm	micrometers
%	percent
SMPS	Scanning Mobility Particle Sizer
EC	Electrostatic Classifier
DMA	Differential Mobility Analyzer
CPC	Condensation Particle Counter
in.	inch
mm	millimeter
UI	user instructions
XS	extra-small
XL	extra-large

9. ATTACHMENTS

9.1. Attachment A: NIOSH Facepiece Direct Probe

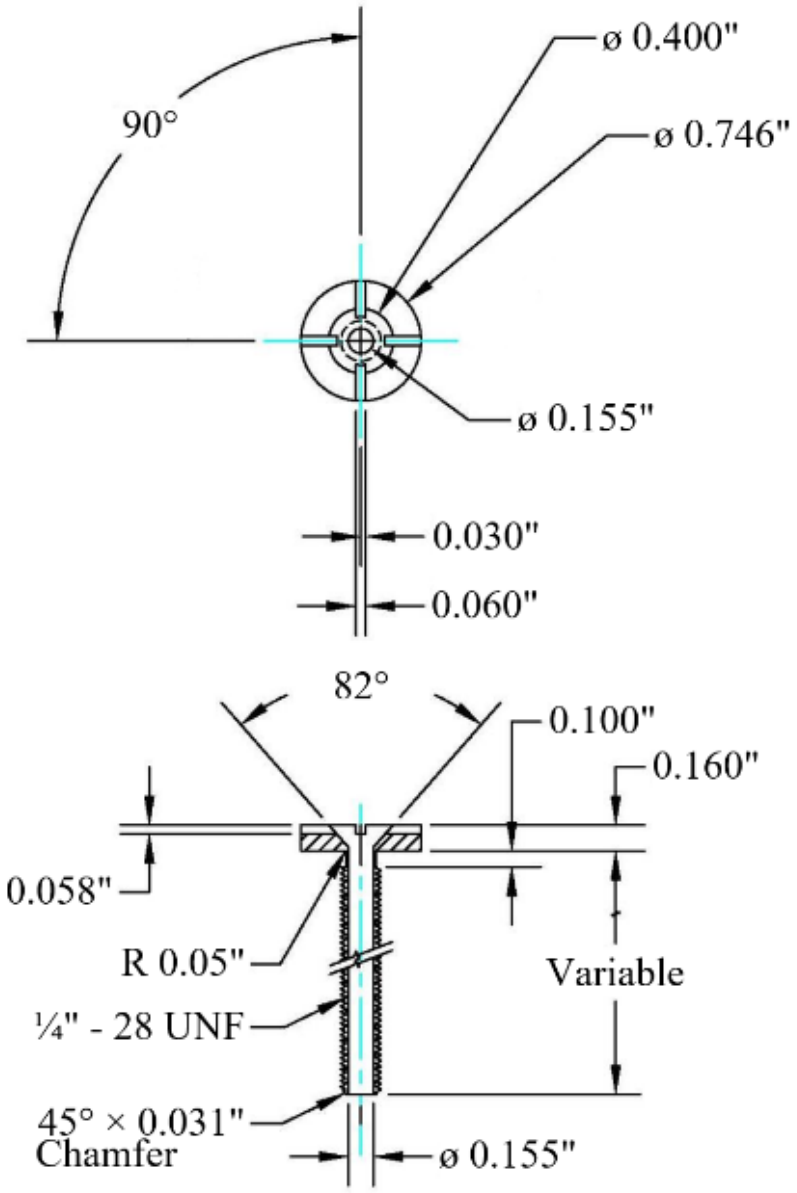
9.2. Attachment B: NIOSH Bivariate Panel (NIOSH Panel)

9.3. Attachment C: Anthropometric Measurements Reference

9.4. Attachment D: Fit Factor Calculations

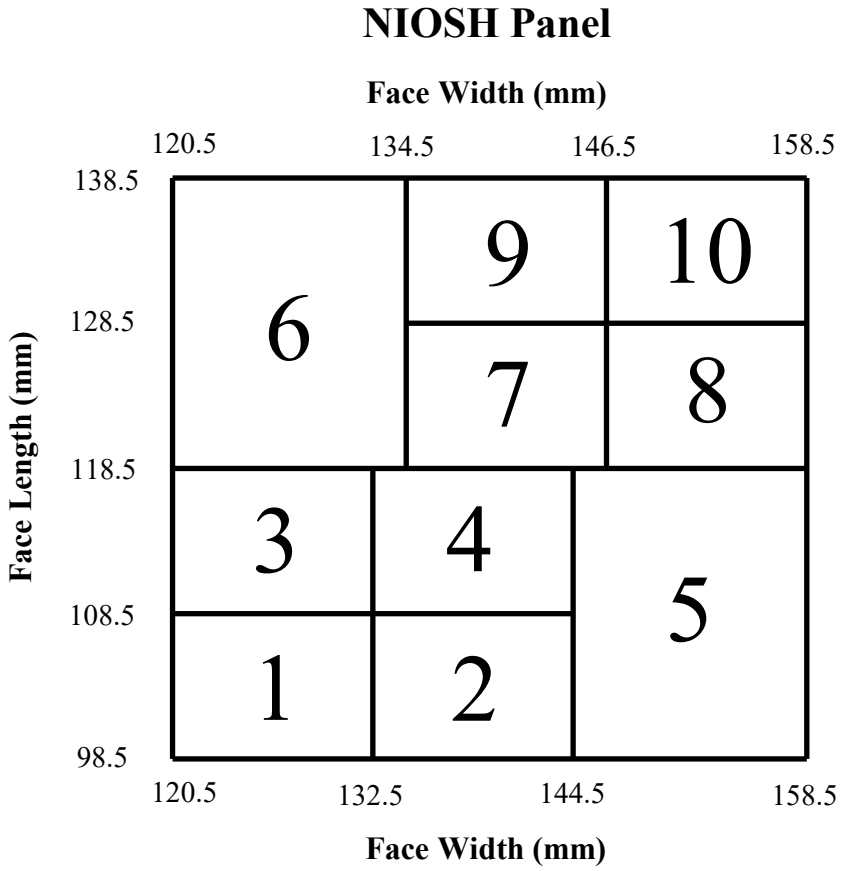
9.5. Attachment E: Example Data Sheet - PAPR Corn Oil Fit Test Data Sheet

Attachment A: NIOSH Facepiece Direct Probe

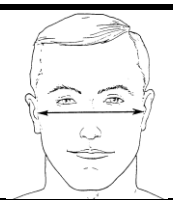
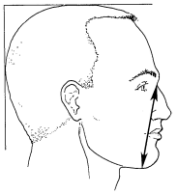


Material:
Stainless steel (304)
Tolerance:
± 0.005"
± 0.5°

Attachment B: NIOSH Bivariate Panel (NIOSH Panel)



Attachment C: Anthropometric Measurements Reference

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.	

Attachment D: Fit Factor Calculations

The PAPR performance is quantitatively determined in terms of a fit factor (*FF*). The fit factor is determined by the ratio of the corn oil challenge concentration in the chamber ([C_{ch}]) to the corn oil breakthrough concentration in the oral/nasal region of the PAPR ([C_{PAPR}]). Under the conditions of the test and the sensitivity of the photometer, the maximum fit factor that can be reported is 100,000.

$$FF = \frac{[C_{ch}]}{[C_{PAPR}]}$$

Attachment E: Example Data Sheet - PAPR Corn Oil Fit Test Data Sheet

National Institute for Occupational Safety and Health
Test Data Sheet

Task Number:
Test:
Manufacturer:
Item Tested:

STP No.:

Test Participant	Face size	Inlet Covering	Trial Result
Overall Result: _____			
Test Administrator: _____		**Date:**	
Comments:			

Was all equipment verified to be in calibration throughout all testing? ◉ **Yes** ◉ **No**

Revision History

Revision	Date	Reason for Revision
0.0	16 March 2020	Original release
1.0	12 February 2024	CVB-APR-STP-0009 and CVB-APR-STP-0010 have been combined into a single procedure and renumbered as NPPTL-APR-STP-0009-0010. Document has been revised for clarity.