



National Institute for Occupational Safety and Health
National Personal Protective Technology Laboratory
P.O. Box 18070
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Procedure No. RCT-APR-STP-0067	Revision: 1.1	Date: 31 August 2005
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PARTICULATE RESPIRATOR QUALITATIVE FIT TEST UTILIZING SACCHARIN OR BITREX SOLUTIONS

1. PURPOSE

1.1 This test establishes the standard procedure for ensuring that the particulate respirators submitted for Approval, Extension of Approval, or examined during Approval Product audits meet fit test requirements established by policy and set forth in 42 CFR Part 84. Specifically for this test, the fitting ability of respirators may be determined for respirators which can not be tested using the isoamyl acetate fit test. Either Saccharin or Bitrex may be used. There is essentially no performance difference.

2. GENERAL

2.1 This STP describes the Saccharin and Bitrex Fit Test in sufficient detail that a person knowledgeable in the appropriate technical field can select proper equipment, conduct the test, and determine whether or not the product passes the test. A Bitrex is a Denatonium benzoate solution. Bitrex is routinely used as a taste aversion agent in household liquids which children should not be drinking and is endorsed by the American Medical Association, the National Safety Council, and the American Association of Poison Control Centers.

3. EQUIPMENT/MATERIAL

3.1 An enclosure that can be worn about the head and shoulders that is approximately 12 inches in diameter by 14 inches tall with at least the front portion clear and that allows free movements of the head when a respirator is worn. An enclosure substantially similar to the 3M hood assembly, parts # FT 14 and # FT 15 combined, is adequate. The test enclosure shall have a 3/4-inch (1.9 cm) hole in front of the test subject's nose and mouth area to accommodate a nebulizer nozzle.

3.2 Two DeVilbiss Model 40 Inhalation Medication Nebulizers or equivalent

3.3 One container of Saccharin or Bitrex

3.4 One container (8 oz. or more) of Salt (NaCl) when Bitrex is used

Approvals:	<u>1st</u> Level	<u>2nd</u> Level	<u>3rd</u> Level
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3.5 One quart (or more)- odor-free water (e.g., distilled or spring water) at approximately 25 deg. C (77 deg. F) for the solutions.

4 TEST PANEL

4.1 Test panel size selection: Particulate respirators are typically offered in sizes. Where respirators submitted by the manufacturer are offered in sizes, respirator panel members shall be selected following the Los Alamos sizing method as follows:

4.1.1 Multiple facepiece sizes:

Small- panel face sizes 1, 2, 3, 4; Number of panel members: 6 (1 or 2 for ea. size to total 6)

Medium- panel face sizes 3, 4, 5, 6, 7, 8; Number of panel members: 6 (1 for ea. size to total 6)

Large- panel face sizes 7, 8, 9, 10; Number of panel members: 6 (1 or 2 for ea. size to total 6)

Small/medium- panel face sizes 1, 2, 3, 4, 5, 6; Number of panel members: 6 (1 for ea. size to total 6)

Medium/large- face sizes- 5, 6, 7, 8, 9, 10; Number of panel members: 6 (1 for ea. size to total 6)

Extra large- face sizes 8, 9, 10; Number of panel members: 6 (2 for ea. size to total 6)

4.1.2 One-size-fits-all: Where respirators submitted by the manufacturer are of a single size facepiece where the single size is intended to fit everyone, the size of the test panel shall be 10 (1 for each size to total 10)

4.1.3 Hoods/ Helmets: The same face size criteria that are used for facepieces apply to hoods and helmets. Reasoning is that head size is generally proportional with face size.

4.1.4 Mouth Bit: When performing this test with a mouth bit respirator the test subject will not be able to stick his/her tongue out. However, this will not affect the ability to detect the saccharin or Bitrex because nose clips must be worn and all air will be inhaled through the wearer's mouth.

5. SOLUTION AEROSOL SCREENING

5.1 The taste threshold screening is performed without wearing a respirator. It is intended to determine whether the test subject can detect the taste of saccharin or Bitrex.

- 5.2 The test subject shall don the test enclosure. Throughout the threshold screening test, the test subject shall breathe with his/her mouth slightly open and with the tongue partially extended (except mouth bit respirators). The subject is instructed to report when he/she detects a sweet taste.
- 5.3 Using a DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent, the test conductor shall spray the threshold check solution into the enclosure by inserting the nebulizer into the hole in the front of the enclosure. The nozzle is directed away from the nose and mouth of the person. This nebulizer shall be clearly marked with words similar to "Saccharin Threshold Solution" or "Bitrex Threshold Solution" to distinguish it from the fit test solution nebulizer.
- 5.4 For **Saccharin**, the threshold check solution shall consist of dissolving 0.83 gram of sodium saccharin USP in 100 ml of warm odor free water. It can also be prepared by putting 1 ml of the fit test solution (described below) in 100 ml of distilled water.
- 5.5 For **Bitrex**, the threshold screening solution is prepared by adding 13.5 milligrams of Bitrex to 100 ml of 5% salt (NaCl) solution in distilled water.
- 5.6 To produce the aerosol, the nebulizer bulb is firmly squeezed so that it collapses completely, then released and allowed to fully expand.
- 5.7 Ten squeezes are repeated rapidly and then the test subject is asked whether the solution can be tasted. If the test subject reports tasting the sweet taste (saccharin) or bitter taste (Bitrex) during the ten squeezes, the screening test is completed. The taste threshold is noted as ten regardless of the number of squeezes actually completed.
- 5.8 If the first response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the solution is tasted. If the test subject reports tasting the solution during the second ten squeezes, the screening test is completed. The taste threshold is noted as twenty regardless of the number of squeezes actually completed.
- 5.9 If the second response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the solution is tasted. If the test subject reports tasting the solution during the third set of ten squeezes, the screening test is completed. The taste threshold is noted as thirty regardless of the number of squeezes actually completed.
- 5.10 The test conductor shall note the number of squeezes required to solicit a taste response.
- 5.11 If the solution is not tasted after 30 squeezes, the test subject is considered as unable to taste saccharin or Bitrex and may not perform this fit test.
- Note:** If the test subject eats or drinks anything other than water before the screening test, he/she may be unable to taste the weak solutions.
- 5.12 If a taste response is elicited, the test subject shall be asked to take note of the taste for reference in the fit test.

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- 5.13 Correct use of the nebulizer means that approximately 1 ml of solution is used at a time in the nebulizer body.
- 5.14 The nebulizer shall be thoroughly rinsed in water and shaken dry following testing. It shall be refilled no more that 4 hours prior to testing.

6. SOLUTION QUALITATIVE TEST PROCEDURES:

- 6.1 The test subject may not eat, drink (except plain water), smoke, or chew gum for 15 minutes before the test.
- 6.2 The fit test uses the enclosure described above.
- 6.3 The test subject shall don the enclosure while wearing the respirator.
- 6.4 The second DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent shall be used to spray the fit test solution into the enclosure. This nebulizer shall be clearly marked with wording similar to “Saccharin Testing Solution” or “Bitrex Testing Solution” to distinguish it from the screening test solution nebulizer.
- 6.5 For **Saccharin**, the fit test solution is prepared by adding 83 grams of sodium saccharin to 100 ml of warm odor free water.
- 6.6 For **Bitrex**, the fit test solution is prepared by adding 337.5 mg of Bitrex to 200 ml of a 5% salt (NaCl) solution in warm water.
- 6.7 As before, throughout the test, the test subject shall breathe with his/her mouth slightly open and with the tongue partially extended (except mouth bit respirators).
- 6.8 The nebulizer is inserted into the hole in the front of the enclosure and an initial concentration of fit test solution is sprayed into the enclosure using the same number of squeezes (either 10, 20 or 30 squeezes) based on the number of squeezes required to elicit a taste response as noted during the screening test. A minimum of 10 squeezes is required.
- 6.9 After generating the aerosol, the test subject shall be instructed to perform the following exercises. The test subject must perform the following test exercises for 1 minute each except for the grimace exercise which shall be performed for 15 seconds. The test subject shall be questioned by the test conductor regarding the comfort of the respirator upon completion of the protocol. If comfort has become unacceptable, this will constitute a failure with this subject. The respirator shall not be adjusted once the fit test exercises begin. Any adjustment following the start of the exercises voids the test, and the fit test must be repeated.
 - (1) Normal breathing in a normal standing position, without talking.
 - (2) Deep breathing in a normal standing position. The subject shall breathe slowly and

deeply, taking caution so as not to hyperventilate.

(3) Turning head side to side. Standing in place, the subject shall slowly turn his/her head from side to side between the extreme positions on each side. The head shall be held at each extreme momentarily so the subject can inhale at each side.

(4) Moving head up and down. Standing in place, the subject shall slowly move his/her head up and down. The subject shall be instructed to inhale in the up position (i.e., when looking toward the ceiling).

(5) Talking. The subject shall talk out loud slowly and loud enough so as to be heard clearly by the test conductor. The subject can read from a prepared text such as the Rainbow Passage, count backward from 100, or recite a memorized poem or song.

Rainbow Passage

When the sunlight strikes raindrops in the air, they act like a prism and form a rainbow.

The rainbow is a division of white light into many beautiful colors. These take the shape of a long round arch, with its path high above, and its two ends apparently beyond the horizon. There is, according to legend, a boiling pot of gold at one end. People look, but no one ever finds it. When a man looks for something beyond reach, his friends say he is looking for the pot of gold at the end of the rainbow.

(6) Grimace. The test subject shall grimace by smiling or frowning.

(7) Bending over. The test subject shall bend at the waist as if he/she were to touch his/her toes. Jogging in place shall be substituted for this exercise in those test environments such as shroud type units that do not permit bending over at the waist.

(8) Normal breathing (same as exercise 1).

6.10 Every 30 seconds the aerosol concentration shall be replenished using one half the original number of squeezes used initially (e.g., 5, 10 or 15).

6.11 The test subject shall indicate to the test conductor if at any time during the fit test the taste of the solution is detected. If the test subject does not report tasting the solution, the test is passed.

6.12 If the taste of the solution is detected, the test with this subject is deemed a failure.

NOTE: The nebulizers have a tendency to clog during use. Therefore, the test operator must make periodic checks of the nebulizer to ensure that it does not clog. If clogging is found at the end of the test session, the test is invalid.

7. PASS/FAIL CRITERIA

- 7.1 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. One failure where the test subject detects saccharin or Bitrex 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 respirator fails testing.
- 7.2 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:
- 7.3 The test subject will don the respirator and perform a user seal check (fit check) per the manufacturer's User's Instructions. If the test subject cannot obtain a successful user seal check, he/she will not be used to perform the test. Upon obtaining a successful user seal check, the subject may perform the test. Up to three different test subjects of a specified size will have the opportunity to obtain a successful user seal check (fit check) before the respirator is considered to fail. 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.
- 7.4 The test subject must not detect the taste of the solution when performing the test exercises. If on initial spraying of the solution (before the exercises begin), the subject immediately tastes the solution, the subject may immediately remove the enclosure, adjust the respirator, perform a second user seal check (fit check), and if successful, re-enter the chamber. If the subject again detects the taste of the solution, the respirator will be considered as failing on the basis that the user seal check process is inadequate to determine fit or the respirator is unable to maintain a fit.

8. RECORDS/TEST SHEETS

- 8.1 All test data collected will be recorded on the attached Particulate Respirator Test Sheet.
- 8.2 Any videotapes and photographs of the actual test being performed, or of the tested equipment shall be maintained in the task (project) file as part of the permanent record.
- 8.3 If the failure occurs to hardware examined under an Off-the-Shelf Audit; the hardware will be examined by a technician and the laboratory staff leader for cause. All equipment failing any portion of this test may be returned to the manufacturer applicant for examination. However, the hardware tested shall be held at the testing laboratory until authorized for release by the Branch Chief, or his designee.

9. ATTACHMENTS

- 9.1 Partial list of test equipment suppliers.

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Allegro Industries

3M

Lab Safety and Supply Co.

Particulate Respirator Test Sheet

TN- _____

Test Date: _____

Mfr. ref. # _____

Respirator Description _____

Subject #	Test subject ID #	Screening Trial: Number of squeezes to solicit a taste response (10, 20, 30)	Testing: Tasted solution during test? Check if Yes	Comment
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				

PASS/FAIL _____ Notes: _____

Testing Technician _____

Revision History

Revision	Date	Reason for Revision
1.0	29 August 2005	Establishment of test procedure
1.1	31 August 2005	Update header and format to present version No changes to method