Program for Respirator Outreach, Training, Education, and Community Testing (PROTECT)

Project Procedures

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1. **Aims**
    a. Project Aims

The primary purpose of this project is to develop a toolkit for community organizations that supports the effective selection and use of respirators by the general public and workers who are not covered under respiratory protection programs (RPPs). Specific project aims include:

- Developing a training for trusted community partners, including how to perform fit testing, background knowledge about respiratory protection, key messages to share with community members, and where to find more in-depth resources if needed.
- Developing educational materials for participants (general public/workers without RPPs), covering topics such as the differences between masks and respirators, when to wear a respirator, proper donning of respirators, where to acquire respirators, and other resources and information.
- Evaluating the efficacy of trainings with pre-/post- surveys for trainees and community participants, using results to improve training and educational materials prior to finalizing the toolkit.
- Compiling a final report, summarizing pilot testing and evaluation findings, to be shared with NIOSH alongside the final training toolkit.

    b. Background

Historically, specific worker groups have used respiratory protective devices, such as N95 respirators, in the workplace, including healthcare workers, industrial workers, construction workers, and emergency responders. Many of these workers are covered by a workplace respiratory protection program (RPP) mandated by the Occupational Safety and Health Administration (OSHA), which includes training on respirator use and fit testing to ensure effective protection. In recent years, many workers who are not covered by RPPs have faced respiratory hazards at work, such as essential workers during the COVID-19 pandemic and agricultural and other outdoor workers faced with increasingly frequent wildfire smoke events. Many of these hazards also affect the general public. However, many workers and members of the general public are not aware of when to use respirators and how to use them correctly, and do not have access to fit testing resources to ensure that the respirators they wear are properly fitted and effective. In addition, during the COVID-19 pandemic, there was widespread confusion and misinformation regarding the proper selection, fit, and use of respirators. Further, certain groups were disproportionately affected by the COVID-19 pandemic, which emphasized the need for better access to respiratory health education and resources across a range of communities.

Based on these gaps, a recent National Academies of Sciences, Engineering, and Medicine (NASEM) report recommended the development of appropriate guidance and training on the use of respirators by the public and workers without an RPP (NASEM, 2022). Targeted efforts are needed to reach a range of populations, including groups such as workers without RPPs, communities disproportionately at risk of exposure to airborne infectious diseases and associated complications, and those living in areas prone to air pollution and wildfire smoke.

In response to this need, the California Department of Public Health (CDPH) Occupational Health Branch staff, in collaboration with the Public Health Institute (PHI), is undertaking a four-year project funded by CDC's National Institute for Occupational Safety and Health (NIOSH). This project, the Program for Respirator Outreach, Training, Education, and Community Testing (PROTECT), will target the general public and workers without RPPs, with an emphasis on populations particularly susceptible to respiratory hazards. This project aims to empower trusted community messengers with training and education to reach these populations.

c. Study Design

This project will be undertaken using a train-the-trainer (TTT) model, in which trusted community partners, such as local health departments, community-based organizations, and emergency responders, are trained to provide education about respiratory protection and to conduct fit testing for members of their communities. Training materials will be developed by CDPH and pilot tested in partnership with three community organizations across California. The pilot sites will be selected based on population and geographical locations within California. The final deliverable will be a toolkit for trusted community organizations to provide respirator education and fit testing for their communities.

This is a multicenter project, with trainings developed centrally by CDPH and PHI staff and piloted with 3 community partners across California. At each site, CDPH will conduct a training for partner organization staff members, who will then conduct a fit testing event for community participants. At each pilot site, at least 5 staff members will be trained, and at least 30 community participants will receive educational materials and be fit tested.

Feedback will be solicited from each site in the form of pre- and post-training surveys completed by the trained staff members to assess effectiveness of the training program. Community participants will also be asked to complete pre- and post-fit testing surveys to assess PKAB (perceptions, knowledge, attitudes, and behaviors) towards respiratory protection to assess training effectiveness. All feedback and surveys will be used to improve the developed materials. There will be 3 community partner pilot sites with testing that will occur in 3 rounds separated by approximately 6 months, with a total testing period of 18 months. Each pilot site testing will inform the next training. Throughout the iterative cycle, the project staff will integrate the received feedback to improve the program for the next pilot iteration.

Following completion of the three community pilots and integration of evaluation feedback, the developed training and educational materials will be compiled into a final toolkit, which will be delivered to NIOSH for more widespread dissemination.

2. Participant Population

This intervention focuses on the general public and workers who are not covered under respiratory protection programs (RPPs). Historically, respiratory protection has focused on workers as they are typically exposed to higher levels of respiratory hazards. However, as described above, there is a need for the general public and a broader population of workers to access quality respiratory protection due to increased wildfire events, infectious disease, and other respiratory hazards.

3. **Recruitment Process**

Community partners will be identified through established contacts and outreach to organizations across California working with communities of interest. The community organizations will be selected to represent varied populations susceptible to respiratory hazards. Criteria for selection will include population served, adequate qualified staff and time for staff participation in fit test training, ability to conduct outreach to community for event participation, and interest in and ability to conduct future fit testing events using skills gained in training. The three sites will be selected in geographically and economically varied areas of California.

Community member participants will be recruited in collaboration with the community partners. Information about the event will be disseminated in partnership with the fit testing site prior to the event, with pre-registration as well as drop-in availability, to ensure a range of participants of sufficient number. Children below the age of 18 (for whom NIOSH-certified respirators are not approved) and those with significant respiratory or cardiovascular impairment – such as late-stage congestive heart failure or those using supplemental oxygen – will be excluded from fit testing participation.

4. **Program Development**

The train-the-trainer program will be developed in collaboration with the 3 pilot sites and other community partners who wish to provide feedback on the training materials, in order to ensure that the included information and messaging is appropriate for participant audiences. Following the development of initial project materials, pilot testing will occur approximately every 6 months, with each test cycle informing the revision of program materials. Feedback on project materials will also be requested by subject matter experts to ensure accuracy of the developed materials. Spanish materials will be developed along with English materials.

5. **Procedures/Testing**
    a. Participants
        i. Community Partners

Community partners will select at least 5 staff trainees per site who will receive qualitative fit test training. The training will take approximately 4 hours and will be a mixture of PowerPoint and interactive learning. CDPH/PHI project staff will conduct the training. Before the training begins, trainees will be given a pre-survey to complete to assess pre-existing knowledge of respiratory protection and fit-testing procedures. The training content will include background information on respiratory hazards, differences between masks and respirators, and potential challenges and barriers associated with respirator use. This training will provide trainees with the ability to teach community members how to use a respirator, when to use a respirator, which respirator to use, and where to find them. Trainees will also be trained to perform qualitative fit testing for community members. The training will focus primarily on N95 respirators, as this is the most common type of respirator that the general public will need. Trainees will also be introduced to elastomeric respirators and provided with information regarding higher-level respirator selection.

During the training, trainees will receive hands-on experience conducting fit testing that will mimic the fit testing performed during the subsequent event with community members. Fit test training will include the standard ANSI qualitative procedures in the ANSI/AIHA Z88.10 procedure (see Appendix A) document under section 8.3 Bitrex™ Solution Aerosol Fit Test or 8.2 Sodium Saccharine Aerosol Fit Test if needed. This test will use a standard 3M qualitative fit test kit for particulate respirators that includes the equipment required under 8.3.1.1 in the ANSI document. The fit-testing procedure is described in more detail in section 6 of this document. After the completion of the training, trainees will complete a post-training survey to assess effectiveness of the training and solicit input on opportunities for improvement.

ii. Community Participants

Upon arrival, community members will be asked for consent before participating. The consent process is described in section 11. Participating community members will first complete a pre-fit testing survey to assess perceptions, knowledge, attitudes, and behaviors (PKAB) associated with respiratory protection. Once surveys are completed, they will be paired with a staff trainee from the partner organization.

Before conducting the fit test, the trainee will provide the community member with brief education about respiratory protection and will provide a wallet card with key information and QR codes with links to more information. The trainee will then begin the fit test, which will ensure that the selected respirator fits correctly and will provide the expected level of protection. The fit test mimics an exposure environment by placing a hood over the wearer and spraying a solution that tastes bitter or sweet. If the wearer cannot taste the solution while wearing the respirator, the respirator is a good fit.

Upon completion of the fit test, the participant will be given a post-fit testing survey to reassess PKAB associated with respiratory protection and effectiveness of the fit testing session. The participant will then be given the option to participate in providing anthropometric facial measurements (described in the procedure section).

The expected time for community members for the full fit test procedure is approximately 15-20 minutes, with an additional 7 minutes for each time a respirator fails the fit test. In total, we estimate that the procedure, education, and surveys will take less than an hour. If the participant elects to take part in the anthropometric measurements (described in section 6c), it will take an additional 15-20 minutes.

6. **Qualitative Testing Equipment and Procedure**
    a. Equipment

A standard 3M qualitative fit test kit for particulate respirators will be provided. The equipment needed follows the guidance in the ANSI document sections 8.3.1.1 (baseline sensitivity test) and 8.3.2.1 (fit test).

b. Procedure
    i. Sensitivity test and Fit test

Fit test training will include the standard ANSI qualitative procedures in the ANSI/AIHA Z88.10 procedure document under section 8.3 Bitrex™ Solution Aerosol Fit Test or 8.2 Sodium Saccharine Aerosol Fit Test (Appendix A). Fit test operators will first try the Bitrex™ bitter solution. If the person cannot taste the bitter solution after 30 squeezes, the operator will use the sweet sodium saccharine solution. First, a

sensitivity taste test threshold screening will be completed without a respirator to measure a baseline ability to taste the bitter solution. The full sensitivity test procedure is written under 8.3.1.2 in the aforementioned ANSI document. After the baseline test is complete, the wearer will be instructed to rinse out their mouth with water. The trainee will then show the wearer how to properly put on, or "don," an N95 respirator and will teach how to do a positive and negative seal check. The trainee will ask the participant if the respirator is comfortable enough to wear for extended periods. If the respirator is not comfortable enough to wear, a new respirator should be chosen prior to the fit test. The fit test will then be performed with the respirator on. The full fit test procedure can be found in section 8.3.2.2 of the ANSI document. Tables I and II on pages 19 and 20 of the ANSI document describe the exercises to be performed during the fit test that mimic normal activities. If the respirator passes, the wearer will be asked to break the respirator seal to ensure they can still taste the bitter solution. If the respirator does not pass, the trainee will check that the respirator is donned correctly then help the participant adjust the respirator. If the respirator is donned correctly, the trainee will select a different respirator and repeat the fit test procedure only, not the sensitivity test. We expect the qualitative fit test procedure to take 15-20 minutes, with an additional 7 minutes for each time a respirator fails the fit test. CDPH/PHI staff will record the type of respirator used and pass/fail results for each participant.

Table 1: Overview of fit test procedures (Refer to the ANSI document in Appendix A for the full procedure descriptions):

Sensitivity Test
1. Place hood over wearer's head, without respirator 2. Put sensitivity solution in nebulizer and test if nebulizer is working 3. Perform threshold screening with sensitivity solution
Prep for Fit Test
4. Rinse Mouth 5. Show wearer how to don a respirator and perform a seal check. The trainee will then assess comfort and perform a visual inspection for gaps NOTE: If the respirator is not comfortable enough to wear for an extended period, select a different respirator.
Fit test
6. Place hood over wearer's head, with respirator in place 7. Put test solution in nebulizer and test if nebulizer is working 8. Perform fit test with test solution, while completing fit test movements described in Tables I and II of the ANSI document 9. If passed, ask wearer to break seal to ensure they can still taste Bitrex™ (bitter solution) or Sodium Saccharine (sweet solution) 10. Determine Pass/Fail

c. Anthropometric data

Anthropometric data will be collected as a separate process following the fit test. The measurements and survey form will be completed by trained PROTECT CDPH and PHI staff. Facial landmarks (i.e., head breadth, minimal frontal breadth, nasal root breadth, interpupillary breadth, face width, nose breadth, bigonial breadth, lip length, nose length,nose protrusion, face length, menton subnasale length, and head circumference) will be measured by CDPH/PHI staff and recorded in the secure CDC REDCap

database described below. These data, which will be paired information about fit test pass/fail and make and model of respirator data, will be shared with NIOSH to inform development of future fit testing resources. No personally identifiable information will be collected by CDPH/PHI or shared with NIOSH.

7. Data Collection and Analysis

We will conduct pre-/post-training/fit testing surveys for both the trainees and community participants to assess changes in perceptions, knowledge, attitudes, and behaviors, (PKAB) about respiratory protection and capture feedback on the training program. Surveys will be completed via tablet and will be administered immediately before and after the training presentation (for trainees) and fit testing (for community members). Survey questions include multiple-choice, Likert scale items, and open-ended questions; data will be collected via CDC REDCap. There will be separate CDC REDCap forms for CDPH and PHI staff to collect respirator pass/fail data and anthropometric data.

Aggregate data will be downloaded from CDC REDCap and analyzed using R Statistical Software. CDPH/PHI staff will summarize the results of the pre/post surveys and draft a report to be submitted to NIOSH. The summary report will include a copy of the TTT and fit-testing frameworks, the aggregate results of the surveys, anthropometric data, fit factor testing results, and observations from the fit-testing pilot.

For the survey results, we will include demographic characteristics (age, sex, race/ethnicity, and education level) of our trainees and pilot-site participants. We will conduct descriptive analyses related to the other survey questions. For example, we will examine the number of correct responses to the knowledge questions on respiratory protection before and after the programs (training and fit-testing). We will provide the mean score for Likert-scale items on the questionnaires before and after the programs, to examine changes in perceptions, attitudes, and intended behaviors related to respiratory protection. We will also measure the confidence of trainees after participating in the TTT program. We plan to present these data for participants overall and also by pilot site.

8. Assessment of Benefits

The community members who participate in this project will receive direct benefits. They will be provided with education about respiratory protection, fit testing to ensure appropriate respirator fit, and a small number of respirators for the respirator make and model that they pass the fit test with.

The community partners who participate in this project will receive training, a supply of respirators, fit test kits for future use, and an incentive payment of $10,000 to complete the training and fit test event.

9. Assessment of Risks/Safety Plan

The risks to participants from this project are minimal. However, risk mitigation procedures will be put in place to ensure the procedures are as safe as possible. Participants may experience mild discomfort from wearing a respirator, such as perceived difficulty breathing, increased breathing resistance, warm skin under respirator, uncomfortable bitter taste, head straps chafing skin, or claustrophobia. Testing will be stopped if there are adverse reactions such as discomfort, facial irritation, blisters, other personal safety concerns. Any report of dizziness, overheating, overexertion, or difficulty breathing will also result in the test being stopped. The test will also end if the respirator is not working properly, or if the person wishes

to terminate the test. People with severe cardiovascular or pulmonary diseases will be excluded from this study.

i. Infectious Disease

Precautions will be in place to mitigate the spread of infectious disease. All surfaces and equipment will be disinfected between participants. During check-in, community members will be asked if they have symptoms of COVID-19, the flu, or other infectious diseases, and will be excluded from participation if they are symptomatic. Staff and trainees will wear respirators upon request to ensure the comfort of community members.

10. Confidentiality

No personally identifiable information will be collected during this project. Upon registration, participants will be given a participant ID on a paper slip and asked to keep the paper slip with them during their participation. This will allow an ID to be assigned without collecting personally identifiable information. The ID will be used during completion of the pre- and post-surveys and recording of fit test results and anthropometric measurements. Anthropometric data and data on fit testing results (pass/fail results with different respirator models) will not be linked to any personally identifiable information, as none will be collected during the study. Data will be collected via CDC REDCap and stored in a secure electronic database. Only approved staff will have access to the data collected.

11. Informed Consent/Documentation

Written information will be provided to community participants about fit testing before taking part in the fit test event. After reviewing the written information, they will be asked to affirm whether they would like to proceed with fit testing. PROTECT team members will be available to answer any questions. Separately, written information about anthropometric measurement procedures will be provided to community participants, who will have the option of opting in or out of this portion of the process. Participants who choose not to participate in anthropometric measurements will still be able to participate in fit testing.

12. Financial Issues

The CDPH and PHI team has no financial disclosures or conflicts of interest.

References

1. National Academies of Sciences, Engineering, and Medicine. 2022. *Frameworks for Protecting Workers and the Public from Inhalation Hazards.* Washington, DC: The National Academies Press. https://doi.org/10.17226/26372.

Inhalation valve must be removed or propped open.

b. Tell the person being fit tested to don the respirator as trained (see Clause 6).

c. Select the instrument test parameters.

7.3.5 Fit Testing

a. Tell the person being fit tested to take a breath and hold it for the duration of the measurement. The person shall remain motionless in the specified head position during the measurement.

b. It is important that the in-facepiece pressure equilibrates to ambient pressure before the initiation of the test.

c. The CNP test system is activated to establish and maintain a negative challenge pressure in the temporarily sealed respirator. The exhaust flow rate required to maintain a constant challenge pressure is averaged over the duration of the measurement, and represents a direct measure of respirator leakage flow rate.

7.3.6 Interpretation of CNP Test Results

a. A CNP fit factor is calculated as the ratio of inspiratory flow rate to measured leakage flow rate.

b. At the completion of the fit test the instrument provides a pass/fail indication and/or a numeric overall fit factor result for the entire test calculated according to the formula below. The person has passed the fit test if the overall fit factor equals or exceeds the required fit factor.

CNP Fit Factor = IFR / LFR

Where:

IFR = inspiratory flow rate associated with CNP challenge pressure
LFR = mean leakage flow rate measured with the head held in a motionless position at the end of each test exercise.

Example:

Given a modeled inspiratory flow rate of 53,800 ml/min (equivalent to a moderate workrate):

LFR1 = 48 mL/min, LFR2 = 69 ml/min, LFR3 = 59 mL/min, LFR4 = 53 ml/min, LFR5 = 58 mL/min

Average LFR = (LFR1+LFR2+….LFRn)/n
= 287/5 = 57.4
Fit Factor = 53,800/57.4 = 937

8 Qualitative Fit Test (QLFT) Methods

This section contains the QLFT methods reviewed by the committee that were found to be acceptable when this standard was published. A qualitative fit test uses a person's ability to sense a challenge agent (such as by taste or smell) to determine if respirator leakage occurs. The tests do not give a numerical indication of fit; no direct measurements of the challenge agent and leak concentrations are made. The reliability of the test depends upon the person's ability to detect and indicate whether the challenge agent is sensed and requires that the operator carefully follow the accepted test protocol.

8.1 Isoamyl Acetate (banana oil) Fit Test. The isoamyl acetate (IAA) fit test uses a person's sense of smell to detect leakage into the respirator. The person being fit tested first must demonstrate the ability to detect a known low (~ 1 ppm) concentration of IAA. Next, while wearing a respirator, the person enters a test enclosure with a higher (> 100 ppm) concentration of IAA. If the banana-like odor of IAA is not detected, the person passes the fit test and is assumed to have a fit factor of at least 100.

Note: Any variation from the procedure specified below may invalidate the results, especially changes in solution concentrations, amount of IAA used during the test, and the size of the test enclosure.

Precautions: The screening test and fit test shall be done in separate areas that do not allow the transfer of IAA vapors

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from the fit test area to the screening area. The sense of smell is adversely affected by even brief exposures to IAA. The fit test should be conducted immediately after the screening test. Review the MSDS for any handling and use precautions.

8.1.1 Odor Threshold Screening

Use of the IAA fit test method requires that the person being fit tested have the ability to smell low concentrations of IAA.

8.1.1.1 Equipment Required

a. Three or more identical 1-liter (1-quart) glass jars with metal lids (e.g., Mason or Ball canning jars);
b. A 1-mL eye dropper, syringe, or other device capable of dispensing in 0.1 mL increments;
c. Odor-free water (e.g., distilled or spring water) at room temperature about 20 to 25°C (~70–77° F); and
d. Isoamyl acetate (IAA), reagent grade (also known as isopentyl acetate, CAS number 123–92–2).

8.1.1.2 Solution Preparation

a. Prepare a stock solution by adding 1 mL of reagent grade IAA to 800 mL water in a glass jar labeled “stock solution” and shake for 30 seconds. This solution shall be prepared at least weekly;
b. Label the remaining jars described below using a switchable identification system (e.g. switchable numbers) so that only the person who conducts the fit test can identify the contents of each jar by sight;
c. Prepare an odor test solution by placing 0.4 ml of the stock solution into 500 ml water in a second jar. Close the lid, shake, and let the jar stand for two minutes before use. This solution is prepared daily;
d. Prepare a blank jar by adding 500 mL water to one or more jars. (Note: more than one blank jar should be used to make it more difficult for someone to guess); and
e. Switch the jar identification labels between tests so that the same jar is not always the one that smells like bananas.

8.1.1.3 Odor Screening Test

a. Ask the person being fit tested to determine which jar smells like bananas by instructing the person to shake each jar briefly, remove the lid, sniff at the mouth of the jar, and recap the lid;
b. If the person correctly identifies which jar contains IAA, then the person may continue with the test. If the correct jar cannot be identified, the IAA fit test method shall not be used.
c. NOTES:

   1) Prevent olfactory fatigue by not allowing IAA vapor to be present in the screening area. The odor-screening test must be done in a separate area (i.e., a different room) to prevent transfer of IAA vapors from the fit testing area.

   2) A card may be prepared with instructions that the person being fit tested can follow to shake the jars, remove the lids, and determine which jar smells like bananas.

   3) Take care not to contaminate the blank jar(s) by switching jar lids.

8.1.2 Fit Testing

The person is fit tested while wearing a respirator in a test enclosure containing a controlled concentration of IAA.

8.1.2.1 Equipment Needed

a. Test enclosure: A clear plastic bag approximately 24 inches (60 cm) in diameter and 60 inches (150 cm) long, (e.g., a 55-gallon plastic drum liner) equipped with a frame to hold the bag open and a suitable device or clip for holding the absorbent paper;
b. A piece of absorbent paper (e.g., a paper towel), approximately 6 by 5 inches (15 x 12 cm). A new piece of

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absorbent paper is needed for each fit test;

c. A quantity of 0.75 mL of IAA (reagent grade) is needed for each fit test; and

d. Respirators used for testing shall be equipped with cartridges that remove organic vapors. Cartridges should be replaced before breakthrough occurs. This could be as often as weekly.

8.1.2.2 Conducting the Test

a. Instruct the person being fit tested to don the respirator, equipped with a cartridge capable of removing organic vapors, as trained (see Clause 6). Adjust the ceiling of the enclosure to a distance about 6 inches (15 cm) above the person's head;

b. Apply 0.75 mL of reagent grade IAA to one piece of absorbent paper, which is folded in half. Hand it to the person in the enclosure, who then attaches it to the inside top of the enclosure. A freshly wetted piece of absorbent paper shall be used for each fit test;

c. Wait two minutes for the IAA concentration to stabilize in the enclosure;

d. Instruct the person that any detection of the smell of IAA (banana-like odor) during the test is to be reported immediately;

e. Instruct the person to begin the series of test exercises according to Clause 9;

f. The fit test is failed if the person reports smelling IAA at any time while conducting the test exercises. At this point a decision must be made, either to retest or select another respirator according to Clause 6. In either case the entire procedure must be repeated (odor screening and fit testing). It may take several minutes for the person being fit tested to regain the ability to smell low concentrations of IAA. Do not repeat the fit test until the person being fit tested successfully completes the odor threshold screening test again;

g. If the person being fit tested does not report smelling the IAA, instruct the person to momentarily break the respirator seal and inhale. If IAA is not detected after breaking the respirator seal, the test is null and void and the reason why the person did not smell the IAA must be identified. If the IAA is detected after breaking the seal, the test is passed;

h. A person who passes the IAA test is assumed to have a fit factor of at least 100;

i. At the end of a passed or failed test, have the person remove the absorbent paper and seal it in a small plastic bag or similar container to lessen the build up of IAA vapor in the fit testing area.

NOTE: The absorbent paper shall not be used for other IAA fit tests.
Note: Operators should be aware that wearing a respirator within a fit test enclosure may elevate inspired carbon dioxide levels and decrease inspired oxygen levels. The operator should inform the person that they may feel hot or experience distress. If this occurs the person should stop the test, exit the enclosure, and remove the respirator.

8.2 Sodium Saccharin Aerosol Fit Test.

The saccharin aerosol fit test uses a person's sense of taste to detect leakage into the respirator. The person being tested must be able to detect a weak solution of sweet-tasting saccharin. This is determined by spraying a weak solution of saccharin into a fit test hood placed over the head. Next, while the person is wearing a respirator, the hood is placed over the head and a stronger saccharin solution (~100 times stronger) is sprayed into the fit test hood. If the person being fit tested does not detect the taste of saccharin, the person passes the fit test and is assumed to have a fit factor of at least 100.

Note: Any variation from the procedure specified below may invalidate the results, including changes in solution concentration, how the bulb is squeezed, the number of squeezes, and the size of the fit test hood.

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Precautions: Since a person's ability to taste the sweet solution is used to determine whether the respirator fits, he or she should refrain from activities that would affect the sense of taste such as consuming any food or beverage (other than plain water), using tobacco products, or chewing gum for about 15 minutes prior to threshold screening. The fit test should be done immediately after the threshold screening test. Review the MSDS for any handling and use precautions.

Note: Operators should be aware that wearing a respirator with a fit test hood will elevate inspired carbon dioxide levels and decrease inspired oxygen levels. The operator should inform the person that they may feel hot or experience distress. If this occurs the person should stop the test and remove the hood and respirator.

8.2.1 Taste Threshold Screening

Use of the saccharin fit test requires that the person being fit tested demonstrate the ability to taste a low concentration of saccharin.

8.2.1.1 Equipment Needed

a. An inhalation nebulizer (DeVilbiss Model 40 or 45 or equivalent). Aerosol particle size and concentration is determined by the characteristics of the nebulizer. An alternative nebulizer shall produce an aerosol concentration and particle size distribution equivalent to the Model 40/45 using the procedure specified below;
b. A fit test hood with a nominal size of 12 inches (300 mm) in diameter by 14 inches (355 mm) high with at least the front portion clear. The fit test hood must allow free movement of the head when a respirator is worn. A hole approximately 1 inch (25 mm) in diameter shall be located at a point that will be in front of the person's nose and mouth to accommodate the nebulizer nozzle; and
c. Sensitivity screening solution with 0.83 g sodium saccharin (CAS number 128-44-9, USP grade) in 100 ml distilled water.

8.2.1.2 Taste Threshold Screening Procedure

a. Place the fit test hood over the person's head. The person being fit tested shall not be wearing a respirator at this time. Ask the person to breathe through the mouth only. Instruct the person to immediately report if the sweet taste of saccharin is detected.
b. Add a small amount of the taste screening solution (~ 3 mL) into the nebulizer.
c. Insert the nebulizer nozzle into the opening at the front of the fit test hood. Direct the nozzle away from the nose and mouth of the person. Be careful not to spray the aerosol onto the surface of the fit test hood or into the eyes. To produce the aerosol, grip the bulb in the palm of the hand (not fingers only) and firmly squeeze the nebulizer bulb so that it collapses completely. Then release it and allow it to fully expand. Maintain the nebulizer in an upright (vertical) position when spraying the aerosol.

   Note: Determine that the nebulizer is working by observing that a visible mist is produced throughout the procedure.

d. Squeeze the nebulizer bulb up to 10 times. If the person reports the sweet taste during the 10 squeezes, stop squeezing the bulb; the screening test is completed. Regardless of the number of squeezes actually completed, assign the taste threshold as 10.
e. If the person being fit tested is unable to detect the sweet taste after 10 squeezes, apply up to another 10 squeezes. If the person reports the sweet taste during the second 10 squeezes, stop squeezing the bulb; the screening test is completed. Regardless of the number of squeezes actually completed, assign the taste threshold as 20.
f. If the person is unable to detect the sweet taste after the second 10

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squeezes, apply up to another 10 squeezes. If the person reports the sweet taste during the third set of 10 squeezes, stop squeezing the bulb; the screening test is completed. Regardless of the number of squeezes actually completed, assign the taste threshold as 30.

g. If the person is unable to detect the sweet taste after 30 squeezes, he or she is unable to taste saccharin and the saccharin fit test method shall not be used. The operator should recognize that some people may not detect the sweet taste of saccharin and therefore should not encourage the person to respond in a falsely positive manner.

8.2.2 Fit Testing

The person is fit tested while wearing a respirator inside the fit test hood while the test solution is sprayed into the hood.

8.2.2.1 Equipment Needed

a. A second nebulizer of the same make and model as that used for the threshold screening test;
b. Fit test solution with 83 g sodium saccharin (CAS number 128-44-9, USP grade) in 100 ml distilled water;
c. Respirators used for testing must be equipped with particulate filter(s); and
d. A fit test hood with a nominal size of 12 inches (300 mm) in diameter by 14 inches (355 mm) high with at least the front portion clear. The fit test hood must allow free movement of the head when a respirator is worn. A hole, approximately 1 inch (25 mm) in diameter shall be located at a point that will be in front of the person's nose and mouth to accommodate the nebulizer nozzle.

8.2.2.2 Conducting the Test

a. Place the fit test hood over the person's head. The person being fit tested shall wear the respirator as trained (see Clause 6).
b. Ask the person to breathe through their mouth only. Instruct the person to immediately report if the sweet taste of saccharin is detected.
c. Add a small amount of the test solution (~ 3 mL) into the nebulizer.

Note: If the test solution has crystallized, do not use it until all of the crystals have been dissolved by gently warming the solution.

d. Position the fit test hood to maximize the space between the front of the hood and the respirator. Insert the nebulizer nozzle into the opening at the front of the hood and direct the aerosol into the void between the side of the respirator and the hood. Spray saccharin aerosol into the fit test hood by squeezing the nebulizer bulb 10, 20, or 30 times based on the taste threshold assigned during the threshold screening test. Be careful not to direct the aerosol spray onto the hood, respirator, or into the eyes. To produce the aerosol, grip the bulb in the palm of the hand (not fingers only) and firmly squeeze the nebulizer bulb so that it collapses completely. Then release it and allow it to fully expand. Maintain the nebulizer in an upright (vertical) position when spraying the aerosol.

Note: Determine that the nebulizer is working by observing that a visible mist is produced throughout the test.

e. Instruct the person to begin the series of test exercises according to Clause 9.
f. Replenish the concentration in the fit test hood every 30 seconds by adding half the original number of squeezes (5, 10, or 15).
g. The person fails the fit test if they report tasting saccharin at any time while conducting the test exercises. At this point a decision must be made, either to retest or select another respirator according to Clause 6. In either case the entire procedure must be repeated (taste threshold screening and fit testing). It may take several minutes for the per-

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son being fit tested to regain the ability to taste low concentrations of saccharin. Rinsing the mouth out with plain water and wiping the lips with a wet towel may help. Do not repeat this test until the person being fit tested successfully completes the taste threshold screening test again;

h. If the person being fit tested does not report tasting saccharin, instruct them to reach into the hood and momentarily break the respirator seal while inhaling through their mouth. If the sweet taste is not detected after breaking the respirator seal, the test is null and void and the reason why the person did not taste the saccharin must be identified. If the sweet taste is detected after breaking the seal, the test is valid and the person passes the fit test;

i. A person who passes the sodium saccharin test is assumed to have a fit factor of at least 100.

Note: Since the saccharin test solution has a tendency to clog during use, the test operator must make periodic checks to determine that it is not clogged. If clogging occurs during the test and it is not immediately cleared, the test is invalid.

8.3 Bitrex™ (denatonium benzoate) Solution Aerosol Fit Test

The bitter aerosol fit test uses a person's sense of taste to detect leakage into the respirator. The person being tested must be able to detect a weak solution of Bitrex™. This is determined by spraying a weak solution of Bitrex™ into a fit test hood placed over the head. Next, while the person is wearing a respirator, the hood is placed over the head and a stronger Bitrex™ solution is sprayed into the fit test hood. If the person being fit tested does not detect the taste of Bitrex™ in the respirator, the fit test is passed and the person is assumed to have a fit factor of at least 100.

Note: Any variation from the procedure specified below may invalidate the results, including changes in solution concentration, how the bulb is squeezed, the number of squeezes, and the size of the fit test hood.

Precautions: Since a person's ability to taste the bitter solution is used to determine whether the respirator fits, they should refrain from activities that would affect the sense of taste such as consuming any food or beverage (other than plain water), or using tobacco products or gum for about 15 minutes prior to threshold screening. The fit test should be done immediately after the threshold screening test. Review the MSDS for any handling and use precautions.

Note: Operators should be aware that wearing a respirator with a fit test hood will elevate inspired carbon dioxide levels and decrease inspired oxygen levels. The operator should inform the person that they may feel hot or experience distress. If this occurs the person should stop the test and remove the hood and respirator.

8.3.1 Taste Threshold Screening

Use of the bitter aerosol fit test requires that the person being fit tested demonstrate the ability to taste a low concentration of Bitrex™.

8.3.1.1 Equipment Needed

a. An inhalation nebulizer (DeVilbiss Model 40 or 45 or equivalent). Aerosol particle size and concentration is determined by the characteristics of the nebulizer. An alternative nebulizer shall produce an aerosol concentration and particle size distribution equivalent to the Model 40/45 using the procedure specified below;

b. A fit test hood with a nominal size of 12 inches (300 mm) in diameter by 14 inches (355 mm) high with at least the front portion clear. The fit test hood must allow free movement of the head when a respirator is worn. A hole approximately 1 inch (25 mm) in diameter shall be located at a point that will be in front of the person's nose and mouth to accommodate the nebulizer nozzle; and

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c. Sensitivity screening solution with 13.5 mg Bitrex™ (CAS number 3734-33-6, USP grade) in 100-mL of a 5% sodium chloride by weight solution in distilled water.

8.3.1.2 Taste Screening Procedure

a. Place the fit test hood over the person's head. The person being fit tested shall not be wearing a respirator at this time. Ask the person to breathe through the mouth only. Instruct the person to immediately report if the bitter taste of Bitrex™ is detected.
b. Add a small amount of the taste screening solution (~ 3 mL) into the nebulizer.
c. Insert the nebulizer nozzle into the opening at the front of the fit test hood. Direct the nozzle away from the nose and mouth of the person. Be careful not to spray the aerosol onto the surface of the fit test hood or into the eyes. To produce the aerosol, grip the bulb in the palm of the hand (not fingers only) and firmly squeeze the nebulizer bulb so that it collapses completely. Then release it and allow it to fully expand. Maintain the nebulizer in an upright (vertical) position when spraying the aerosol.

   Note: Determine that the nebulizer is working by observing that a visible mist is produced throughout the procedure.

d. Squeeze the nebulizer bulb up to 10 times. If the person reports the bitter taste during the 10 squeezes, stop squeezing the bulb; the threshold screening is completed. Regardless of the number of squeezes actually completed, assign the taste threshold as 10.
e. If the person being fit tested is unable to detect the bitter taste after 10 squeezes, apply up to another 10 squeezes. If the person reports the bitter taste during the second 10 squeezes, stop squeezing the bulb; the threshold screening is completed. Regardless of the number of squeezes actually completed, assign the taste threshold as 20.
f. If the person is unable to detect the bitter taste after the second 10 squeezes, apply up to another 10 squeezes. If the person reports the bitter taste during the third set of 10 squeezes, stop squeezing the bulb; the screening test is completed. Regardless of the number of squeezes actually completed, assign the taste threshold as 30.
g. If the person is unable to taste the bitter taste after 30 squeezes, he or she is unable to taste Bitrex™ and the Bitrex™ fit test method shall not be used. The operator should recognize that some people may not detect the bitter taste of Bitrex™ and therefore should not encourage the person to respond in a falsely positive manner.

8.3.2 Fit Testing

The person is fit tested while wearing a respirator inside the fit test hood while the test solution is sprayed into the hood.

8.3.2.1 Equipment Needed

a. A second nebulizer of the same make and model as that used for the threshold screening test;
b. Fit test solution with 337.5 mg of Bitrex™ in 200 mL of a 5% sodium chloride by weight solution in distilled water;
c. Respirators used for testing must be equipped with particulate filter(s); and
d. A fit test hood with a nominal size of 12 inches (300 mm) in diameter by 14 inches (355 mm) high with at least the front portion clear. The fit test hood must allow free movement of the head when a respirator is worn. A hole, approximately 1 inch (25 mm) in diameter shall be located at a point that will be in front of the person's nose and mouth to accommodate the nebulizer nozzle.

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8.3.2.2 Conducting the Test

a. Place the fit test hood over the person's head. The person being fit tested shall be wearing the respirator as trained (see Clause 6).
b. Ask the person to breathe through their mouth only. Instruct the person to immediately report if the bitter taste of Bitrex™ is detected.
c. Add a small amount of the test solution (~ 3 mL) into the nebulizer.
d. Position the fit test hood to maximize the space between the front of the hood and the respirator. Insert the nebulizer nozzle into the opening at the front of the hood and direct the aerosol into the void between the side of the respirator and the hood. Spray Bitrex™ aerosol into the fit test hood by squeezing the nebulizer bulb, either 10, 20, or 30 times based on the taste threshold assigned during the threshold screening test. Be careful not to spray the aerosol onto the hood, respirator, or into the eyes. To produce the aerosol, grip the bulb in the palm of the hand (not fingers only) and firmly squeeze the nebulizer bulb so that it collapses completely. Then release it and allow it to fully expand. Maintain the nebulizer in an upright (vertical) position when spraying the aerosol.

   Note: Determine that the nebulizer is working by observing that a visible mist is produced throughout the test.

e. Instruct the person to begin the series of test exercises according to Clause 9.
f. Replenish the concentration in the hood every 30 seconds by adding half the original number of squeezes (5, 10, or 15).
g. The person fails the fit test if they report tasting Bitrex™ at any time while conducting the test exercises. At this point a decision must be made, either to retest or select another respirator according to Clause 6. In either case the entire procedure must be repeated (taste threshold screening and fit testing). It may take several minutes for the person being fit tested to regain the ability to taste low concentrations of Bitrex™. Rinsing the mouth out with plain water and wiping the lips with a wet towel may help. Do not repeat this test until the person being fit tested successfully completes the taste threshold screening test again;
h. If the person being fit tested does not report tasting Bitrex™, instruct them to reach into the hood and momentarily break the respirator seal while inhaling through their mouth. If the bitter taste is not detected after breaking the respirator seal, the test is null and void and the reason why the person did not taste the Bitrex™ must be identified. If the bitter taste is detected after breaking the seal, the test is valid and the person passes the fit test;
i. A person who passes the Bitrex™ test is assumed to have a fit factor of at least 100.

9 Fit Test Exercises

Exercises are performed during a fit test to simulate the movements that occur during respirator use.

9.1 Duration of Fit Test Exercises

Each fit test exercise shall be at least 30 seconds in duration, unless otherwise specified in Table II.

9.2 Required and Elective Exercises

Table I lists the required and elective exercises for each type of fit test method. At least one elective exercise is to be performed along with the required exercises. Table II describes how the required and elective exercises are to be performed. Additional elective and/or optional exercises can be performed, if desired.

9.3 Optional Exercises

Table II also provides examples of optional exercises that could be added, if desired.

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10 Record Keeping

Fit test records shall be kept in a manner consistent with current legal requirements and company policies.

10.1 Fit Test Records

The records should include the following:

a. Name and/or identification number of respirator user;
b. Test date;
c. Name of the person who conducted the test;
d. Name of the fit test method and exercises used:
e. For quantitative tests, record the fit factor and indication of pass or fail;
f. For qualitative tests, record an indication of pass or fail;
g. Make, model, style, size, and other pertinent information (e.g., facepiece material, type of straps, etc.);
h. Fit test expiration date or next test due date;
i. Other factors such as, safety equipment worn during the test(s), e.g., hard hat, eye wear, etc.; and
j. If fit test certification cards are issued, they shall contain as a minimum the person's name; make, model, style, and size facepiece(s) permitted to be used; and fit test expiration date.

Note: It may be desirable for some programs to maintain records of unsuccessful fit tests.

10.2 Equipment Records

The equipment records should include the following:

a. Test equipment used;
b. Where applicable, identify the equipment model and serial number;
c. Test equipment maintenance, repair, and calibration records; and
d. A copy of the equipment manual(s) for fit testing instrument(s).

10.3 Training Records of Fit Test operators

The training records of the person conducting the fit test should include.

a. Name;
b. Training date;
c. Training content; and
d. Method of instruction (for example workshop, seminar, etc.).

Table I Required and Elective Fit Test Exercises

Test Method	Normal Breathing	Deep Breathing	Side to Side	Up & Down	Re-don/ follow NB	Bending Over	Talking	Jog in Place	Stepping	Grimace & Normal Breathing	Vigorous head shake
Generated aerosol or particle counting	Req.	Req.	Req.	Req.	Elect.	Req.	Req.	Elect.	Elect.	Elect.	Elect.
Controlled negative pressure	Req.	Elect.	Elect.[1]	Elect.[1]	Req.*	Req.	N/A	N/A	Elect.	Elect.	Req.
Sodium saccharin, Bitrex™, or IAA	Req.	Req.	Req.	Req.	N/A	Elect.	Req.	Elect.	Elect.	N/A	Elect.

Perform all required and at least one elective exercise for any fit test method.
[1] Requires two measurements.
Req. = Required Exercise
Elect. = Elective Exercise
N/A = Not Applicable
* One re-donning is required for CNP. A second re-donning can be used as an elective exercise

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Table II Exercise Description

This table describes the required and elective exercises in Table I. Exercises can be conducted in the sitting or standing position. It also shows examples of other job specific exercises that may be added if desired.

For controlled negative pressure where measurement of a fit factor cannot be done during the exercise, static fit factors shall be measured at the end of the exercise. For example, in the side to side exercise, the head is moved side to side for 30 seconds. Fit factors are then measured with the head facing left and right.

Exercise	Description
Normal breathing	The person shall breathe normally, without talking.
Deep breathing	The person shall breathe deeply at a comfortable pace with no head movement.
Side to side	The person shall turn the head from side to side, pausing at each extreme position for two breath's duration. Warn the person not to bump the respirator or filters/cartridges on the shoulder. For controlled negative pressure, one measurement is made at each extreme position.
Up and down	The person shall move the head up and down, pausing at each extreme position for two breath's duration. Warn the person not to bump the respirator or filters/cartridges on the chest. For controlled negative pressure, one measurement is made at each extreme position.
Re-don followed by normal breathing	The fit factor is measured after the person loosens all straps and completely removes the respirator from the head and dons it again as trained.
Bending over	The person shall bend at the waist, and try to keep the head and back parallel to the floor. Repeat the movement at a comfortable pace pausing long enough to inhale twice at each extreme position. For controlled negative pressure the measurement is made while in the bent position.
Talking	The person shall speak loudly enough to be heard by the person who conducts the test. A person may count, recite letters of the alphabet, chat, or read a prepared passage such as the one below.
Jogging in place	The person shall jog in place comfortably.
Stepping	The person shall continuously step up and down at a comfortable pace using a platform that is approximately 6 inches (15 cm) in height.
Grimace and normal breathing	This elective exercise is used for QNFT only. The person shall grimace for approximately 15 seconds followed by the normal breathing exercise. The grimace is an attempt to break the seal of the respirator to the face by smiling or frowning. The purpose is to determine if the respirator reseals itself to the face. The fit factor for the grimace portion of this exercise is excluded from the calculation of the overall fit factor.
Vigorous head Shake	The person shall shake the head vigorously from side to side while making a "BRRRR" sound loudly. This exercise shall be performed for at least one exhalation and may be less than 30 seconds in duration.
Examples of Optional Exercises	
Abrasive blasting	The person shall hold a rod in both hands, and slowly swing the arms from side to side in a fashion similar to a blaster's movements.
Job specific	The person shall move in a fashion that simulates a specific work activity. The abrasive blasting exercise is an example of a job specific exercise.

Suggested passage for reading during the talking exercise.

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.

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Annex A1: Evaluation Form for Respirator Fit Test Operator

Name of operator evaluated: _____ Date: _____

Fit test method: _____

Evaluated by (program administrator or designee): _____

Demonstration of knowledge and performance	Acceptable	Not Acceptable
5.2.2 Demonstrates knowledge of respirators to be fit tested:		
– Respirator components and their function.	❑	❑
– Respirator inspection, cleaning, and maintenance.	❑	❑
– Different make, model, style, & size respirators.	❑	❑
– Respirator capabilities and limitations as related to respirator fit testing.	❑	❑
– Proper donning and doffing procedures including user seal checks.	❑	❑
5.2.3 Demonstrates knowledge of the fit test method:		
– Purpose of respirator fit testing.	❑	❑
– Fit test procedures.	❑	❑
– Limitations of the fit test method.	❑	❑
– Questionable fit test results.	❑	❑
– Health and safety hazards associated with the chemicals and equipment used in the fit test.	❑	❑
5.2.4 Demonstrates ability to set up fit test equipment:		
– Selection of proper cartridges or filters for the fit test method.	❑	❑
– Preparation of required equipment and materials.	❑	❑
– Performance of operational checks.	❑	❑
– Proper installation of probes or fit test adapters used in quantitative fit test methods.	❑	❑
5.2.5 Demonstrates the ability to conduct the respirator fit test:		
– When to refuse to conduct a fit test.	❑	❑
– Explanation of fit test purpose and procedures to person being fit tested.	❑	❑
– Observation and evaluation of unassisted donning procedure.	❑	❑
– Observation that user seal checks are performed according to manufacturer's recommended procedures.	❑	❑
– Observes the person being fit tested throughout the entire fit test procedure to ensure it is conducted correctly.	❑	❑
– Conducts the fit test method according to ANSI Z88.10.	❑	❑
– Properly interprets and records results.	❑	❑
– Performs respirator cleaning, sanitizing, or disposal.	❑	❑
5.2.6 Identifies likely causes of fit test failure.	❑	❑

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