Fit testing can be performed using either a quantitative or qualitative method:

Quantitative fit testing is conducted by utilizing a Porta Count electronic device. The Porta Count fit testing device determines the fit factor based on the ratio of particle concentrations outside the respirator versus inside the respirator. Tubing connected to the respirator facepiece measures the particle concentration inside the facepiece while the ambient particle concentration outside the respirator is simultaneously measured by the Porta Count fit testing device.

Qualitative fit testing determines fit by relying on the user to identify a test agent to indicate improper fit. This method uses a gustatory (taste) test to indicate penetration or leakage of particles inside a fit testing hood. Prior to the fit test, applicants are tested for the sensitivity to the non-toxic test agent to ensure valid test results. Either Saccharin or Britrix (denatonium benzoate) are used for the test aerosol. Once users have verified sensitivity to the agent, both the respirator and fit testing hood are donned. The hood is filled with a high concentration of aerosolized test agent and a successful test is indicated if the user cannot taste the agent while wearing the respirator.

MSU EH&S conducts fit testing for respirator users using the following procedures:

A. General Requirements

1. The individual is allowed to pick the most acceptable respirator from a sufficient number of respirator models and sizes so that the respirator is acceptable to, and correctly fits, the user.

2. Prior to the selection process, the individual will be shown how to put on a respirator, how it should be positioned on the face, how to set strap tension, and how to determine an acceptable fit. A mirror will be available to assist the individual in evaluating the fit and positioning of the respirator. This instruction will not constitute the individual's formal training on respirator use, because it is only a review.

3. The individual will be informed that he or she is being asked to select the respirator that provides the most acceptable fit. Each respirator represents a different size and shape, and if fitted and used properly, will provide adequate protection.

4. The individual will be instructed to hold each chosen face-piece up to their face and eliminate those that obviously do not give an acceptable fit.

5. The more acceptable face-pieces are noted in case the one selected proves unacceptable. The most comfortable mask is donned and worn at least 5 minutes to assess comfort. Assistance in assessing comfort can be given by discussing the points in #6. If the individual is not familiar with using a particular respirator, the individual will be directed to don the mask several times and to adjust the straps each time to become adept at setting proper tension on the straps.

6. Assessment of comfort will include a review of the following points with the individual and allowing the individual adequate time to determine the comfort of the respirator:

    a. Position the mask on the nose
    b. Room for eye protection
    c. Room to talk
    d. Position of mask on face and cheeks

7. The following criteria will be used to help determine the adequacy of the respirator fit:

    a. Chin properly placed
    b. Adequate strap tension, not overly tightened
    c. Fit across nose-bridge
    d. Respirator of proper size to span distance from nose to chin
    e. Tendency of respirator to slip
    f. Self-observation in mirror to evaluate fit and respirator position

8. The individual will conduct a user seal check, by both negative and positive pressure seal checks as recommended by the respirator manufacturer. Before conducting the negative and pressure seal checks, the individual will be told to seat the mask on the face by moving the head from side-to-side and up and down slowly while taking in a few slow deep breaths. Another face-piece will be selected and retested if the individual fails the user seal check tests.

9. The fit test will not be conducted if there is any hair growth between the skin and the face-piece sealing surface, such as stubble beard growth, beard, mustache, or sideburns which cross the respirator sealing surface. Any type of apparel that interferes with a satisfactory fit must be altered or removed.

10. If an individual exhibits difficulty in breathing during the fit test, he or she will be referred to a licensed medical professional, as appropriate, to re-determine whether the individual can wear a respirator while performing his or her duties.

11. If the individual finds the fit of the respirator unacceptable, the individual will be given the opportunity to select a different respirator and will be retested.

12. Exercise Regimen: Prior to commencement of the fit test, the individual will be given a description of the fit test and the individual's responsibilities during the test procedure. The description of the process will include a description of the test exercises that the individual will be performing. The respirator to be tested will be worn for at least 5 minutes before the starting of the fit testing.

13. The fit test will be performed while the individual is wearing any applicable safety equipment that may be worn during actual respirator use that could interfere with the respirator fit.

14. Test Exercise: The following test exercises are to be performed for all fit testing methods described herein, except for the CNP method. A separate fit testing exercise regiment is contained in the CNP protocol. The individual will perform exercises, in the test environment, in the following manner:

    1) Normal Breathing: In a normal standing position, without talking, the individual will breathe normal.

    2) Deep Breathing: In a normal standing position, the individual will breathe slow and deep, taking caution so as not to hyperventilate.

    3) Turning Head Side to Side: Standing in place, the individual will slowly turn his or her head from side to side between the extreme positions on each side. The head will be held at each extreme position momentarily so that the individual can inhale at each side.

    4) Moving Head Up and Down: Standing in place, the individual will slowing move his or her head up and down. The individual will be instructed to inhale in the up position (i.e., when looking toward the ceiling).

5) Talking: The individual will talk out loud slowly and loud enough so as to be heard clearly by the test conductor. The individual 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 from 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 find 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 individual will grimace by smiling or frowning. (This applies only to QNFT testing; it is not performed for the QLFT.)

7) Bending Over: The individual will bend at the waist as if he or she were to touch his or her toes. Jogging in place will be substitutes for this exercise in those test environments such as shroud type QNFT or QLFT units that do not permit bending over at the waist.

8) Normal Breathing: Same as exercise #1.

14. (Cont.) Each test exercise will be performed for 1 minute except for the grimace exercise which will be performed for 15 seconds. The individual will be questioned by the test conductor regarding the comfort of the respirator upon completion of the testing. If it has become unacceptable, another model of respirator will be tried. The respirator will not be adjusted once the fit test exercise begins. Any adjustments voids the test, and the fit test must be repeated.

B. Qualitative Fit Test (QLFT) Protocols

1. General

a) The employer will ensure that the persons administering the QLFT are able to prepare test solutions, calibrate equipment, perform tests properly, recognize invalid tests, and ensure that test equipment is in proper working order.

b) The employer will ensure that the QLFT equipment is kept clean and well maintained so as to operate within the parameters for which it was designed.

2. Isoamyl Acetate Protocol

Note: This protocol is not appropriate to use for fit testing of particulate respirators. If used to fit test particulate respirators, the respirator must be equipped with an organic vapor filter.

a) Odor Threshold Screening: Performed without wearing a respirator and intended to determine if the individual tested can detect the odor of isoamyl acetate at low levels.

1) Three [1-liter] glass jars with lids are required.

2) Odor-free water (e.g., distilled or spring water) at approximately 25°C (77°F) must be used for the solution.

4) The isoamyl acetate (IAA) (also known as isopentyl acetate) stock solution is prepared by adding 1 ml of pure IAA to 800 ml of odor-free water in a 1-liter jar, closing the lid and shaking or 30 seconds. A new solution shall be prepared at least weekly.

5) The screening test will be conducted in a room separate from the room used for the actual fit testing. The two rooms must be well ventilated to prevent the odor of IAA from beginning evident in the general room air where testing takes place.

6) The odor test solution is prepared in a second jay by placing 0.4 ml of the stock solution into 500 ml of odor-free water using a clean dropper or pipette. The solution must be shaken for 30 seconds and allowed to stand for 2 to 3 minutes so that the IAA concentration above the liquid may reach equilibrium. This solution must only be used for one day.

7) A test blank will be prepared in a third jar by adding 500 cc of odor-free water.

8) The odor test and test blank jar lids will be labeled (e.g., 1 and 2) for identification. Labels will be placed on the lids so that they can be peeled off periodically and switched to maintain the integrity of the test.

9) The following instruction will be typed on a card and placed on the table in front of the two test jars:

> "The purpose of this test is to determine if you can smell banana oil at a low concentration. The two bottles in front of you contain water. One of these bottles also contains a small amount of banana oil. Be sure the covers are on tight, then shake each bottle for 2 seconds. Unscrew the lid of each bottle, one at a time, and sniff at the mouth of the bottle. Indicate to the test conductor which bottle contains banana oil."

i) The mixtures used in the IAA odor detection test will be prepared in an area separate from where the test is performed, in order to prevent olfactory fatigue in the individual.

j) If the individual is unable to correctly identify the jar containing the odor test solution, the IAA qualitative fit test must not be performed.

k) If the individual correctly identifies the jar containing the odor test solution, the individual may proceed to respirator selection and fit testing.

b) <u>Isoamyl Acetate Fit Test</u>

1) The fit test chamber will be a clear 55-gallon drum liner suspended inverted over a 2-foot diameter frame so that the top of the chamber is about 6-inches above the individual's head. If no drum liner is available, a similar chamber will have a small hook attached.

2) Each respirator used for the fitting and fit testing will be equipped with organic vapor cartridges or offer protection against organic vapors.

3) After selecting, donning, and properly adjusting a respirator, the individual will wear it to the fit testing room. This room will be separate from the room used for odor threshold screening and respirator selection, and will be well ventilated, as by an exhaust fan or lab hood, to prevent general room contamination.

4) A copy of the test exercises and any prepared text from which the individual is to read will be taped to the inside of the test chamber.

5) Upon entering the test chamber, the individual will be given a 6-inch by 5-inch piece of paper towel, or other porous, absorbent, single-ply material, folded in half and wetted with 0.75 ml of pure IAA. The individual will hang the wet towel on the hook at the top of the chamber. An IAA test swab or ampule may be substituted for the IAA wetted paper towel provided it has been demonstrated that the alternative IAA source will generate an IAA test atmosphere with a concentration equivalent to that generated by the paper towel method.

6) Allow 2 minutes for the IAA test concentrations to stabilize before starting the fit test exercises. This would be an appropriate time to talk with the individual, to explain the fit test or the importance of his or her cooperation, and the purpose for the test exercises or to demonstrate some of the exercises.

7) If at any time during the fit test, the individual detects the banana-like odor of IAA, the test has failed. The individual must quickly exit the test chamber and leave the test area to avoid olfactory fatigue.

8) If the test has failed, the individual will return to the selection room and remove the respirator. The individual will repeat the odor sensitivity test, select and put on another respirator, return to the test area and again begin the fit test procedure described in 1 through 7 listed above. The process continues until a respirator that fits well has been found. Should the odor sensitivity test fail, the individual must wait at least 5 minutes before retesting. Odor sensitivity will usually have returned by this time.

9) If the individual passes the test, the efficiency of the test procedure will be demonstrated by having the subject break the respirator face seal and take a breath before exiting the test chamber.

10) When the individual leave the chamber, the individual will remove the saturated towel and return it to the person conducting the test, so that there is no significant IAA concentration building in the chamber during subsequent tests. The used towels will be kept in a self-sealing plastic bag to keep the test area from being contaminated.

3. Saccharin Solution Aerosol Protocol

The entire screening and testing procedure will be explained to the individual prior to the conduct of the screening test.

a) Taste Threshold Screening: The saccharin taste threshold screening, performed without wearing a respirator, is intended to determine whether the individual being tested can detect the taste of saccharin.

1) During threshold screening, as well as during fit testing, individuals will wear an enclosure 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.

2) The test enclosure shall have a ¾-inch (1.9 cm) hole in the front of the individual's nose and mouth area to accommodate the nebulizer nozzle.

3) The individual will don the test enclosure. Throughout the threshold-screening test, the individual will breathe through his or her slightly open mouth with tongue extended. The individual is instructed to report when he or she detects a sweet taste.

4) Using a DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent, the test conductor will spray the threshold check solution into the enclosure. The nozzle is directed away from the nose and mouth of the individual. This nebulizer will be clearly marked to distinguish it from the fit test solution nebulizer.

5) The threshold check solution is prepared by dissolving 0.83 grams of sodium saccharin USP in 100 ml of warm water. It can be prepared by putting 1 ml of the fit test solution in 100 ml of distilled water.

6) To produce the aerosol, the nebulizer bulb is firmly squeezed so that it collapses completely, then released and allowed to fully expand.

7) Ten (10) squeezes are repeated rapidly and then the test subject is asked whether the saccharin can be tested. If the individual reports tasting the sweet taste during the 10 squeezes, the screening test is completed. The taste threshold is noted as 10 regardless of the number of squeezes actually completed.

8) If the first response is negative, 10 more squeezes are repeated rapidly, and the individual is again asked whether the saccharin is tasted. If the individual reports tasting the sweet taste during the second 10 squeezes, the screening test is completed. The taste threshold is noted as 20 regardless of the number of squeezes actually completed.

9) If the second response if negative, 10 more squeezes are repeated rapidly, and the individual is again asked whether the saccharin is tasted. If the individual reports tasting the sweet taste during the third set of 10 squeezes, the screening test is completed. The taste threshold is noted as 30 squeezes actually completed.

10) The test conductor will take note of the number of squeezes of required to solicit a taste response.

11) If the saccharin is not tasted after 30 squeezes, the individual is unable to taste saccharin and may not perform the saccharin fit test.

12) If a taste response is elicited, the individual will be asked to take note of the taste for reference in the fit test.

13) Correct use of the nebulizer means that approximately 1 ml of liquid is used at a time in the nebulizer body.

14) The nebulizer will be thoroughly rinsed in water, shaken dry, and refilled at least each morning and afternoon or at least every 4 hours.

b) <u>Saccharin Solution Aerosol Fit Test</u>

1) The individual may not eat, drink (except plain water), smoke, or chew gum for 15 minutes before the test.

2) The fit test uses the same enclosure as for the threshold screening.

3) The individual will don the enclosure while wearing the selected respirator. The respirator will be properly adjusted and equipped with a particulate filter(s).

4) A second DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent is used to spray the fit test solution into the enclosure. This nebulizer will be clearly marked to distinguish it from the screening test solution nebulizer.

5) The fit test solution is prepared by adding 83 grams of sodium saccharin to 100 ml of warm water.

6) As before, the individual will breathe through the slightly open mouth with tongue extended, and report if he or she tastes the sweet taste of saccharin.

7) The nebulizer is inserted into the hole in the front of the enclosure and an initial concentration of saccharin 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.

8) After generating the aerosol, the individual will be instructed to perform the general exercises described above.

9) Every 30 seconds the aerosol concentration will be replenished using half of the original number of squeeze used initially (e.g., 5, 10, or 15).

10) The individual will indicate to the test conductor if at any time during the fit test the taste of saccharin is detected. If the individual does not report tasting the saccharin, the individual passed the fit testing.

11) If the taste of saccharin is detected, the fit is deemed unsatisfactory and the fit test failed. A different respirator will be tried, and the entire fit test procedure is repeated (taste threshold screening and fit testing).

12) Since the nebulizer has a tendency to clog during use, the test operator will make periodic checks of the nebulizer to ensure that it is not clogged. If clogging is found at the end of the fit testing session, the fit test is invalid.

4. BitrexTM (Denatonium Benzoate) Solution Aerosol Qualitative Fit Test Protocol

This QLFT protocol uses the saccharin test protocol because that protocol is widely accepted. Bitrex is routinely used as a taste aversion agent in household liquids and is endorsed by the American Medical Association, the National Safety Council, and the American Association of Poison Control Centers. The entire screening and testing procedure will be explained to the individual prior to the conduct of the screening test.

a) Taste Threshold Screening: Performed without wearing a respirator and intended to determine whether the individual being tested can detect the taste of Bitrex.

1) During threshold screening as well as during fit testing, individuals will wear an enclosure about the head and shoulders that is approximately 12-inches in diameter by 14-inches tall. The front portion of the enclosure will be clear from the respirator and allow free movement 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.

2) The test enclosure will have a ¾ inch hole in front of the individual's nose and mouth area to accommodate the nebulizer nozzle.

3) The individual will don the test enclosure. Throughout the threshold-screening, the individual will breathe through his or her slightly open mouth with their tongue extended. The individual is instructed to report when he or she detects a bitter taste.

4) Using a DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent, the test conductor will spray the Threshold Check Solution into the enclosure. This nebulizer will be clearly marked to distinguish it from the test solution nebulizer.

5) The Threshold Check Solution is prepared by adding 13.5 milligrams of Bitrex to 100 ml of 5% salt (NaCl) solution in distill water.

6) To produce the aerosol, the nebulizer bulb is firmly squeezed so that the bulb collapses completely and is then released and allowed to fully expand.

7) An initial 10 squeezes are repeated rapidly and then the individual is asked whether the Bitrex can be tasted. If the individual reports tasting the bitter taste during the 10 squeezes, the screening test is completed. The taste threshold is noted as 10 regardless of the number of squeezes actually completed.

8) If the first response is negative, 10 more squeezes are repeated rapidly, and the individual is again asked whether the Bitrex is tasted. If the individual reports tasting the bitter taste during the second 10 squeezes, the screening test is completed. The taste threshold is noted as 20 regardless of the number of squeezes actually completed.

9) If the second response is negative, 10 more squeezes are repeated rapidly and the individual is again asked whether the Britex is tasted. If the individual reports tasting the bitter taste during the third set of 10 squeezes, the screening test is completed. The taste threshold is noted as 30 regardless of the number of squeezes actually completed.

10) The test conductor will take note of the number of squeezes required to solicit a taste response.

11) If the Bitrex is not tasted after 30 squeezes, the individual is unable to taste Bitrex and may not perform the Bitrex fit test.

12) If a taste response elicited, the individual will be asked to take note of the taste for reference in the fit taste.

13) Correct use of the nebulizer means that approximately 1 ml of liquid is used at a time in the nebulizer body.

14) The nebulizer will be thoroughly rinsed in water, shaken to dry, and refilled at least each morning and afternoon or at least every four hours.

b) <u>Bitrex Solution Aerosol Fit Test Procedure</u>

1) The individual may not eat, drink (except plain water), smoke, or chew gum for 15 minutes before the test.

2) The fit test uses the same enclosure as that described above.

3) The individual will don the enclosure while wearing the selected respirator. The respirator will be properly adjusted and equipped with any type of particulate filter(s).

4) A second DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent is used to spray the fit test solution into the enclosure. This nebulizer will be clearly marked to distinguish it from the screening test solution nebulizer.

5) The fit test solution is prepared b adding 337.5 mg of Bitrex to 200 ml of 5% salt (NaCl) solution in warm water.

6) As before, the individual will breathe through his or her slightly open mouth with their tongue extended and be instructed to report if he or she tastes the bitter taste of Bitrex.

7) The nebulizer is inserted into the hole in the front of the enclosure and an initial concentration of the fit test solution is sprayed into the enclosure using the same number of squeezes (10, 20, or 30 squeezes) based on the number of squeezes required to elicit a taste response as noted during the screening test.

8) After generating the aerosol, the individual will be instructed to perform the general exercises described above.

9) Every 30 seconds the aerosol concentrations shall be replenished using ½ of the number of squeezes (e.g., 5, 10, 15).

10) The individual will indicate to the test conductor if at any time during the fit test the taste of Bitrex is detected. If the individual does not report tasting the Bitrex, the individual passed the fit testing.

11) If the taste of Bitrex is detected, the fit is deemed unsatisfactory, and the fit test failed. A different respirator will be tried, and the entire test procedure is repeated (taste threshold screening and fit testing).

5. Irritant Smoke (Stannic Chloride) Protocol

This qualitative fit test uses an individual's response to the irritating chemicals released in the "smoke" produced by a stannic chloride ventilation smoke tube to detect leakage into the respirator.

a) General Requirements and Precautions

1) The respirator to be tested will be equipped with a high efficiency particulate air (HEPA) or P100 series filter(s).

2) Only stannic chloride smoke tubes must be used for this protocol.

3) No form of test enclosure or hood for the individual will be used.

4) The smoke can be irritating to the eyes, lungs, and nasal passages. The test conductor must take precautions to minimize the exposure to irritant smoke. Sensitivity varies, and certain individuals may respond to a greater degree to irritant smoke. Care must be taken when performing the sensitivity screening checks that determine whether the test subject can detect irritant smoke to use only the minimum amount of smoke necessary to elicit a response from the individual.

5) The fit test must be performed in an area with adequate ventilation to prevent exposure of the person conducting the fit test or the build-up of irritant smoke in the general atmosphere.

b) Sensitivity Screening Check

The person to be tested must demonstrate his or her ability to detect a weak concentration of the irritant smoke.

1) The test operator will break both ends of a ventilation smoke tube containing stannic chloride and attach one end of the smoke tube to a low flow air pump set to deliver 200 milliliters per minute, or an aspirator squeeze bulb. The test operator will cover the other end of the smoke tube with a short piece of tubing to prevent potential injury from the jagged end of the smoke tube.

2) The test operator will advise the test subject that the smoke can be irritating to the eyes, lungs, and nasal passages and instruct the subject to keep his or her eyes closed while the test is performed.

3) The individual will be allowed to smell a weak concentration of irritant smoke before the respirator is donned to become familiar with its irritating properties and to determine if he or she can detect the irritating properties of the smoke. The test operator will carefully direct a small amount of the irritant smoke in the individual's direction to determine that he or she can detect it.

c) Irritant Smoke Fit Test Procedure

1) The individual being fit tested will don the respirator without assistance and perform the required user seal check(s).

2) The individual will be instructed to keep his or her eyes closed.

3) The test operator will direct the stream of the irritant smoke from the smoke tube toward the face-seal area of the individual, using the low flow pump or the squeeze bulb. The test operator will begin at least 12-inches from the face-piece and move the smoke stream around the whole perimeter of the mask. The operator will gradually make 2 more passes around the perimeter of the mask, moving to within 6-inches of the respirator.

4) If the individual being tested has not had an involuntary response and/or detects the irritant smoke, proceed with the test exercises.

5) The general exercises identified previously will be performed by the individual while the respirator seal is being continually challenged by the smoke, directed around the perimeter of the respirator at a distance of 6-inches.

6) If the individual being fit tested reports detecting the irritant smoke at any time, the fit test failed. The individual being retested must repeat the entire sensitivity check and fit test procedure.

7) Each individual passing the irritant smoke test without evidence of a response (involuntary cough, irritation) will be given a second sensitivity screening check, with the smoke from the same smoke tube used during the fit test, once the respirator has been removed, to determine whether he or she still reacts to the smoke. Failure to evoke a response must void the fit test.

8) If a response is produced during this second sensitivity check, then the fit test is passed.

C. Quantitative Fit (QNFT) Protocols

The following quantitative fit testing procedures have been demonstrated to be acceptable: Quantitative fit testing using a non-hazardous test aerosol (such as corn oil, polyethylene glycol 400 [PEG 400], di-2-ethyl hexyl sebacate [DEHS], or sodium chloride) generated in a test chamber, and employing instrumentation to quantify the fit of the respirator; Quantitative fit testing using ambient aerosol as the test agent and appropriate instrumentation (condensation nuclei counter) to quantify the respirator fit; Quantitative fit testing using controlled negative pressure and appropriate instrumentation to measure the volumetric leak rate of face-piece to quantify the respirator fit.

1. General

a) MSU will ensure that persons administering QFNT are able to calibrate the equipment and perform tests properly, recognize invalid tests, calculate fit factors properly and ensure that test equipment is in proper working order.

b) MSU will ensure that QNFT equipment is kept clean and is maintained and calibrated according to the manufacturer's instructions so as to operate at the parameters for which it was designed.

2. Generated Aerosol Quantitative Fit Testing Protocol

a) Apparatus

1) Instrumentation – Aerosol generation, dilution, and measurement systems using particulates (corn oil, polyethylene glycol 400 [PEG 400], di-2-ethyl hexyl sebacate [DEHS] or sodium chloride) as test aerosols will be used for quantitative fit testing.

2) Test Chamber – will be large enough to permit all individuals to perform freely all required exercises without disturbing the test agent concentrations or the measurement apparatus. The test chamber will be equipped and constructed so that the test agent is effectively isolated from the ambient air, yet uniform in concentrations throughout the chamber.

3) When testing air-purifying respirators, the normal filter or cartridge element will be replaced with a high efficiency particulate air (HEPA) or P-100 series filter supplied by the same manufacturer.

4) The sampling instrument will be selected so that a computer record or strip chart record may be made of the test showing the rise and fall of the test agent concentration with each inspiration and expiration at fit factors of at least 2,000. Integrators or computers that integrate the amount of test agent penetration leakage into the respirator for each exercise may be used provided a record of the readings is made.

5) The combination of substitute air-purifying elements, test agent and concentration will be such that the individual is not exposed in excess of an established exposure limit for the test agent at any time during the testing process, based upon the length of the exposure and the exposure limit duration.

6) The sampling port on the test specimen respirator will be placed and constructed so that no leakage occurs around the port (e.g., where the respirator is probed), a free air flow is allowed into the sampling line at all times, and there is no interference with the fit or performance of the respirator. The in-mask sampling device (probe) will be designed and used so that air sample is drawn from the individual's breathing zone, midway between the nose and mouth and with the probe extending into the face-piece cavity at least ¼-inch.

7) The test setup will permit the person administrating the test to observe the individual inside the chamber during the test.

8) The equipment generating the test atmosphere will maintain the concentration of the test agent constant to within 10% variation for the duration of the test.

9) The time lag (interval between an event and the recording of the event on the strip chart or computer or integrator) must be kept to a minimum. There has to be a clear association between the occurrence of an event and its being recorded.

10) The sampling line tube for the test chamber atmosphere and for the respirator sampling port will be of equal diameter and of the same material. The length of the two lines will be equal.

11) The exhaust flow from the test chamber will pass through an appropriate filter (i.e., high efficiency particulate filter) before release.

12) When sodium chloride aerosol is used, the relative humidity inside the test chamber will not exceed 50%.

13) The limitations of instrument detection will be taken into account when determining the fit factor.

14) Test respirators will be maintained in proper working order and be inspected regularly for deficiencies such as cracks or missing valves and gaskets.

b) Procedure Requirements

1) When performing the initial user seal check using a positive or negative pressure check, the sampling line will be crimped closed in order to avoid air pressure leakage during either of these pressure check.

2) The use of an abbreviated screening QLFT test is optional. Such a test may be utilized in order to quickly identify poor fitting respirator that passed the positive or negative pressure test and reduce the amount of QNFT time. The use of CNC QNFT instrument in the count mode is another optional method to obtain a quick estimate of fit and eliminate poor fitting respirators before going on to perform a full QNFT.

3) A reasonably stable test agent concentration will be measured in the test chamber prior to testing. For canopy or shower curtain types of test units, the determination of the test agent's stability may be established after the individual has entered the test environment.

4) Immediately after the individual enters the test chambers, the test agent concentration inside the respirator will be measured to ensure that the peak penetration does not exceed 5% for a half mask or 1% for a full face-piece respirator.

5) A stable test agent concentration will be obtained prior to the actual start of testing.

6) Respirator restraining straps will not be over-tightened for testing. The straps will be adjusted by the individual without assistance from other persons to give a reasonably comfortable fit typical of normal use.

7) The test will be terminated whenever any single peak penetration exceeds 5% for half masks and 1% for full face-piece respirators. The test subject will be refitted and retested.

8) Calculations of fit factors:

i. The fit factor will be determined for the quantitative fit test by taking the ratio of the average chamber concentration to the concentration measured inside the respirator for each test exercise except the grimace exercise.

ii. The average test chamber concentration will be calculated as the arithmetic average of the concentration measured before and after each test (i.e., 7 exercises) or the arithmetic average of the concentration measured before and after each exercise or the true average measured continuously during the respirator sample.

iii. The concentration of the challenge agent inside the respirator will be determined by one of the following methods:

A. Average peak penetration method means the method of determining test agent penetration into the respirator utilizing a strip chart recorder, integrator, or computer. The agent penetration is determined by an average of the peak heights on the graph or by computer integration, for each exercise except the grimace exercise. Integrators or computers that calculate the actual test agent penetration into the respirator for each exercise will also be considered to meet the requirements of the average peak penetration method.

B. Maximum peak penetration means of determining test agent penetration in the respirator as determined by strip chart recording of the test. The highest peak penetration for a given exercise is taken to be representative of average penetration into the respirator for that exercise.

C. Integration by calculation of the area under the individual peak for each exercise except the grimace exercise. This includes computerized integration.

D. The calculation of the overall fit factor using individual exercise fit factors involves first converting the exercise fit factors to penetration values, determining the average, and then converting that result back to a fit factor. This procedure is described in the following equation:

Where ff1, ff2, ff3, etc. are the fit factors for exercises 1, 2, 3, etc.

9) The individual will not be permitted to wear a half mask or quarter face-piece respirator unless a minimum fit factor of 100 if obtained, or a fill face-piece respirator unless a minimum fit factor of 500 is obtained.

10) Filters used for quantitative fit testing will be replaced whenever increased breathing resistance is encountered, or when the test agent has altered the integrity of the filter media.

3. Ambient Aerosol Condensation Nuclei Counter (CNC) Quantitative Fit Testing Protocol

The ambient aerosol CNC quantitative fit testing (Portacount TM) protocol quantitatively fit test respirators with the use of a probe. The probed respirator is only used for quantitative fit tests. A probed respirator has a special sampling device, installed on the respirator, that allows the probe to sample the air from inside the mask.

A probed respirator is required for each make, style, model, and size that are used and can be obtained from the respirator manufacturer or distributor. The CNC instrument manufacturer, TSI Inc., also provides probe attachments (TSI sampling adapters) that permit fit testing an individual's own respirator.

A minimum fit factor pass level of at least 100 is necessary or a half-face respirator and a minimum fit factor pass level of at least 500 is required for a full face-piece negative pressure respirator. The entire screening and testing procedure will be explained to the individual prior to the conduct of the screening test.

a) Portacount Fit Test Requirement

1) Check the respirator to make sure the sampling probe and line are properly attached to the face-piece and that the respirator is fitted with a particulate filter capable of preventing significant penetration by the ambient particles used for the fit test (e.g., NIOSH 42 CFR 84 series 100, series 99, or series 95 particulate filter) per manufacturer's instruction.

2) Instruct the individual being fit tested to don the respirator for 5 minutes before the fit test starts. This purges the ambient particles trapped inside the respirator and permit the individual to make certain the respirator is comfortable. The individual will already have been trained on how to wear the respirator properly.

3) Check the following conditions for the adequacy of the respirator fit:

a) Chin properly placed
b) Adequate strap tension

c) Fit across nose bridge
d) Respirator of proper size to span distance from nose to chin
e) Tendency of the respirator to slip
f) Self-observation in a mirror to evaluate fit and respirator position

4) Have the individual wearing the respirator conduct a user seal check. If leakage is detected, determine the cause. If leakage is from a poorly fitting face-piece, try another size of the same mode respirator, or another model of respirator.

5) Follow the manufacturer's instructions for operating the Portacount and proceed with the test.

6) The individual will be instructed to perform the general exercise given previously.

7) After the test exercises, the individual will be questioned by the test conductor regarding the comfort of the respirator upon completion of the protocol. If it has become unacceptable, another model of respirator will be tried.

b) Protacount Test Instrument

1) The Portacount will automatically stop and calculate the overall fit factor for the entire set of exercises. The overall fit factor is what counts. The Pass or Fail message will indicate whether or not the test was successful. If the test was a Pass, the fit is over.

2) Since the pass or fail criterion of the Portacount is user programmable, the test operator must ensure that the pass or fail criterion meet the requirements for minimum respirator performance.

3) A record of the test will be kept on file, assuming the fit test was successful. The record must contain the following:

a) Individual's name
b) Overall fit factor
c) Make, model, style, and size of the respirator used
d) Date tested

3. Controlled Negative Pressure (CNP) Quantitative Fit Testing Protocol

The CNP protocol provides an alternative to aerosol fit test methods. The CNP fit test method technology is based on exhausting air from a temporarily sealed respirator face-piece to generate and then maintain a constant negative pressure inside the face-piece. The rate of air exhaust is controlled so that a constant negative pressure is maintained in the respirator during the fit test.

The level of pressure is selected to replicate the mean inspiratory pressure that causes leakage into the respirator under normal use conditions. With pressure held constant, airflow out of the respirator is equal to airflow into the respirator. Therefore, measurement of the exhaust stream that is required to hold the pressure in the temporarily sealed respirator constant yields a direct measure of leakage airflow into the respirator. The CNP fit test method measures leak rate through face-piece as a method for determining the face-piece fit for negative pressure respirators. The CNP instrument manufacturer Dynatech Nevada also provides attachments (sampling manifolds) that replace the filter cartridges to permit fit testing in the individual's own respirator.

To perform the test, the individual closes his or her mouth and holds his or her breath, after which an air pump removes air

From the respirator face-piece at a pre-selected constant pressure. The face-piece fit is expressed as the leak rate through the face-piece, expressed as milliliters per minute. The quality and validity of the CNP fit tests are determined by the degree to which the in-mask pressure tracks the test pressure during the system measurement time of approximately 5 seconds. Instantaneous feedback in the form of a real-time pressure trace of the in-mask pressure is provided and used to determine test validity and quality. A minimum fit factor pass level of 100 is necessary for a half-mask respirator and a minimum fit factor of at least 500 is required for a full face-piece respirator. The entire screening and testing procedure will be explained to the individual prior to the conduct of the screening test.

a) CNP Fit Test Requirements

1) The instrument will have a non-adjustable test pressure of 15.0 mm water pressure.

2) The CNP system defaults selected for test pressure will be set at -15 mm of water (-0.58 inches of water) and the modeled inspiratory flow rate shall be 53.8 liter per minute for performing fit tests.

(NOTE: CNP systems have built-in capability to conduct fit testing that is specific to unique work rate, mask, and gender situations that might apply in a specific workplace. Use of system default values, which were selected to represent respirator wear with medium cartridge resistance at low-moderate work rate, will allow inter-test comparison of the respirator fit.)

3) The individual who conducts the CNP fit testing must be thoroughly trained to perform the test.

4) The respirator filter or cartridge needs to be replaced with the CNP test manifold. The inhalation valve downstream from the manifold either needs to be temporarily removed or propped open.

5) The individual will be asked to hold his or her breath for at least 20 seconds.

6) The individual will don the test respirator without any assistance from the individual who conducts the CNP fit test.

7) The QNFT protocol will be followed with an exception for the CNP test exercises.

b) CNP Test Exercises

1) Normal Breathing: In a normal standing position, without talking, the individual will breathe normally for 1 minute. After the normal breathing exercise, the individual needs to hold his or her head straight ahead and hold his or her breath for 10 seconds during the test measurement.

2) Deep Breathing: In a normal standing position, the individual will breathe slowly and deeply for 1 minute, being careful not to hyperventilate. After the deep breathing exercise, the individual will hold his or her head straight ahead and hold his or her breath for 10 seconds during the test measurement.

3) Turning Head Side to Side: Standing in place, the individual will slowly turn his or her head from side to side between the extreme positions on each side for 1 minute. The head will be held at each extreme momentarily so the individual can inhale at each side. After the turning head side to side exercise, the individual needs to hold their head full left and hold his or her breath for 10 seconds during the test measurement. Next, the individual needs to hold their head full right and hold his or her breath for 10 seconds during the test measurement.

4) Moving Head Up and Down: Standing in place, the individual will slowly move his or her head up and down for 1 minute. The individual will be instructed to inhale in the up position (i.e., when looking toward the ceiling). After moving their head up and down, the individual will hold his or her head full up and hold their breath for 10 seconds during the test measurement. Next, the individual will hold his or her full down and hold their breath for 10 seconds during the test measurement.

5) Talking: The individual will talk out loud slowly and loud enough so as to be heard clearly by the test conductor. The individual can read from a prepared text such as the "Rainbow Passage", count backward from 100, or recite a memorized poem or song for 1 minute. After the talking exercise, the individual will hold his or her head straight ahead and hold their breath for 10 seconds during the test measurement.

6) Grimace: The individual will grimace by smiling or frowning for 15 seconds.

7) Bending Over: The individual will bend at the waist as if he or she were to touch his or her toes for 1 minute. Jogging in place will be substituted for this exercise in those test environment such as shroud-type QNFT units that prohibit bending at the waist. After the bending over exercise, the individual will hold his or her head straight ahead and hold their breath for 10 seconds during the test measurement.

8) Normal Breathing: The individual will remove and re-don the respirator within a 1-minute period. Then, in a normal standing position, without talking, the individual will breathe normally for 1 minute. After the normal breathing exercise, the individual will hold his or head straight ahead and hold their breath for 10 seconds during the test measurement. After the test exercises, the individual will be questioned by the test conductor regarding the comfort of the respirator upon completion of the protocol. If it has become unacceptable, another model of a respirator will be tried.

c) CNP Test Instrument

1) The test instrument will have an effective audio warning device when the individual fails to hold his or her breath during the test. The test will be terminated whenever the individual failed to hold their breath. The individual may be refitted and retested.

2) A record of the test will be kept on file, assuming the fit test was successful. The record must contain the following:

    a) Individual's name
    b) Overall fit factor
    c) Make, model, style, and size of respirator used
    d) Date tested