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# Comparison of Six Respirator Fit-Test Methods with an Actual Measurement of Exposure in a Simulated Health Care Environment: Part II — Method Comparison Testing

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# Comparison of Six Respirator Fit-Test Methods with an Actual Measurement of Exposure in a Simulated Health Care Environment: Part II — Method Comparison Testing

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This article, the second in a series of three, describes the method comparison testing portion of a study conducted to compare the fit factors from six quantitative fit-tests (QNFT) with a measure of a respirator wearer's actual exposure assessed by end-exhaled air analysis for 1,1,2-trichloro-1,2,2-trifluoroethane (Freon-113) under the same conditions. The six QNFT methods were (1) continuous low flow, flush probe; (2) continuous high flow, deep probe (CHD); (3) exhalation valve discharge (EVD); (4) controlled negative pressure; (5) 10-minute Ambient Aerosol 1 (AA1); and (6) 30-minute Ambient Aerosol 2. The first three methods utilized corn oil and a forward light scattering photometer. The last two methods used the TSI Portacount. Respirators used in the study were both disposable and elastomeric organic vapor/high efficiency half-masks. The characterization equations from the preliminary research (described previously) were used to determine the actual exposure to Freon-113 during the method comparison testing. The fit factors resulting from the QNFT methods were then individually correlated with the Freon-113 exposures using the coefficient of determination, $R^2$. The lowest $R^2$ value, 0.20, was found with the EVD method. The highest $R^2$ values, 0.81 and 0.78, were associated, respectively, with the CHD and AA1 methods. This study suggests that some QNFT methods may be used to estimate actual respirator performance under laboratory conditions.

**Keywords: exposure measurement, fit factor, quantitative fit test, respirator, 1,1,2 trichloro-1,2,2 trifluoroethane (Freon-113), workplace protection factor**

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This is the second in a series of three articles describing a study developed to evaluate and compare the fit factors from six quantitative fit-test (QNFT) methods against an actual measure of total exposure dose measurements of 1,1,2 trichloro-1,2,2 trifluoroethane vapor (Freon-113) in end-exhaled air. The pharmacokinetic properties of Freon-113 enable the concentration inside the respirator to be determined experimentally by measuring end-exhaled air levels. Using the concentration of Freon-113 in a subject's end-exhaled air as the measure of the actual dose received eliminates or minimizes the documented biases inherent with current in-facepiece sampling techniques and hardware such as probe location and depth relative to face seal leak location,[1] particle loss,[2] and the relationship of leak sites and facial characteristics.[3,4] This article describes the method comparison testing phase of the study. The

**TABLE I. Simulated Health Care Motions**

| Motion | Duration (min) | Motion | Duration (min) |
|---|---|---|---|
| Hang IV bag | 1 | reach side to side | 2 |
| Bending | 2 | reaching overhead | 2 |
| Insert syringe into IV bag | 1 | talking aloud while sitting | 2 |
| Carrying weight | 2 | nodding and turning head | 2 |
| Twisting and turning head | 2 | reaching overhead | 1 |
| Open and close door | 1 | stand and talking aloud | 1 |
| Talking aloud | 3 | control panel motions | 1 |
| Bending | 3 | walking | 1 |
| Turning head | 2 | | |

preliminary studies (chamber characterization, end-exhaled air sampling, skin absorption testing, pharmacokinetic modeling, subject characterization) on which the protocol is based are described in a previous article.[5]

In this study 11 subjects wore half-mask respirators in a laboratory test chamber containing a known concentration of Freon-113 and corn oil aerosol. The six QNFT methods evaluated were (1) continuous high flow, deep probe (CHD); (2) continuous low flow, flush probe (CLF); (3) exhalation valve discharge (EVD); (4) controlled negative pressure (CNP); (5) Ambient Aerosol 1 (AA1), using 6 exercises with a duration of approximately 90 seconds each; and (6) Ambient Aerosol 2 (AA2), using 17 exercises and lasting 30 minutes. Fit factors for each subject were obtained with all six methods. A fit factor is a quantitative measure of the fit of a particular respirator facepiece to a particular individual. It is defined under the conditions of quantitative fit-testing as the ratio $C_{out}/C_{in}$.[6] A CNP fit factor is not computed from $C_{out}/C_{in}$ but rather is calculated from the ratio of modeled inspiratory flow and measured leakage flow rate.

The challenge with Freon-113 was conducted simultaneously with four of the QNFT methods (CHD, CLF, EVD, and AA2). The remaining two QNFT methods (AA1 and CNP) were conducted immediately after the Freon-113 exposure. Exposure to the Freon-113 was determined from concentration in the end-exhaled air measured 30 minutes after the end of the exposure. To evaluate each QNFT method, the correlation between the fit factors and the total Freon-113 exposure doses was analyzed.

The experimental approach using Freon-113 as a biological indicator of exposure and the research needed to develop the end-exhaled breath protocol has been described in a previously published article.[7] This article presents the protocol, results, and findings of the method comparison testing. A subsequent article deals with the validation testing of the QNFT method that provided fit factors having the highest correlation with the Freon-113 exposure.

## METHODS AND MATERIALS

The methods and materials for the preliminary studies have been described in detail in a previous article.[5] That article should be referred to for further detailed information on the end-exhaled air sampling, skin absorption testing, and subject characterization.

### Simulated Health Care Movements

This study employed different motions to simulate movements made by various health care workers as they perform their duties. These motions were selected based on the professional opinion of several experts in the health care industry regarding the health care workers who would be most likely exposed to patients with tuberculosis (emergency medical service personnel; emergency room clerks, clinicians, nurses, and doctors; nurses doing home health visits, and health care workers in prisons) and likely to have a positive skin test. These motions are based only on expert opinion but they are reasonable in the absence of other data. The simulated health care workplace motions are listed in Table I.

### QNFT Methods

The following six QNFT methods were evaluated by each subject during the method comparison testing.

**(1)** CHD used a corn oil aerosol (having a mass median aerodynamic diameter of 0.58 μm) with a concentration of approximately 16 mg/m³. The method of detection for the corn oil was a light scattering photometer (Dynatech Frontier Corp., model FE250A portable aerosol test system [Albuquerque, N.M.] with a Zenith Data Systems Model Z-386/20 computer [Buffalo Grove, Ill.] equipped with Laboratory Technologies Corp. LabTech Acquire Software [Wilmington, Mass.]), which could detect fit factors up to approximately 100,000. The throat and inlet of the sampling probe was located one-half to three-quarters of an inch away from the subject's mouth. The sampling flowrate was 5 L/min. In the CHD method as originally developed, the sampling flow is returned to the facepiece. In this study the flow was not returned to the facepiece. This was because the hardware necessary to return the flow is complicated and, therefore, would not be used during actual fit-testing in the field. This procedure was chosen for this study based on laboratory research on mannequins that studied the effect of different wearer-respirator parameters on the accuracy of in-facepiece sampling.[8]

**(2)** The EVD method used the same challenge aerosol and method of detection as the CHD method described above. Therefore, fit factors up to approximately 100,000 could be detected. The EVD sampling method continuously sampled the air released through the exhalation valve. This was accomplished by modifying the respirator through the incorporation of a piece of tubing (a few milliliters in volume) to the exhalation valve assembly of the respirator. A second exhalation valve was attached to the opposite end of the tubing to minimize the possibility of room air flowing back into the tubing. The sampling rate was 3 L/min and, as in the CHD procedure, it was not replaced. As was the case with the CHD method, the EVD method was chosen based on the laboratory mannequin research described above.[8]

**(3)** CLF was chosen for inclusion in this study because it is characteristic of a common in-facepiece sampling procedure used in the United States for evaluations of respirator fit using aerosols and it also has been used for some workplace protection factor

(WPF) studies. The CLF method used the same challenge aerosol and detection method as the CHD and EVD methods. Therefore, fit factors up to approximately 100,000 could be detected. The CLF sampling method was a continuous, low sampling rate procedure with the throat and inlet of the probe located flush on the respirator wall in the general area of halfway between the nose and mouth. The flow rate was 1.1 L/min. This flow was not replaced in the facepiece.

The CHD, CLF, and EVD methods were conducted using a $4 \times 4 \times 7$ foot laboratory chamber (Dynatech Frontier Corp. model 222-6) that contained a spatially and temporally uniform concentration of Freon-113 (Aldrich Chemical Co., catalog number 24,281-0, Milwaukee, Wis.) and a corn oil. While in the chamber the subjects performed the movements listed in Table I.

**(4)** The CNP method is commercially available as the Dynatech Nevada FitTester 3000 (Dynatech Nevada Inc., Carson City, Nev.). The CNP method was developed to avoid the problems and biases normally associated with generated aerosol methods.[9] The CNP method was conducted by sealing the air-purifying paths into the respirator through the use of special test adapter manifolds installed into the respirator replacing the normal air-purifying element. One of the manifolds had a valve to provide for a breathing path for the test subject between tests. To start a test the subject closed his or her mouth; held his or her breath (for approximately 10 seconds), which temporarily sealed the back of the respirator; and closed the valve on the manifold. A pump and a control valve were used to exhaust air from the temporarily sealed facepiece at a rate that was controlled to generate and maintain a selected negative pressure inside the respirator. With the pressure held constant, the exhaust flow equaled the mask leakage flow rate, which was used as an index of respirator face seal fit. This leak rate was determined while the subject faced forward, faced left, faced right, with head up, with head down, and faced forward a second time. The CNP method detected fit factors in the range of 11 to 26,000.[10] The CNP was conducted immediately after the Freon-113 exposure.

In addition, the CNP test is the only test demonstrated to give fit factors that correlate with actual exposures to a challenge agent.[7] Because of the nature of the method, the respirator was taken off and redonned between the Freon-113 challenge and the fit-test. This was not necessary for any of the other methods.

**(5)** The AA1 method used the TSI Portacount™ 8020 (TSI Inc., St. Paul, Minn.) with the six exercises and lasted about 10 minutes. This method was chosen because a large number of fit-tests conducted in the workplace are done with this method. The AA1 method is normally done without a chamber and measures the ambient aerosols inside and outside of the respirator to determine the fit factor. A condensation nuclei counter is used to detect the aerosols. The AA1 method can detect fit factors greater than 10,000.[11] For this test the subject performed six exercises for approximately 1.5 minutes each: (1) normal breathing while holding the head forward and motionless, (2) deep breathing, (3) normal breathing while turning the head side to side, (4) normal breathing while moving the head up and down, (5) reading aloud the rainbow passage, and (6) normal breathing while holding the head forward and motionless. Like the CNP test, the AA1 test was performed immediately after the Freon-113 exposure.

**(6)** The AA2 method also used the TSI Portacount 8020 but lasted 30 minutes with the same 17 exercises used with the CHD, EVD, and CLF methods (Table I). The AA2 method can detect fit factors greater than 10,000.[11] When the subjects conducted this test, they were exposed simultaneously to the Freon-113. Table II is a summary of these methods.

## Subjects

The same 11 subjects (6 women and 5 men) who participated in the preliminary research phase of the study and in having their face and lip lengths measured were used in this phase.[5,12] The subjects were provided the manufacturer's instruction manual for each of the respirators they received and were instructed to don and fit check the respirator per those instructions. In addition, subjects were instructed, including written procedures provided by the manufacturers of the fit-test systems, about the different types of QNFT methods and how to perform them properly. The CNP method requires the subject to participate in the fit-test in a different manner than the other methods (i.e., remaining motionless, holding breath, and sealing the respirator properly). Therefore, subjects were trained in the proper procedure for conducting a CNP fit-test more extensively than the other methods. A practice session using the CNP method was held with each subject prior to actual data collection.

## Respirators

Seven combination organic vapor and high-efficiency respirator models with elastomeric half-mask facepieces certified by the National Institute for Occupational Safety and Health (NIOSH) were used in this study. A NIOSH-certified disposable high-efficiency half-mask respirator was also used in this study. It was modified to remove organic vapors as well as particulates. The cartridges were changed after every third test as described in the previous paper.[5]

## Method Comparison Testing

Prior to entering the chamber, each subject was given a half-mask organic vapor/high-efficiency respirator chosen at random for each test. For those respirators having multiple sizes, subjects with small faces (based on their facial measurements) were given the choice of wearing either a small or medium facepiece, subjects with medium faces were given the choice of wearing any of the sizes, and subjects with large faces were given a choice of either a medium or large facepiece.[12] The subject selected the facepiece size to be worn based on performing a fit check and on the perception of which size felt more comfortable.

After donning the respirators, the subjects entered the chamber containing corn oil if the CHD, CLF, or EVD methods were being evaluated or just ambient aerosols if the AA2 method was being evaluated in addition to 500 ppm Freon-113 (the NIOSH recommended exposure limit and short-term exposure limit are 1000 and 1250 ppm, respectively).[13] While in the chamber, subjects performed the movements listed in Table I.

During the time the subjects were in the chamber (30 minutes), their fit factors were measured using the QNFT method under evaluation. The penetration curves of the corn oil into the facepiece for CHD, EVD, and CLF methods were continuously monitored and recorded by the data system for later analysis and conversion. The fit factors obtained by the AA2 method were recorded for later comparison.

After exiting the chamber, the subjects waited 30 minutes to provide an end-exhaled air sample as described in the previous paper.[5] Since the nature of the CNP method did not allow it to be run simultaneously with the Freon-113 present and for a duration of 30 minutes, it was conducted during this 30-minute wait period. The visits when the subject performed the CNP were chosen at random. The CNP fit factor was recorded for later comparison to the subject's total Freon-113 exposure dose. In

**TABLE II. Description of Fit-Test Methods**

| Fit-Test | Description | Notes |
|---|---|---|
| CLF[A] (continuous low flow with flush probe) | Challenge was an oil aerosol with 0.6 MMAD generated in a test chamber. Detector was light scattering photometer. Aerosol was sampled from facepiece cavity at L/min from a probe mounted flush with inside wall. | Similar to the system originally developed for NIOSH |
| CHD[A] (continuous high flow with deep probe) | Challenge was an oil aerosol with 0.6 MMAD generated in test chamber. Detector was light scattering photometer. Aerosol was sampled from facepiece cavity at 5 L/min using a probe deeply inserted into facepiece above upper lip. | Incorporates the deep probe and high sampling rates to minimize sampling bias.[8] |
| EVD[A] (exhalation valve discharge) | The same as CHD test except sample was taken from a chamber designed to capture the discharge of the exhalation valve at 3 L/min. | |
| CNP[B] (controlled negative pressure) | Based on the principle of controlled negative pressure in which the volumetric leak rate of air into the facepiece was measured while subject held breath. | Commercially available as the FitTester 3000NPS from Dynatech Nevada Inc.[C] Instrument does not give a specific value for a fit factor less than 11. It is reported as $<11$. |
| AA1[D] (ambient aerosol 1) | Ambient aerosol was used as challenge. Aerosol was sampled from facepiece cavity at 0.7 L/min from a probe mounted flush inside facepiece wall. | Commercially available as the Portacount Plus™ from TSI Inc.[E] |
| AA2[A] (AA1 for 30 minutes) | The AA1 test modified to be conducted in Freon-113 chamber simultaneously with the 30 minute exposure to Freon-113. | Oil aerosol was not generated in the chamber during this test. |

[A]Fit-testing was conducted simultaneously with Freon-113 challenge of respirator.
[B]Fit-testing conducted immediately after Freon-113 challenge with redonning and care taken to obtain same fit.
[C]Dynatech Nevada Inc., 2000 Arrowhead Drive, P.O. Box 1925, Carson City, NV 89702-1925
[D]Fit-testing was conducted immediately after Freon-113 challenge of respirator without respirator being removed and redonned.
[E]TSI Inc., P.O. Box 64394, St. Paul, MN 55164-4394

addition, the AA1 method takes only a few minutes in a normal room atmosphere, so it was also performed during the waiting period after the AA2 method was completed.

After the subject provided an end-exhaled air sample, it was immediately analyzed. The amount of Freon-113 to which the subject was exposed while wearing the respirator was determined from inputting the Freon-113 concentration in the end-exhaled air sample minus the contribution from skin absorption into the subject's characterization equation described in the previous paper.[5] The 11 subjects evaluated each QNFT method in triplicate on different days (for a total of 33 data points for each QNFT method).

The fit factors obtained from each of the six QNFT methods were compared with the total Freon-113 exposure dose in parts per million per minute. The total Freon-113 exposure dose was determined by the analysis of the end-exhaled air sample. The end-exhaled air sample Freon-113 concentration was converted into a Freon-113 exposure level through the use of the subject's characterization equation. The total Freon-113 exposure dose was calculated by multiplying this exposure level by 30 minutes (the time the subject was in the chamber). The maximum value for the total Freon-113 exposure dose was 15,000 ppm-min (500 ppm times 30 minutes). This would have occurred if the respirator did not provide any protection (protection factor = 1).

The correlation of the fit factors and total Freon-113 exposure dose was accomplished using simple linear regression. Six linear regression models (one each for AA2, CHD, CLF, EVD, CNP, and AA1 methods) were developed from the data. The method having the highest coefficient of correlation and a slope close to negative one would be selected as the method that provided fit factors that correlated best to the actual total Freon-113 exposure dose.

## RESULTS AND DISCUSSION

The data from the six QNFT tests were plotted (Figures 1 through 6) to provide a visual indication of whether a relationship existed between the method fit factor and the total Freon-113 exposure dose. It should be noted that both axes of these figures are logarithmic scales due to the large differences between the smallest and largest values for both variables. Figures 1 though 6 demonstrate a general tendency for the total Freon-113 exposure dose to decrease with increasing method fit factor.

Then, a simple linear regression analysis was performed on the combined logarithmically transformed data for each method from all 11 subjects. In the analysis the method fit factor was the independent variable and the total Freon-113 exposure dose was the dependent variable.

Table III shows the coefficient of determination, $R^2$, for each of the six fit-test methods and the regression equation in order of decreasing $R^2$ value, a measure of the correlation between the total Freon-113 exposure dose and the method fit factor. The CHD, AA1, and AA2 methods had the highest $R^2$ values, ranging from

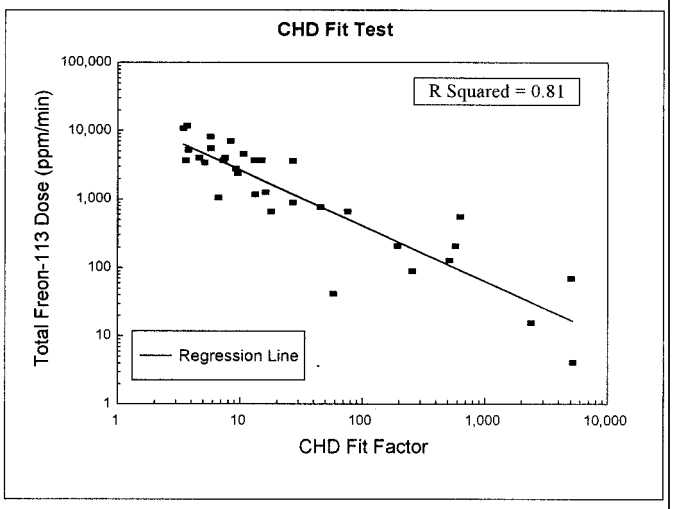


FIGURE 1. Study results for the CHD fit-test method. Total Freon-113 dose is calculated by multiplying Freon-113 exposures as determined from end-exhaled air concentration 30 minutes after exposure by the time the subject was in the chamber. The CHD test is defined in Table I. N = 33 for the CHD test.

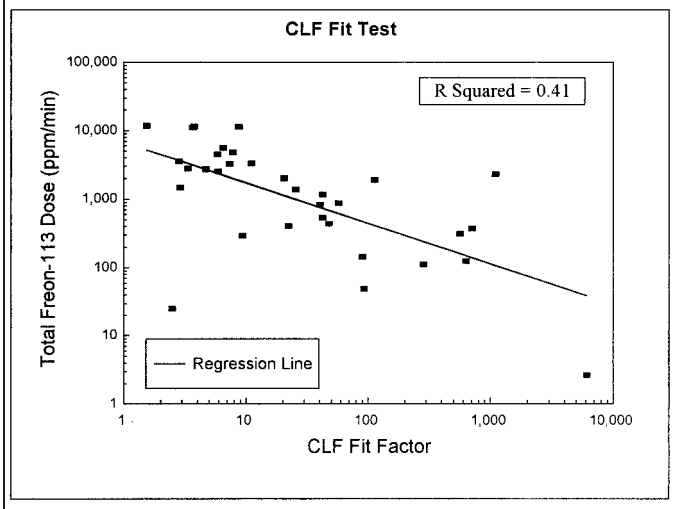


FIGURE 3. Study results for the CLF fit-test method. Total Freon-113 dose is calculated by multiplying Freon-113 exposures as determined from end-exhaled air concentration 30 minutes after exposure by the time the subject was in the chamber. The CLF test is defined in Table I. N = 33 for the CLF test.

0.70 to 0.81. A $R^2$ value of 0.81 suggests that 81% of the variation in the total Freon-113 exposure dose is accounted for by the variation in the method fit factor. At the other extreme, the fit factors of the EVD test showed little correlation ($R^2 = 0.20$) with the total Freon-113 exposure dose.

The slope of the regression line was lowest, approximately negative one, for the two methods with the highest correlation coefficients. The method with the lowest correlation coefficient also had the highest slope. Both the slope and $R^2$ of a model must be considered since the possibility exists that a method would have a high value of $R^2$ but a slope near zero. A slope near zero would cause large differences in the method fit factor to be reflected in small differences in the total Freon-113 exposure dose. A method that resulted in this situation would not be suitable for fit-testing. Since the AA1 method is more common than the CHD method, it was selected for further analysis, which will be described in a subsequent article.

However, the possibility of changes in fit during the Freon-113 exposure in the chamber may have placed the AA1 and CNP methods at a disadvantage; any change in fit during the Freon-113 exposure would tend to decrease the observed correlation. The high $R^2$ value for the AA1, however, suggests this was not an important factor in this study. The $R^2$ value for the CNP method from this study differed from the $R^2$ value in a previous correlation

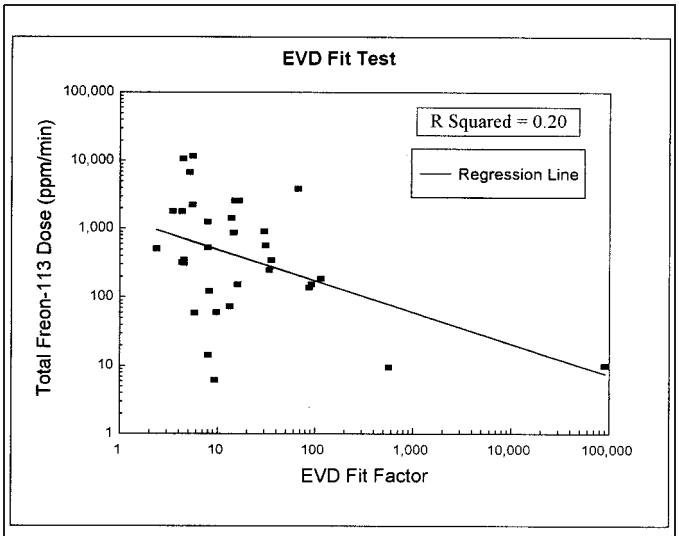


FIGURE 2. Study results for the EVD fit test method. Total Freon-113 dose is calculated by multiplying Freon-113 exposures as determined from end-exhaled air concentration 30 minutes after exposure by the time the subject was in the chamber. The EVD test is defined in Table I. N = 33 for the EVD test.

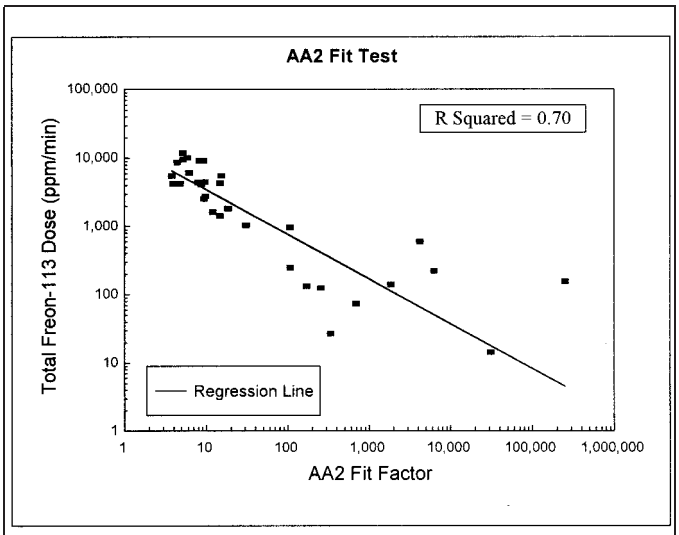


FIGURE 4. Study results for the AA2 fit-test method. Total Freon-113 dose is calculated by multiplying Freon-113 exposures as determined from end-exhaled air concentration 30 minutes after exposure by the time the subject was in the chamber. The AA2 test is defined in Table I. N = 33 for the AA2 test.

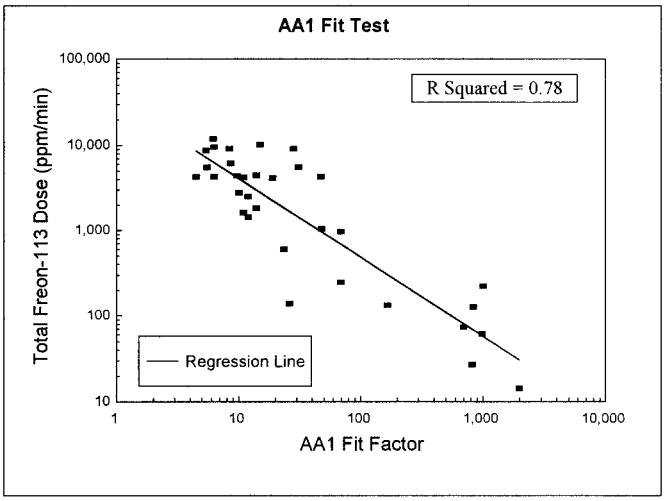


**FIGURE 5. Study results for the AA1 fit-test method. Total Freon-113 dose is calculated by multiplying Freon-113 exposures as determined from end-exhaled air concentration 30 minutes after exposure by the time the subject was in the chamber. The AA1 test is defined in Table I. N = 33 for the AA1 test.**

study.[7] The reason for the discrepancy is not entirely known. Perhaps it is due to the replacment of the adapters with cartridges and redonning of the respirator necessitated by the replacement of the inhalation valves in this study. In the Decker and Crutchfield study the respirator was not removed or adjusted between the CNP test and the exposure chamber test.[7] The discrepancy needs further investigation.

The approach used in this present study has advantages over the usual approach of comparing fit factors with WPF values determined during workplace studies. The majority of workplace

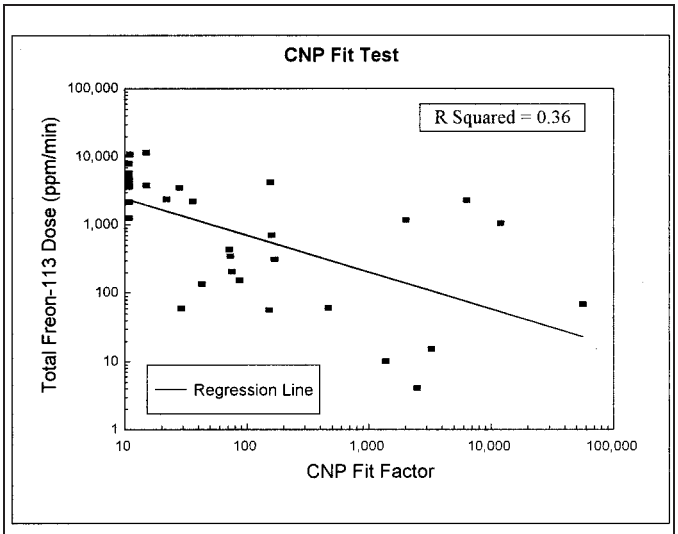


**FIGURE 6. Study results for the CNP fit-test method. Total Freon-113 dose is calculated by multiplying Freon-113 exposures as determined from end-exhaled air concentration 30 minutes after exposure by the time the subject was in the chamber. The CNP test is defined in Table I. N = 33 for the CNP test. Instrument does not provide a specific value for a fit factor less than 11. It is reported as <11.**

**TABLE III. Summary of Correlation Results**

| Fit-Test Method | $R^2$ | Linear Regression[A] |
|---|---|---|
| Continuous high flow deep probe | 0.81 | Y = 4.2359 − 0.8113*X |
| AA1 | 0.78 | Y = 4.5366 − 0.9238*X |
| AA2 | 0.70 | Y = 4.0454 − 0.5443*X |
| Continuous low flow flush probe | 0.41 | Y = 3.8278 − 0.5896*X |
| Controlled negative pressure[B] | 0.36 | Y = 3.9244 − 0.5379*X |
| Exhalation valve discharge | 0.20 | Y = 3.1524 − 0.4568*X |

[A]Y = Log of total Freon-113 exposure dose; X = Log of method fit factor.
[B]Respirator was taken off and redonned between the chamber exposure and CNP method. The random variation introduced by removing and redonning the respirator may have masked the correlation between exposures and fit-test results.

studies used in-facepiece sampling to determine the concentration of the contaminant present inside the respirator. In-facepiece sampling has associated with it random and systematic errors.[4] This error introduced variation during WPF determinations. Using exhaled breath to estimate the in-facepiece Freon-113 concentration eliminated this. Since method fit factors for four of the methods and corresponding total Freon-113 exposure doses were determined simultaneously, it eliminates variation introduced because the exercises and body motion during fit-testing are different from those during workplace studies. It eliminates variation introduced because fit-testing is not done simultaneously with WPF measurements and the fit may have changed between the two measurements. (This was not true for the CNP and AA1 test, because they had to be conducted immediately after, rather than during, the Freon-113 exposure.) Most importantly, this laboratory approach does not require a study population of workers to be prescreened with a fit-test as a WPF study does. Workers in a WPF study must have already passed a fit-test and it is not possible for conventional WPF studies to evaluate the ability of a fit-test to screen out workers with a poorly fitting respirator. However, further research is needed to determine whether fit factors have the same degree of correlation to respirator performance in the workplace measured biological monitoring as those obtained in this study.

Differences between fit factors and WPFs could be due to the following possibilities: (1) the standard QNFT exercises may not mimic closely enough the movements of a worker, (2) the difference between the breathing rate during fit-testing and the breathing rate while performing job tasks could affect correlation, (3) penetration of QNFT agents through a respirator face seal could be different from that of workplace contaminants due to differences in particle size distributions, (4) moisture in the breath could artificially lower QNFT, and (5) a short-term fit-test may not predict long-term protection.[14] Others have suggested that the underlying assumptions of the QNFTs may not be valid.[9] These assumptions are that (1) aerosol fit-test results can be applied to all other types of contaminants, (2) aerosol samples taken inside the respirator are representative of the exposure the wearer is actually receiving, and (3) exercise protocols used during quantitative fit-testing make them more predictive.

## Comparison with Workplace Studies

It is informative to consider further why previous workplace studies found no correlation between WPF values and fit factors. To do this, data from the three methods with the highest correlation were pooled. Pooled data, displayed in Figure 7, show a correlation between total Freon-113 exposure dose and the method fit factors that suggest an obvious value in using fit-tests to screen individuals with poorly fitting respirators.

However, in respirator workplace studies, workers have already

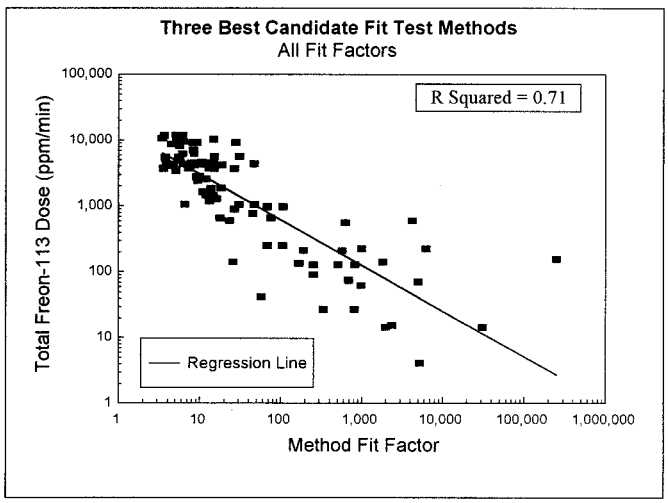


**FIGURE 7. Pooled results for the three fit-test methods with the highest $R^2$ values: CHD, AA1, and AA2. N = 99.**

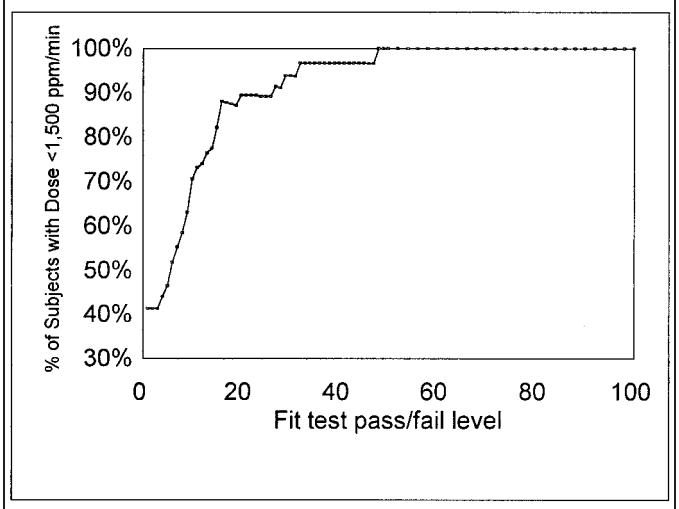


**FIGURE 9. To consider the appropriateness of the traditional safety factor used for fit-testing, the protection provided to a group of workers as a function of the fit-test pass/fail level used to qualify an individual for respirator use is simulated. The percentage of subjects who achieve the protection (i.e., total Freon-113 dose less than or equal to 1500 ppm-min) expected of a negative pressure half mask (assigned protection factor of 10) is shown as a function of the fit-test pass/fail level.**

been screened to eliminate those workers with fit factors less than 100. By eliminating all the data associated with fit factors less than 100, such a screening can be simulated. The result, shown in Figure 8, is no observed correlation between total Freon-113 exposure doses and fit factors. In this regard the results of this study are consistent with the observations of previous workplace studies. Thus, in addition to supporting the inherent value of quantitative fit-testing (i.e., as a screening tool), this study also provides a possible explanation of why workplace studies find no correlation between fit-test results and the protection provided by the respirator. However, it should be noted that this conclusion may be affected by the detection limit of the Freon-113 measurement method as discussed under the limitations section.

## Fit-Test Pass-or-Fail Level

It is also informative to consider the traditional fit-testing safety factor approach in which the pass or fail level in quantitative fit-testing is set at 10 times the assigned protection factor (APF) of a respirator class. The half-mask respirators studied here have an APF of 10 and in workplace practice would be required to achieve a fit factor of 100 before a worker would be considered to have an adequately fitting respirator. An APF of 10 means that the wearer's total Freon-113 exposure dose would be equal to less than 1500 ppm-min (i.e., the chamber concentration of 500 ppm would be reduced to a maximum of 50 ppm times the 30 minutes the subject was in the chamber).

Figure 9 characterizes the protection provided to a population of workers as a function of the fit-test pass-or-fail level used to qualify the individual for respirator wear. This figure shows the combined data from all of the method comparison testing (n=198). When fit-testing is not done (corresponding to a required fit factor of 1), only about 40% of the subjects received the level of protection expected of a half-mask respirator (i.e., a total Freon-113 exposure dose of 1500 ppm-min or less). When the required fit factor is 10, approximately 70% of workers achieve the expected level of protection. Only when the required fit factor is set at 50 or above did all subjects in this study receive the expected protection.

These results should be interpreted with care. In this study, there was no redonning of the respirator between the measurement of the fit factor and the measurement of the total Freon-113 exposure dose (except for the CNP test). In actual workplace use of respirators there is, of course, redonning, which introduces additional variation. Because of this additional variation, the limited number of subjects, and the use of Freon-113 to measure laboratory respirator performance whose relationship to workplace performance is unknown, this study should not be taken as a basis to adjust the traditional safety factor of 10.

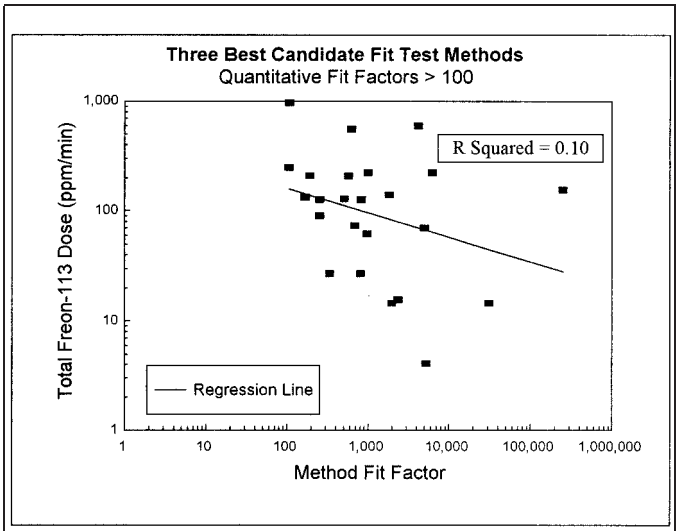


**FIGURE 8. Pooled results for the three fit-test methods with the highest $R^2$ values (as in Figure 7) with all subjects who "failed" the fit test (with a fit factor < 100) removed from the data set.**

## Potential Improvements to AA1 Fit-Test Method

Based on results of previous studies of in-facepiece sampling bias, the AA1 method might perform even better if it utilized a deep

sampling probe and a larger sampling rate.[4,8] This is supported in this study by a comparison of the CHD and CLF fit-tests. The CHD test removes an aerosol sample from inside a facepiece at 5 L/min with a sampling probe deeply inserted into the facepiece so that its inlet is about one-half inch from the skin between the upper lip and nose. The CLF test removes an aerosol sample from inside the facepiece at 1 L/min with the opening of the sampling probe mounted flush with the inner surface of the facepiece. Consistent with other studies, the CHD test correlated significantly better that the CLF test.[8] The AA1, like the CLF, uses a flush-mounted probe and samples at approximately 1 L/min. These results suggest its performance may be improved if the sample rate were increased and if the probe were inserted further into the facepiece. Further research is needed to determine whether the AA1 could be improved with a higher in-facepiece sampling rate and deep probe.

### Exercises and APFs

This study does not provide insight into the appropriateness of particular exercises. Accordingly, as a result of these studies, recommendations to change the traditional exercises used are not made. Similarly, when QNFT techniques are adapted to estimate APF values for respirator classes, this study gives no basis to recommend changing exercises used to simulate workplace activity. However, these results suggest that, with appropriate exercises and a demonstrated relationship between the Freon-113 method and actual respirator performance in the workplace, either the CHD or AA1 QNFT could be adapted to conduct laboratory tests on panels of individuals for the purpose of estimating APF values for half-mask respirators.

### Fit-Testing and Fit Checks

As stated under the Method Comparison Testing section, for those respirators having multiple sizes, subjects were given a choice of at least two sizes of facepieces. The subject selected the facepiece size to be worn based on performing a fit check and perception of which size felt more comfortable. It should be noted that even with this procedure a significant number of individuals had a very poor fit (a fit factor less than 10). The reason for this was not investigated and is, therefore, not known. It may be that fit checking is only useful for wearers of respirators that have been shown to provide a proper fit through the use of a fit-test in maintaining the quality of respirator donning. This was the conclusion of a study conducted by Myers et al.[15] Fit checking may not be a useful tool in selecting a respirator to be fit-tested.

### Limitations of the Study

There are a number of limitations associated with this study. The CNP method cannot be performed on disposable filtering facepiece respirators since there is no way to seal the filtering area of these respirators. Another limitation of the study was that the CNP method had to be conducted without the inhalation valves in place in the facepiece, and special adaptors were used in place of the organic vapor/high-efficiency cartridges. Therefore, the subject had to take off the respirator and redon it prior to the CNP test being performed. Even though every effort was made to put the respirator on exactly the same, the fit for the CNP test may not have been exactly the same as it was when the subject was exposed to the Freon-113. This placed the CNP method at a disadvantage not shared by the other fit-test methods. The random variation introduced by having to remove and redon the respirator may have tended to mask the correlation between exposures and fit-test results.

In addition, the types of tests that could be performed on the modified disposable respirator were limited. Since the disposable filtering facepiece did not have an exhalation valve, the EVD method could not be performed. Only the AA1, AA2, the CHD, and the CLF tests were performed on this respirator.

As stated in the first article, the subjects'' exhaled breath was analyzed using either a Fourier transform infrared (FT-IR) spectrometer or a gas chromatograph with a mass selective detector (GC/MD).[5] Therefore, another limitation of the method comparison portion of the study was the limit of detection of both the FT-IR and the GC/MD. The limit of detection was approximately 0.02 ppm for both instruments. Therefore, total Freon-113 exposure doses based on end-exhaled air concentrations less than 0.02 ppm may not be exact values. The concentrations may be due to the noise (error) inherent in the analytical method. The Freon-113 exposure level may have been much higher in reality. In addition, the minimum total Freon-113 exposure dose that could be measured would be limited due to instrument variation from the analytical method, time of exposure, and skin absorption. Total Freon-113 exposure doses less than 60 ppm-min would not be expected to be reliably measured. However, the analysis proceeded with these numbers since they provided a conservative estimate of the Freon-113 exposure dose if indeed the end-exhaled air concentration was below the minimum level of detection. It should also be noted that the total Freon-113 exposure doses, especially the very low ones, have an error in them due to the contribution of skin absorption in the end-exhaled air samples. There are total Freon-113 exposure doses for each of the subjects that are less than the subject's skin absorption Freon-113 level. This means that the contribution of skin absorption to the subject's Freon-113 exhaled breath concentration was greater than that of the contribution of the face seal leakage. This would affect the accuracy of the Freon-113 exposure doses.

Another limitation is that 100 ppm was the highest exposure level used in the characterization phase of the study. This may introduce some error when extrapolating method correlation exposures greater than 100 ppm. However, the pharmacokinetic model described in the first article of the series suggests that this is not a problem.[5]

The final limitation has to do with the number of respirators that were NIOSH certified and commercially available when the project started. The 7 elastomeric half-mask respirators (out of approximately 50 certified by NIOSH) used in this project were selected from companies that had large market shares of the total half-mask sales.[16] Therefore, the results obtained with the half-mask respirators tested should be representative of all certified half-mask respirators.

## SUMMARY AND CONCLUSIONS

For approximately 15 years, no relationship between quantitative fit factors and the level of protection afforded by a respirator could be found. This study has found that for three of the QNFT methods tested a predictive relationship exists between the method fit factor and the level of protection of the respirator (measured by the total Freon-113 exposure dose) in a simulated health care environment. The study supports Hyatt's assumption that there is a relationship between QNFTs and respirator performance at least during simulated use conditions.[17]

The study also supports the value of some fit-test methods as

a screening tool to identify workers with poorly fitting respirators. In addition, the study provides a possible explanation of why previous workplace studies found no correlation between QNFT results and WPFs. Further, the study supports the incorporation of a safety factor of 10 in setting the pass-or-fail level for a QNFT. This study is only the beginning of the process to develop a laboratory test that is predictive of actual respirator performance in the workplace. Other researchers need to corroborate the results under the same conditions. Further studies are needed to examine the relationships under different conditions and with other respirator types.

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