

Feasibility of a New Method to Determine Respirator Performance by Biological Monitoring of Exhaled Air

John A. Decker

National Institute for Occupational Safety and Health,
Division of Preventive Health Services, 101 Marietta Tower, Atlanta, Georgia 30323

Clifton D. Crutchfield

Division of Community and Environmental Health
University of Arizona, Tucson, Arizona 85719

Abstract

Current methods of quantifying respirator fit and performance usually involve tests or studies conducted with aerosol-based systems. Data generated by aerosol systems, however, are subject to various parameters that bias the measurement of aerosol concentrations within a respirator. Previous attempts to define the relationship between measured respirator fit and actual workplace protection have not established a solid basis for making vital decisions concerning respirator selection, fit, and use.

A new method that may be applicable to determining respirator performance through biological monitoring of exhaled air is described. Concentrations of chlorofluorocarbon-113 in exhaled breath (measured 30 min. post-exposure) were correlated to a generated challenge concentration when a full-facepiece negative pressure respirator was worn at rest in an exposure chamber. Resting respirator protection factors generated by breath analysis were compared with fit factors generated by concurrent in-mask sampling, as well as with sequential fit factors measured by a controlled negative pressure fit test system. A moderately high correlation ($r = 0.86$) between resting respirator performance and controlled negative pressure fit factors was observed. Little correlation ($r = 0.24$) was found between the protection factors and fit factors based on the in-mask sampling technique. Essentially no correlation ($r < 0.01$) was found between the controlled negative pressure and in-mask sampling methods.

The breath analysis technique for determining respirator performance eliminates differential aerosol leak penetration effects and increases test challenge rigor by using

a vapor instead of an aerosol as a challenge agent. It also eliminates in-mask sampling biases by using 30 min. post-exposure exhaled breath as the index of challenge agent penetration into the respirator. Since the method is complicated and time-consuming, its utility for defining actual wearer exposure and respirator performance is probably limited to research applications.

Introduction and Significance

Respirators are widely used as a control strategy to protect workers from exposures to harmful atmospheres. The level of protection afforded by a respirator is determined by several factors, including the extent to which the respirator is actually used, the ability of the respirator cartridge to remove contaminants, and the effectiveness of the seal between the respirator and the face of the subject.

A number of Occupational Safety and Health Administration (OSHA) regulations specifically require that employees be fit tested with respirators provided for protection against airborne contaminants (29 CFR 1910.134, 29 CFR 1910.1001, 29 CFR 1910.1025, 1991). Either qualitative or quantitative respirator fit testing can generally be used to meet this requirement. Qualitative fit testing is subjective in that it relies on test subject response to a sensory challenge agent, such as the smell of isoamyl acetate or the taste of saccharin. Significant variability in subject threshold response and inability to differentiate between two adequately fitting respirators are some of the factors that limit the usefulness of qualitative fit testing.

The standard approach to quantitative respirator fit testing (QNFT) involves exposing a respirator wearer to a test atmosphere containing a challenge agent. Commercial systems are normally based on using either a generated aerosol or ambient aerosol as the challenge agent. The QNFT result, or fit factor, is used to estimate how well a respirator fits an individual worker. The fit factor is described by the ratio of measured outside to in-mask challenge agent concentration. Although currently used QNFT methods remove test subjectivity and produce a numerical description of respirator fit, a number of problems have been associated with aerosol based QNFT methods (Brown, 1992).

No studies that validate the current standard aerosol QNFT methodology have been published,

although the method is currently specified as the validation standard for other fit test methods (ANSI, 1989). A number of parameters have been identified that affect the quality of in-mask samples used to describe respirator fit and performance, including: size of challenge agent (Holton, et al., 1987; Hinds and Kraske, 1987); leak site (Oestenstad et al., 1990a; 1990b); location and depth of sample probes, and breathing pattern (Myers et al., 1986); sample flow rate (Liu et al., 1984); and differential aerosol deposition in the lung (Willeke et al., 1990). Even in the absence of these problems, it has not been demonstrated that results from fit tests conducted with a given aerosol size distribution can be specifically applied to a workplace with a different aerosol size distribution, or to a gas or vapor contaminant.

A significant source of in-mask sampling bias involves the streamlining of air and aerosol within a respirator during the inhalation portion of the respiratory cycle. Such streamlining leads to nonuniform distributions of contaminant within the respirator. A study by Myers et al. (1986) utilized acetone as a challenge agent to document in-mask sampling biases ranging from -99% to +98%, with a mean bias of -17%. The location of air streamlines relative to the position of the sampling probe was thought to contribute to the observed sampling bias. Any factor that reduces or limits aerosol migration from the mask cavity to the sampling probe causes an understatement of aerosol penetration and a subsequent over-estimation of respirator fit.

Another major problem with the standard aerosol QNFT method is the lack of demonstrated correlation between measured fit factors and protection factors determined for respirators as they are actually worn in the work environment (Myers et al., 1984; Dixon and Nelson, 1984). Since a strong relationship between respirator fit and performance level is at least intuitive, the inability to substantiate it in workplace protection factor studies may indicate a need for a different approach

to measuring respirator fit and performance.

Aerosol-based methods have been used to determine both respirator fit factors and workplace protection factors. Despite efforts to make fit tests more representative of respirator wear in the workplace by including specific QNFT exercise protocols (ANSI, 1980), a sound basis for estimating workplace performance on the basis of measured respirator fit has not been demonstrated. Measured fit factors have historically shown significant variation with no consistent pattern between specific test exercises and measured respirator fit (da Roza et al., 1983). As recently outlined by Bien (1990) and Hewett et al. (1990), workplace protection factor studies based on the **in-mask** sampling method have not established a clear picture of the level of protection currently provided to millions of workers who use respirators as a defense against occupational hazards. It again seems evident that a different measurement approach may be required to clearly examine the relationships that surely exist between the fit of respirators and the amount of protection they provide in the workplace.

A new approach to determining respirator performance as a function of measuring actual subject exposures to a challenge agent by breath analysis has been developed. The breath analysis approach eliminates particle size effects, increases test rigor by using a more challenging test agent (e.g., vapor instead of an aerosol), and eliminates in-mask sampling problems by using exhaled breath as an index of worker exposure. This study describes a pilot application of the breath analysis approach to the measurement of respirator performance.

In the breath analysis approach the performance of the respirator is evaluated as the ratio of exposure concentration to post-exposure alveolar breath concentration of a gas or vapor challenge agent. In this case, performance is assessed by measuring the level of challenge agent reduction achieved by the respirator/purifying element system while the subject remains at rest during the exposure period. A principal advantage of such a measure of respirator performance is that it is directly related to actual exposures experienced by the test subject's lungs.

Materials and Methods

General Breath Analysis Procedure

The breath analysis technique for determining respirator performance uses challenge agent concentrations measured in exhaled breath, instead of in-mask sample results, as the index of subject exposure during the test. Application of the protocol is accomplished in two phases. In the first phase, a test subject is, in effect, calibrated for a range of low level exposures to an appropriate gas or vapor challenge agent. The calibration procedure involves determining the relative relationship between challenge agent exposure concentration and post-exposure levels in the subject's breath.

After a relative calibration curve for a given subject is established, that subject can then participate in phase two studies designed to measure respirator performance. These studies involve wearing a respirator in a chamber or area in which the challenge agent is maintained at a known, relatively high concentration. Mean exposure concentrations inside the respirator are estimated by application of the subject's calibra-

tion curve to post-exposure measurements of challenge agent concentrations in the breath. An assumed critical aspect of the breath analysis technique involves matching subject activity or work rates during both calibration and performance testing phases.

Pilot Study Parameters

The feasibility of the breath analysis protocol was assessed through a pilot study involving multiple tests of a single subject at rest. The development of the study protocol is briefly described below, along with supporting rationale for its various components.

Selection of Challenge Vapor—The ideal challenge vapor or gas should be relatively non-toxic, so that moderate to high challenge concentrations can be safely used to extend the dynamic range of performance tests. The challenge agent should also have relatively low uptake and metabolic rates so that a consistent relationship between exposure and dose can be documented during the calibration phase.

Of a number of potential challenge agents examined for the pilot study, chlorofluorocarbon 113 (CFC-113, 1,1,2 trichloro-1,2,2 trifluoroethane) was selected for use because of its toxicological profile, anticipated pharmacokinetic characteristics, and analytical sensitivity.

Since CFC-113 vapor distributes into numerous physiologic compartments, its concentration in a subject's breath is a complex function of exposure concentration, exposure duration, and elapsed time between exposure cessation and collection of the breath sample. A series of range-finding tests revealed that 30-min. exposures to challenge concentrations ranging from 0.5 to 60 ppm generated detectable concentrations in alveolar breath for more than an hour following exposure termination. The subsequent use of a challenge concentration of 500 ppm, coupled with a calibration curve covering the range of 0.5 to 60 ppm, generated a test working range of respirator protection factors from 8 to 1000.

It should be noted that exposures to high concentrations of chlorofluorocarbons have been implicated in deaths from cardiac arrest, presumably the result of cardiac sensitization to epinephrine (NIOSH, 1989). During this study the potential for serious adverse effects was judged to be low because of the low exposure concentrations of CFC-113 relative to its Permissible Exposure Limit and Recommended Exposure Limit of 1000 ppm (NIOSH, 1990).

Pharmacokinetics—An initial investigation of the pharmacokinetics of CFC-113 was necessary to design a rational protocol for breath analysis. The number of CFC-113 pharmacokinetic compartments in the body and their respective desaturation half-lives were characterized so that optimal exposure profiles and post-exposure sampling times could be determined.

The rate and extent of absorption and elimination of vapor through the lungs shows a high correlation with the blood:gas partition coefficient, which is a measure of the vapor's solubility in blood (Fiserova-Bergrova et al., 1980; Marshall et al., 1980). The partition coefficient for CFC-113 (approximately 0.8) was expected to result in an analytically usable uptake and elimination curve for CFC-113 over a reasonable amount of time (Morgan et al., 1972). This was determined by comparing the approximate partition coefficient of CFC-113 with other related halogenated vapors with known uptake and elimination rates.

Most low-molecular-weight halogenated vapors are eliminated quickly from the blood and highly perfused tissues after exposure ends (Morgan et al., 1972). However, biological tissues having low blood perfusion coupled with a high storage capacity for lipophilic substances may accumulate vapors that can be used to biologically integrate an exposure to certain chemical substances (APHA, 1988). The CFC-113 released from adipose and other tissues having low perfusion was measured to calculate the subject's mean 30-minute exposure level in the chamber.

The degree to which breath samples represent exposure depends to a large extent on the sampling time chosen with respect to exposure. A disadvantage of collecting breath samples during or immediately after exposure is that the chemical concentrations in breath are essentially a reflection of instantaneous uptake, and do not correlate well with the average exposure to variable concentrations. In order to correlate breath data with the concentration of CFC-113 inhaled, the subject was exposed to a known concentration of CFC-113 for 30 minutes. The subject's alveolar breath concentration was then monitored at three post-exposure time points (25, 30, and 35 min.). The mean of these three breath measurements was correlated with known exposure concentrations to develop the subject's calibration curve, and subsequently to estimate mean in-mask exposure levels.

Subject Calibration Curve—A subject calibration curve was developed by exposing the subject (without respirator) to a range of known CFC-113 concentrations. In-mask concentrations corresponding to a respirator protection factor range of 8 to 1000, given a challenge concentration of 500 ppm, were used to select calibration points. The subject was exposed for 30 min periods to calibration concentrations of 0.5, 1.5, 6.0, 12.0, 30, 50, and 60 ppm. Each exposure for each calibration point was conducted with the subject at rest, and repeated in triplicate.

The choice of a 30-minute post-exposure sampling time was based on a set of experiments in which resting subjects were exposed for 30 min to low levels of CFC-113 concentrations (1.25, 6.0, 12.0 ppm), and then monitored over a 60 min post-exposure period. Breath desaturation curves for these three concentrations were plotted and used to determine an optimum post-exposure sampling time.

Respirator Performance Tests—A probed full facepiece negative pressure respirator (MSA Ultratwin®, no nose cup) equipped with organic vapor cartridges (MSA type GMA) was used for the respirator performance tests. New cartridges were used for each trial. Simulated leaks were used to expand the range of resting respirator protection factors over which the breath analysis protocol was assessed. For those trials that included simultaneous sampling of in-mask CFC-113 concentrations, leaks were induced by placing latex bands between the subject's forehead and the sealing periphery of the respirator. During CNP/breath analysis trials, leaks were created by inserting a hypodermic needle through a septum installed on the respirator's sampling port. A range of needle sizes was used to control the leakage rate into the respirator.

A respirator test chamber (Dynatech Frontier® Model 226) with an airlock bulkhead was used for subject exposures. CFC-113 vapor was produced by pushing air through a midjet impinger containing liquid CFC-113. Chamber concentration was monitored continuously with an infrared analyzer (Wilks Miran 1A-CVF®), and recorded each minute with a computer controlled data acquisition unit (Hewlett Packard Model 85B/3421A®). During respirator performance testing, the chamber was maintained at a CFC-113 vapor concentration of 500 ± 1 ppm. The respirator was worn for 5 minutes after the subject exited the exposure chamber to reduce the possibility of significant inhalation exposure from residual CFC-113 vapors out-gassing from the subject's clothing or hair. The subject maintained a normal resting breathing pattern during the post-exposure period prior to breath-sample collection.

The use of alveolar air has been shown to produce the most consistent results from breath sampling (APHA, 1988). Alveolar breath samples were collected by sampling the expiratory reserve volume (collected by forced expiration following a passive exhalation) into glass tubes (15 mm i.d., 100 mm length, 46 mL internal volume when capped). As the subject exhaled the expiratory reserve volume through the tube, the distal end of the tube was capped. After the distal cap was secure, the proximal end was removed from the mouth and immediately secured with a cap. The caps were equipped with a septum that facilitated sample withdrawal.

Exposures of less than 50 ppm CFC-113 were expected to result in low exhaled breath concentra-

tions during post-exposure. The use of a gas chromatograph with electron capture detection provided good analytical sensitivity since CFC-113 has six electronegative halogens. Breath is reported to contain more than 250 separate chemical entities (Ganong, 1989). An advantage of electron capture detection is that it has low sensitivity to potentially interfering substances in breath. The higher boiling point of CFC-113 relative to other chlorofluorocarbons (CFCs) permitted the use of gas chromatography to separate CFC-113 from other major low-boiling-point constituents of breath, such as oxygen, nitrogen, carbon dioxide, water vapor, and certain ambient CFCs.

Breath samples were analyzed immediately after collection by gas chromatography. The analytical system consisted of a gas chromatograph (HP 5890) equipped with a megabore capillary column (J&W Scientific Model DB-624) and an electron-capture detector. Ultra-high purity nitrogen was used as both carrier gas (12 mL/min., 100 kPa) and make-up gas (60 mL/min.). Chromatographic temperatures were set as follows: oven temperature, 30°C; injector temperature, 40°C; and detector temperature, 275°C. A precisely measured quantity of halothane vapor was used as an internal standard.

Two measures of respirator fit were determined in conjunction with the respirator performance measurements made with the breath analysis protocol. Integrated samples of in-mask CFC-113 concentrations were collected from the respirator probe and accumulated in an aluminumized Teflon® sampling bag. A sample flow rate of 0.20 L/min. was used for the 30-minute exposure period. The low sample rate, compared to traditional QNFT, was chosen to reduce the possibility of disturbing the air flow dynamics within the respirator.

Immediately prior to subject entry into the exposure chamber, quantitative respirator fit factors were determined using a controlled negative pressure (CNP) fit test system (Crutchfield et al., 1991a; 1991b). The CNP method is based on exhausting air from a temporarily sealed respirator facepiece at a rate sufficient to generate and sustain a pre-selected negative pressure inside the respirator while the wearer holds his breath. The magnitude of sustained negative pressure is selected to replicate the inspiratory pressure in the mask during normal wear. With the air inlets into the respirator blocked, measurement of the exhaust flow rate yields a synonymous measure of

the leakage flow rate into the mask during inspiration under normal use conditions. Five sequential face forward (analogous to the normal breathing exercise) CNP fit factors were recorded immedi-

ately prior to each chamber trial. The respirator was not removed or adjusted by the subject between the CNP fit test and the exposure chamber test.

Results

Pharmacokinetics

Breath desaturation curves for the 1.25, 6.0, and 12.0 ppm CFC-113 exposures showed similar rates of decay. Figure 1 illustrates the breath-decay curve following a 30 min exposure to 6.0 ppm CFC-113. Estimates of the exponential decay rates and half-lives for the desaturation process were computed by application of the method of residuals or back-feathering (Klaassen, 1986; Harvey, 1980). The back-feathering technique attempts to divide a complex exponential function into two or more basic underlying functions which are then characterized by a sequential stripping process; it is similar to the approach used for curve stripping of radionuclide energy spectra when multiple sources are present.

The data from all three desaturation curves best fit a two compartment pharmacokinetic model, of the general form:

$$C = Ae^{-\alpha t} + Be^{-\beta(t)} \quad (1)$$

where:

C = breath concentration

A = concentration at time 0 for the central compartment

α = first-order elimination rate constant for the central compartment

B = concentration at time 0 for the peripheral compartment

β = first order elimination rate constant for the peripheral compartment

e = Napierian constant (2.71828...)

A compartment is described mainly by its pharmacokinetic parameters since it may be difficult to define in precise anatomical terms. The compartment into which vapor is directly absorbed is called the central compartment, and includes certain fractions of the blood and other highly perfused tissues. The peripheral compartment includes tissues that only communicate with the environment through the central compartment (Harvey, 1980).

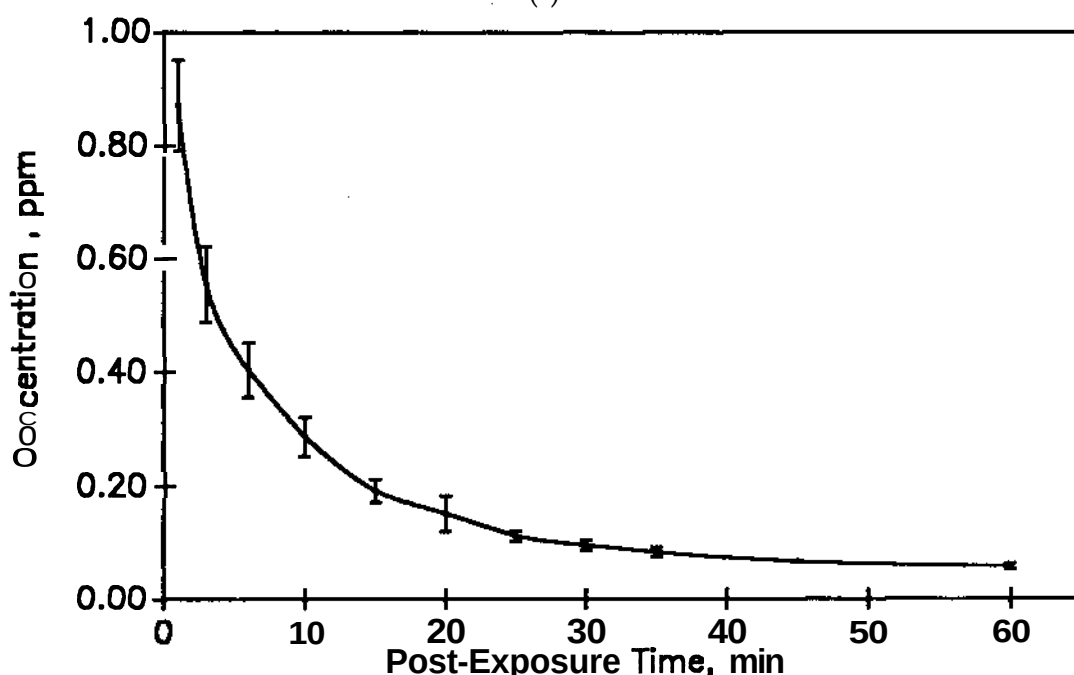


Figure 1. Mean CFC-113 concentration in alveolar breath following a 6.0 ppm 30 min. exposure in a single subject. Error bars indicate ± 1 standard deviation from three separate trials.

An illustration of the application of back-feathering to the breath desaturation curve shown in Figure 1 is illustrated in Figure 2.

Mean CFC-113 desaturation half-lives (for a single individual) of the central and peripheral compartments were calculated to be 4.2 min. and 52 min., respectively. Therefore, measurement of the breath CFC-113 concentration from the peripheral compartment (representing a 30-minute integrated exposure) could begin 25 minutes post-exposure (more than 5 half-lives of the central compartment). At this time, the fraction of CFC-

113 contributed by the central compartment would be minimal. From these data, it was determined that breath sample collection would be appropriate at 25, 30, and 35 minutes post-exposure.

Biological Calibration Curve: Figure 3 illustrates the subject's biological calibration curve, which correlates CFC-113 concentrations in alveolar breath to their corresponding challenge exposure concentrations. A second-order regression model provided a better fit to the data than a linear regression model. The reason for the non-linearity of the calibration curve is not known and needs further investigation.

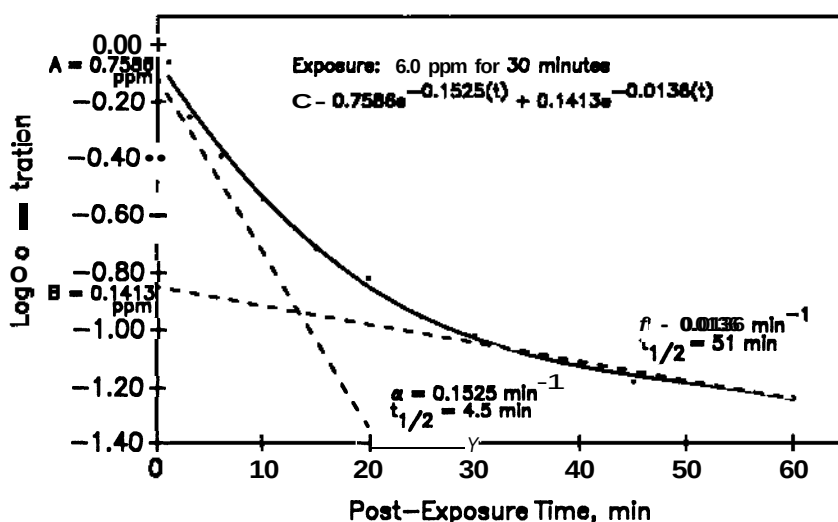


Figure 2. Example of the back-feathering technique applied to the breath desaturation curve shown in Figure 1.

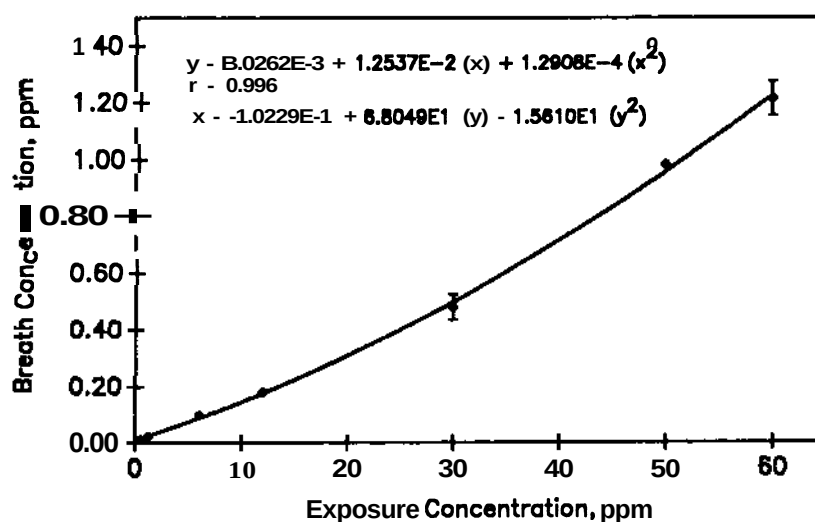


Figure 3. Mean alveolar breath concentrations (30 min. post-exposure) resulting from 30 min. calibration exposures to CFC-113 for a single subject. Error bars indicate ± 1 standard deviation from three separate trials; r is the correlation coefficient.

Comparison of In-Mask Sampling, Breath Analysis, and Negative Pressure Methods

Since low rates of leakage into a respirator result in large fit factors, a small change in a measured low leak rate can cause a dramatic change in the resulting fit factor. Therefore percent penetrations (reciprocal of fit factor expressed as a percent) rather than fit factors were used to reduce the large numerical variability associated with higher fit factors. Figure 4 illustrates the relationship between respirator leakage measured with the controlled negative pressure fit

test system and respirator penetration measurements made at rest with the breath analysis protocol. A moderately high correlation ($r = 0.86$) was observed between the two methods of determining respirator leakage.

As shown in Figure 5, measurements of respirator leakage based on integrated **in-mask** sampling from the respirator probe showed a poor correlation ($r = 0.24$) with breath analysis results. Essentially no correlation ($r < 0.01$) between in-mask sampling results and pre-test respirator leakage determined with the negative pressure system was observed, as indicated in Figure 6.

Description and Results of Associated Experiments

Characterization of Clothing and Skin Absorption Effects

Residual CFC-113 vapor in the subject's clothing or hair could be a significant source of inhalation exposure during the immediate post-exposure period. Additionally, absorption of CFC-113 vapor through the subject's skin during the 30 min. exposure period could also confound breath analysis results. The potential for such confounding variables to significantly affect the breath analysis protocol was assessed by using a self-

contained breathing apparatus (SCBA) in a pressure demand mode. It was assumed that the SCBA would essentially eliminate the subject's inhalation route of exposure while in the chamber. Any CFC-113 vapor found in alveolar breath was assumed to result from skin absorption or from post-exposure inhalation of out-gassing from clothing or hair.

Individual trials were conducted for 15- and 30-min. exposure periods at a chamber concentration of 500 ppm. A reasonable assumption is that

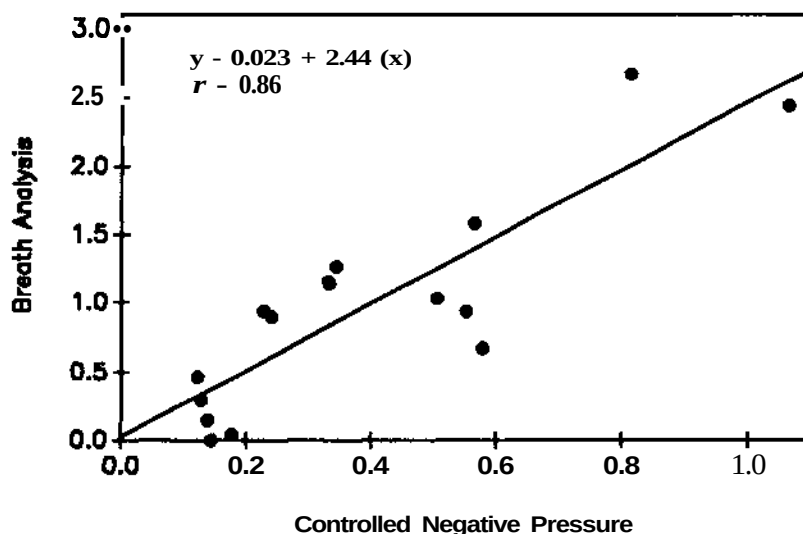


Figure 4. Comparison of respirator penetration (percent) measured with controlled negative pressure and breath analysis methods. Each data point represents a single trial; r is the correlation coefficient.

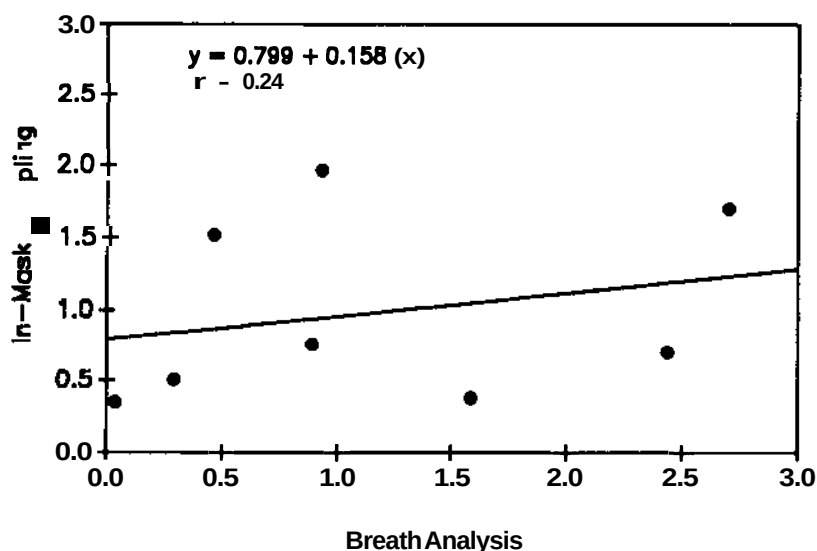


Figure 5. Comparison of respirator penetration (percent) measured with breath analysis and in-mask sampling methods; r is the correlation coefficient.

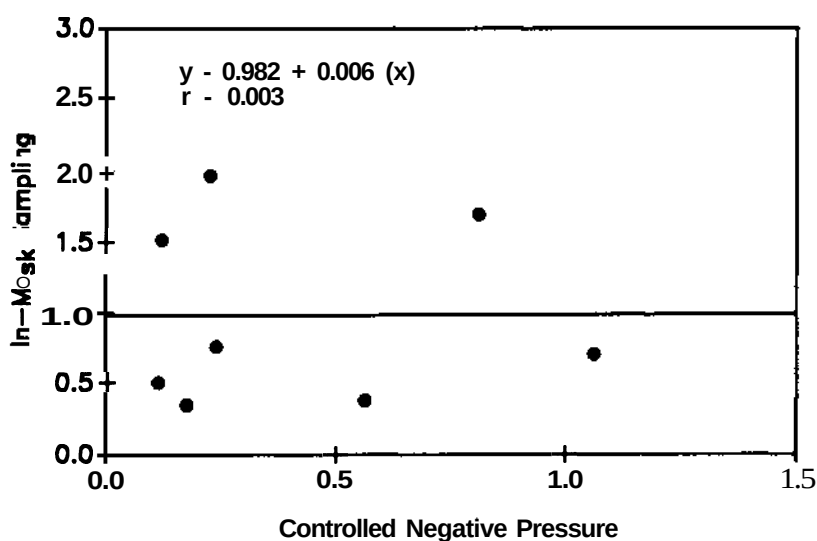


Figure 6. Comparison of respirator penetration (percent) measured with controlled negative pressure and in-mask sampling methods; r is the correlation coefficient.

saturation of the clothing by CFC-113 would be the same whether the subject was exposed for a 15 or 30-min. period. Therefore, if the amount of CFC-113 detected in breath did not differ significantly between the 15- and 30-min. exposures, it could be assumed that clothing desorption after leaving the chamber was causing the exposure. On the other hand, if the breath concentration for the 15-min. exposure was half that of the 30-min. exposure, it

might be assumed that skin absorption or some leakage through the SCBA was contributing to the exposure, since the results of these exposure routes should be directly related to the exposure time.

The measured equivalent exposure in breath following the 15-min. SCBA experiment was 55% less than the level for the 30-min. exposure period, indicating that post-exposure inhalation from

residual CFC-113 on clothing and hair was probably not a significant route of contamination. If the SCBA did indeed preclude inhalation exposure, another exposure route (possibly dermal) must have contributed to the CFC-113 levels measured in the breath. The inhalation equivalent exposure by this other route was 1.35 ± 0.10 ppm over three trials.

Respirator Effects

The effects of respirator dead space and cartridge scrubbing efficiency on challenge exposures were also investigated during the pilot study. Increased carbon dioxide content in the dead space of the respirator results in an increased ventilation rate. When an individual wears a respirator, the total volume of air breathed is increased to overcome the dead space effect of the respirator.

Respirator dead space effects were assessed by having the subject wear a full-face respirator equipped with particulate filters instead of organic vapor cartridges. The subject was then exposed for

30 min. to 5.0 ppm CFC-113 for three trials. The measured mean post-exposure breath concentration of 0.081 ppm was very close to the 0.079 ppm level predicted by the subject's breath calibration curve, indicating minimal dead space effects. The exposure to CFC-113 was virtually the same regardless of whether no respirator was worn or whether a respirator with particulate filters was worn.

Cartridge vapor removal efficiency was characterized by continuously drawing 500 ppm CFC-113 through individual organic vapor cartridges at a flow rate of 15 lpm for 30 minutes. Analysis of pump exhaust air showed a cartridge penetration range of 0.006 to 0.018 ppm. The highest observed cartridge penetration rate could conceivably increase the in-mask exposure associated with the highest anticipated protection factor (1000) by 3.2%. A shift of this magnitude is not probable since the total airflow through the cartridges during respirator performance trials would be much lower because of the cyclic nature of respiration.

Discussion and Conclusions

The breath analysis protocol was developed to eliminate in-mask sampling problems that have been found to substantially bias measures of respirator fit and performance. Results of this pilot study indicate that challenge agent vapors recovered from a subject's breath can be used to estimate in-mask exposures under controlled conditions. A strong, positive correlation between exposures to CFC-113 and post-exposure alveolar breath concentrations was demonstrated. A key advantage of the breath analysis protocol is that, as a product of alveolar breath, it reflects actual subject exposures to a challenge agent.

A low level of correlation was observed between measures of respirator leakage determined with the breath analysis protocol and the in-mask sampling technique. As discussed previously, streamlining within the mask is a major factor that can bias sampling within the mask. The low rate of sampling from the respirator probe might also have contributed to the lack of correlation between the methods, since it was only a fraction of the subject's mean inhalation flow rate. Vapor losses in the sample bag used to integrate the in-mask sample would also contribute to the reduced respirator leakage detected with in-mask sam-

pling. The tendency for in-mask sampling techniques to substantially underestimate respirator leakage, as occurred in this study, has been observed in previous comparative studies of controlled negative pressure (CNP) and aerosol fit test systems (Crutchfield et al., 1992a; 1992b).

Essentially no correlation was found between leakage measurements made with the CNP system and the in-mask sampling method. The CNP system provided a direct measure of air leakage into the respirator under static conditions. The driving force for leakage, inspiratory pressure, was closely matched for test purposes, especially given the resting nature of the subject during the CFC-113 exposure trials. As noted above, CNP systems tend to detect substantially more leakage into respirators than aerosol based fit test systems, which rely on in-mask sampling.

The same situation appears to hold for in-mask sampling of vapor challenge agents.

Moderately high correlation was observed between CNP leakage measurements and breath analysis results. The observed level of correlation is especially significant since it indicates that the

CNP fit test method was able to predict with a fair measure of success the level of protection provided by the respirator under controlled conditions. If it can be demonstrated through further research that fit tests can be predictive of respirator performance under conditions that are more representative of actual work, the value that can be ascribed to fit test results would be substantially increased.

The nature of the CNP fit test method allows it to challenge respirator fit over a range of challenge pressures that can mimic inspiratory pressures at a variety of different work rates (Crutchfield et al., 1992c).

It is interesting to note that the breath analysis protocol indicated respirator leakage rates approximately 2.5 times greater than the rates measured with the negative pressure method. A number of possible reasons are discussed below.

1. *Leakage Resulting from Head Movement:*

The difference in measurements could be partly related to the different methodologies of determining respirator leakage. The CNP system provided a static measure of respirator fit while the individual held his breath and did not move. During the breath analysis protocol, the subject was able to move his head freely during the 30-minute exposure period, although the test was conducted at rest without any deliberate head movements or test exercises. Instantaneous changes in fit may occur as a result of head or facial movements during inhalation and exhalation. These effects cannot be characterized using the negative pressure system. Since negative pressure fit tests performed immediately before and after the 30-min. CFC-113 exposure period indicated virtually no difference in fit, the basic fit of the respirator did not appear to change during the exposure test.

2. *Increased Dose Caused by Re-breathing:* At the end of an exhalation, the dead space in the respirator contains exhaled air that is re-breathed during the next inhalation. When CFC-113 is inhaled, only a very small fraction is absorbed into the body through the lungs. More than 95% of the CFC-113 that reaches the alveoli in a single breath is exhaled, some of which remains within the respirator (Morgan et

al., 1972). During the next inhalation, the exhaled CFC-113 plus additional leakage during inhalation reaches the lungs. This process continues, resulting in a higher plateau of exposure than originally inhaled. The increase in dose resulting from this phenomenon is dependent on the fraction of vapor retained by the body after exhalation. In a worst case situation, as much as a twofold increase in mask concentration can occur (Hinds and Bellin, 1990).

3. *Efficiency of Respirator Cartridges:* Experiments to evaluate the scrubbing efficiency of carbon cartridges for CFC-113 indicated only small amounts of leakage through the cartridges (6-18 ppb under challenge conditions of 15 ppm, 500 ppm CFC-113). New cartridges of the same lot number were used for each trial. The possibility of a significant contribution to dose by this route seems remote.

4. *Absorption of Vapor by Another Route:* Preliminary experiments involving CFC-113 exposures while wearing an SCBA indicated the presence of another possible route of exposure, such as dermal. The equivalent inhalation exposure by this route could have been as high as 1.35 ppm with a challenge exposure level of 500 ppm CFC-113. The breath concentration resulting from an exposure to 1.35 ppm CFC-113 would only affect numerically high protection factors determined with the breath analysis protocol.

5. *Contamination from Clothing or Hair:* The possibility of breath sample contamination by residual vapor out-gassing from the subject's clothing or hair was investigated during exposure trials in which the subject wore an SCBA to preclude inhalation exposure. It was assumed that vapor saturation of hair and clothing would occur fairly rapidly in the 500 ppm vapor challenge concentration in the chamber. Therefore, breath sample contamination by residual vapor out-gassing should show little effect from a decrease in chamber exposure time from 30 to 15 min. The result of halving the exposure time for the subject/SCBA combination was an approximate halving of the resultant breath vapor

concentration. This result indicates a low probability of breath sample contamination by residual vapor out-gassing. As previously discussed, vapor uptake in the chamber by a non-inhalation (e.g., dermal) route is a more likely explanation for the observed relationship between exposure time and resultant vapor breath concentrations.

6. *Leakage through the Exhalation Valve:* The passage of CFC-113 through the exhalation valve would not explain the difference in apparent penetration rates since this type of leak should also be detected by the CNP system.
7. *Increased Ventilation Caused by Respirator Dead space:* It was initially thought that an increase in apparent CFC-113 penetration rates might be related to increased ventilation resulting from the additional dead space contributed by the respirator. However, the concentration of CFC-113 in breath following a 5.0 ppm 30-min. exposure was virtually the same, whether no respirator or a respirator equipped with particulate filters was worn. These results were expected since CFC-113 is classified as a low solubility vapor. Its extent and rate of uptake is, therefore, probably more dependent on cardiac output than on ventilation (Klaassen, 1986). Although not addressed in this study, dose differences resulting from respirator dead space might be amplified to the point of being observable under conditions of work or other high metabolic states.

The finding that the breath analysis technique produced higher estimates of respirator leakage than the CNP system is especially interesting when the results of previous comparative studies between CNP and aerosol fit test systems are considered. CNP systems have consistently measured higher levels of respirator leakage, by up

to an order of magnitude, than generated and ambient aerosol fit test systems, which are both based on in-mask sampling (Crutchfield et al., 1992a; 1992b; 1992d; Graffeo, 1992). Workplace measures of respirator performance have historically been determined with in-mask sampling techniques. To the degree that the breath analysis protocol generated a representative measure of actual subject exposures, then measures of respirator fit and performance based on in-mask sampling results may be substantially more in error than has been previously recognized (Myers et al., 1986).

Further development and refinement of the breath analysis protocol may provide a means of determining respirator performance that is fundamentally related to actual lung exposures. Specific topics related to the breath analysis method that require further study include determinations of the impact of intra- and inter-subject variability, and the influence of work rate on the body's uptake and elimination of CFC-113 vapor. A mathematical model developed by Fiserova-Bergerova (1980) might be applicable to the prediction of individual differences in uptake and excretion rates. Predictable factors include body build, cardiac output, ventilation rate, blood:gas partition coefficient, metabolic clearance, and duration of exposure.

It is not anticipated that the breath analysis protocol can be routinely applied to the measurement of respirator performance. It is obviously a complex and time consuming technique. However, the described methodology, with additional refinement, might be able to describe with much greater clarity actual levels of protection afforded to subjects by a wide range of respirator types during simulated workplace protection factor studies. Employed in well designed studies, it could help establish a more solid basis for assigning protection factors to classes of respirators. Given its direct link to actual lung exposures, the breath analysis method may also help clarify the relationship that surely exists between respirator fit factors and respirator performance.

References

- 29 *Code of Federal Regulations* 1910.134. "OSHA Respiratory Protection Standard," Occupational Safety and Health Administration, Washington (1991).
- 29 *Code of Federal Regulations* 1910.1001. "OSHA Asbestos Standard," Occupational Safety and Health Administration, Washington (1991).

- 29 *Code of Federal Regulations* 1910.1048. "OSHA Lead Standard," Occupational Safety and Health Administration, Washington (1991).
- ANSI Z88.10: *Respirator Fit Test Methods*. Draft Standard Dated August, 1989, American National Standards Institute, New York (1989).
- American Public Health Association: *Methods for Biological Monitoring*, APHA, Washington, DC (1988).
- Bien, C.: "Workplace Protection Factor Studies—Unanswered Questions." *J. Int. Soc. Resp. Prot.* 8:9 (1990).
- Brown, R.C.: "Review: Protection Factors of Respirators with Special Reference to Dust Respirators." *J. Int. Soc. Resp. Prot.* 10(1):5 (1992).
- Crutchfield, C.D.; Eroh, M.P.; Van Ert, M.D.: "A Feasibility Study of Quantitative Respirator Fit Testing by Controlled Negative Pressure." *Am. Ind. Hyg. Assoc. J.* 52(4):172-177 (1991).
- Crutchfield, C.D.; Murphy R.W., Van Ert, M.D.: "A Comparison of Controlled Negative Pressure and Aerosol Quantitative Respirator Fit Test Systems by Using Fixed Leaks." *Am. Ind. Hyg. Assoc. J.* 52(6):249-252 (1991).
- Crutchfield, C.D.; Murphy, R.W.; Van Ert, M.D.: "A Comparison of Controlled Negative Pressure and Aerosol Quantitative Respirator Fit Test Systems Using Human Subjects." *Am. Ind. Hyg. Assoc. J.* 53(12):in press (1992).
- Crutchfield, C.D.; Ruiz, A.M.; Van Ert, M.D.: "A Validation Study of Respirator Fit Testing by Controlled Negative Pressure." Presented at American Industrial Hygiene Conference, Boston, 1992. (Submitted to *Appl. Occ. Environ. Hyg.*, September, 1992).
- Crutchfield, C.D.; Pham, T.K.; Van Ert, M.D.: "Determination of Inspiratory Pressures and Flow Rates for Work Rate Dependent Quantitative Respirator Fit Testing." *Appl. Occup. Environ. Hyg.* (accepted for publication, September, (1992).
- Crutchfield, C.D.; Park, D.L.; Henshel, J.L.; et al.: "Determinations of Known Respirator Leakage Using Controlled Negative Pressure and Ambient Aerosol QNFT Systems." *Am. Ind. Hyg. Assoc. J.* (submitted for publication, September, 1992).
- da Roza, R.A.; Cadena-Fix, C.A.; Carlson, G.J.; Hardis, K.E.; Held, B.J.: "Reproducibility of Respirator Fit as Measured by Quantitative Fitting Tests." *Am. Ind. Hyg. Assoc. J.* 44(11):788 (1983).
- Dixon, S.W.; Nelson, T.J.: "Workplace Protection Factors for Negative Pressure Half-Mask Facepiece Respirators." *J. Int. Soc. Resp. Prot.* 2(4):347 (1984).
- Fiserova-Bergrova, V.; Vlach, J.; Cassady, J.C.: "Predictable Individual Differences in Uptake and Excretion of Gases and Lipid Soluble Vapours Simulation Study." *Brit. J. Ind. Med.* 37:42-49 (1980).
- Ganong, W.F.: *Review of Medical Physiology*. Lange Medical Publications, Los Altos, California. pp. 497-498 (1989).
- Graffeo, J.B.: *The Classification of Respirator Fit as Determined by an Aerosol Method and a Negative Pressure Method*. Master's Research Project Report, Department of Environmental Health Sciences, University of Alabama at Birmingham, (1992).

- Harvey, S.C.: "Basic Pharmacokinetics." In: *Remington's Pharmaceutical Sciences*, 16th ed., Mack Publishing Company, Easton Pennsylvania (1980).
- Hewett, P.; Gamble, J; Pallay B.: "The Role of Lung Deposition, Sampling Losses, Leak Penetration, and Particle Size in Estimating Workplace Protection Factors for **Particulate** Air Purifying Respirators." Presented at American Industrial Hygiene Conference, Orlando (May, 1990).
- Hinds, W.C.; Kraske, G.: "Performance of Dust Respirators with Facial Seal Leaks, I. **Experimental.**" *Am. Ind. Hyg. Assoc. J.* 48(10):836 (1987).
- Hinds, W.C.; Bellin, P.: "Respirator Dead Space, Effect on Estimates of Dose." Presented at the American Industrial Hygiene Association Conference, Orlando (May 1990).
- Holton, P.M.; Tackett, D.L.; Willeke, K.: "Particle Size-Dependent Leakage and Losses of Aerosols in Respirators." *Am. Ind. Hyg. Assoc. J.* 48(10):848 (1987).
- Klaassen, C.D.: "Distribution, Excretion, and Absorption of Toxicants." In: *Casarett and Doull's Toxicology*, 3rd edition. Macmillan, New York (1986).
- Liu, B.Y.; Sega, K.L.; Rubow, S.W. et al.: "In-Mask Aerosol Sampling for Powered Air Purifying Respirators." *Am. Ind. Hyg. Assoc. J.* 45:278 (1984).
- Marshall, B.E.; Wollman, H.: "General Anesthetics." In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics*, Macmillan Publishing Co., New York (1980).
- Morgan, A.; Black, A.; Walsh, M.; Belcher, D.R.: "The Absorption and Retention of Inhaled Fluorinated Hydrocarbon Vapours." *International Journal of Applied Radiation and Isotopes* 23:285-291 (1972).
- Myers, W.R.; Allender, J.; Plummer, R.; Strobbe, T.: "Parameters that Bias the Measurement of Airborne Concentration Within a Respirator." *Am. Ind. Hyg. Assoc. J.* 47(2):106 (1986).
- Myers, W.J., Peach, M.J., and Allender, J.: "Workplace Protection Factor Measurements on Powered Air-Purifying Respirators at a Secondary Lead Smelter: Results and **Discussion.**" *Am. Ind. Hyg. Assoc. J.* 45:681-688 (1984).
- NIOSH Alert: *Preventing Death from Excessive Exposure to Chlorofluorocarbon 113*. DHHS (NIOSH) Pub. No. 89-109. National Institute for Occupational Safety and Health, Cincinnati, OH (1989).
- NIOSH Pocket Guide to Chemical Hazards. DHHS (NIOSH) Pub. No. 90-117. National Institute for Occupational Safety and Health, Cincinnati, OH (1990).
- Ostenstad, R.K.; Perkins, J.L.; Rose, V.E.: "Identification of Faceseal Leak Sites on a Half-Mask Respirator." *Am. Ind. Hyg. Assoc. J.* 51(5):280-284 (1990).
- Ostenstad, R.K.; Dillon, H.K.; Perkins, J.L.: "Distribution of Faceseal Leaks in a Half-Mask Respirator and Their Association with Facial Dimensions." *Am. Ind. Hyg. Assoc. J.* 51(5):285-290 (1990).
- Willeke, K; Krishnan, U.: "Present Procedures in Quantitative Respirator Fit Testing: Problems and Potential Solutions." *Appl. Occup. Environ. Hyg.* 5(11): 762-768 (1990).