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Parameters that Bias the Measurement of Airborne Concentration Within a Respirator

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This paper describes the theoretical basis upon which a test system has been set up to evaluate the sampling error associated with in-facepiece sampling on half-mask respirators. The in-facepiece sampling technique evaluated in this study is the one currently used in the U.S. to conduct quantitative facepiece fit testing. An experimental design was developed to study the sampling bias associated with in-facepiece sampling when selected parameters of the man/respirator system were varied. The results indicated that significant errors can be made in estimating concentration within a respirator when the current in-facepiece sampling technique is employed. Sampling bias was determined when in-facepiece samples were collected only during the inhalation phase of the respiratory cycles. They were found to range from greater than -99% to greater than +98%. The mean sampling bias was -17 ± 38%. When measured in-facepiece concentrations were used to calculate a fit factor the resulting range was 44 to 4728 even though the actual fit factor was only 87. Based upon the data presented, it was hypothesized that faceseal leakage was streamlining within the respirator cavity. As a result, quantitative facepiece fit data on half-mask respirators may be biased by the large measurement error.

Introduction

The primary goal of any sampling system designed to measure the concentration of airborne contaminant(s) is to provide a quantitative estimate of the airborne concentration in the environment from which it is obtained. In the occupational setting, this environment is the workplace; for example, concentrations of contaminants are measured by general area sampling or by personal sampling. In regard to this investigation, however, the environment is the facepiece cavity: the cavity between the body of a respirator and a wearer's face. In this case, the concentration of contaminants within the facepiece cavity are measured by in-facepiece sampling.

In-facepiece sampling refers to a measurement system which is composed of two general aspects. The first aspect is sampling or sample collection, which involves collecting a sample of contaminant from within the facepiece cavity. The second aspect is sample analysis which deals with quantifying the amount of contaminant present. The validity of contaminant measurements made by in-facepiece sampling or any other sampling system is dependent upon the actual representativeness of the collected samples to the environment from which they were obtained and upon the accuracy, precision, sensitivity and sample recovery associated with the analytical methods. In regard to negative pressure respirators, the environment from which samples are collected is subject to dramatic changes in instantaneous airflow rates, minute volumes and inboard contaminant leakages.

The most familiar use of in-facepiece sampling is in quantitative fit testing[1] with more recent application to respira-

TABLE I
Test Variables and Levels of Effect Used in the Factorial Experimental Design

Test Variable	Variable Description	Level of Effect 0	1	2
PL	probe location on respirator midline	nose	between nose and mouth	mouth
PD	depth of probe mouth	1/8"	1/4"	1/2"
LS	leak site	nose	cheek	chin
BP	breathing distribution pattern	equal	all mouth	all nose
SR	measurement sample rate	1 L/min	2 L/min	3 L/min

PL = probe location; PD = probe depth; LS = leak side, BP = breathing pattern; and SR = sample rate

tor field studies to determine workplace protection factors.[2,3,4] Quantitative facepiece fit testing (QNFT) involves real-time sampling of an aerosol within a facepiece cavity. The measure of aerosol concentration inside the facepiece is compared to the measure of aerosol concentration outside the respirator in the form of a ratio, which is defined as the fit factor. Workplace protection factor determination involves calculating the ratio of the time-weighted average (TWA) concentration of a contaminant(s) within a facepiece cavity to the TWA concentration of contaminant(s) outside the respirator.[5] In both applications the accuracy, sensitivity, *etc.* of the analytical methods are generally well defined and are presented in the published literature.[6,7] The same cannot be said, however, about the technique used to obtain the sample from the facepiece cavity. The current technique[1,6] for sample collection on half mask respirators in the U.S. is to locate a sampling probe on the midline of the respirator body at a position that falls somewhere between the nose and mouth of the wearer. Generally, the probe is attached directly to the wall of the respirator. The internal diameter of the sampling probe and the sampling flow rate used for in-facepiece sampling are not standardized and vary widely. Furthermore, samples are collected during both the inhalation and exhalation phases of the respiratory cycle.

The efficacy of in-facepiece sampling has never been demonstrated in the published literature even though in-facepiece sampling has been done since the early 1960s. One possible reason for this is the often applied assumption that leakage through the faceseal perimeter mixes uniformly and completely within the facepiece cavity. The purpose of this research is to investigate whether or not that assumption is true and determine how certain parameters of the man/respirator system may affect the representativeness of samples collected by current in-facepiece sampling techniques.

System Definition and Discussion

In order to accomplish the experiment a model was developed to predict the actual concentration that would be present within the facepiece cavity. We define the quantity C_I as the average concentration present during inhalation. Defined as such, C_I would represent the true respiratory exposure experienced by a worker. The tidal volume inhaled during a single breath is designated as $\mathring{V}_I$. The respiratory minute volume Q_R is simply $\mathring{V}_I$ times the breathing frequency expressed in respirations or cycles per minute. The concentration of a substance measured outside the front of the respirator (not necessarily the same as the ambient concentration) is denoted as C_0.

At any instant C_I will be equal to the sum of all the leakages coming into the respirator at that instant. If we let P_i be the penetration through any leak source (i = 1, 2 . . . n) and Q_i be the respective flow rate through those leak sources then we can develop the following expression for C_I.

$$C_I = \frac{(C_0P_FQ_F) + (C_0P_LQ_L) + \sum_{i=1}^{n} (C_0P_iQ_i)}{Q_F + Q_L + \sum_{fi=1}^{fn} Q_i} \qquad (1)$$

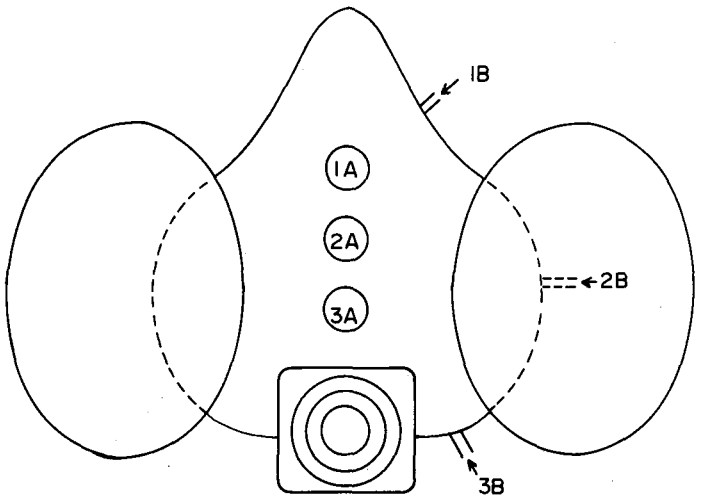

Figure 1 — Representation of probe locations on respirator midline and leak sites on the faceseal perimeter. Probe locations 1A-nose; 2A-between nose and mouth; 3A-mouth. Leak sites 1B-nose; 2B-cheek; and 3B-chin.

where P_F = penetration through the filter;
P_L = penetration through the faceseal;
P_i = penetration through other sites of leakage;
Q_F = flow rate through the filter;
Q_L = flow rate through the faceseal;
Q_i = flow rate through other sites of leakage.

If filter efficiency, η_F is known, then P_F can be replaced by $1-\eta_F$ in Equation 1. By mass flow balance the following relationship exists;

$$Q_R = Q_F + Q_L + \sum_{i=1}^{n} Q_i$$

and if it is assumed that $\sum_{i=1}^{n} (C_0P_iQ_i) = 0$ then Equation 1 reduces to

$$C_I = \frac{C_0(P_FQ_F + P_LQ_L)}{Q_R} \qquad (2)$$

The assumption $\sum_{i=1}^{n} (C_0P_iQ_i) = 0$ is in general suitable; however, the most notable exception would be for consideration of exhalation valve leakage. To consider multiple sites of faceseal leakage the term P_LQ_L in Equation 2 needs to be replaced by a summation term $\sum_{L=1}^{n} P_LQ_L$ for 1 to n number of sites.

For particulate aerosols P_F and P_L are a function of the aerodynamic equivalent particle size of the aerosol and the flow rate through the filter or leak. Additionally, P_F is a function of various filter characteristics (*e.g.* fiber packing density, electrostatic charge, fiber diameter, *etc.*) For a gas or vapor, however, it is generally recognized that $P_F = 0$ until the cartridge begins to experience breakthrough and that $P_L = 1$; that is, the leak has a gas collection efficiency of 0. With the assumption that $P_F = 0$ and $P_L = 1$ for a gas/vapor situation, Equation 2 further simplifies to

$$C_I = C_0\left(\frac{Q_L}{Q_R}\right) \qquad (3)$$

For this experiment Equation 3 was used to calculate the theoretical concentration of vapor present in the facepiece cavity during inhalation.

In actual practice, however, C_I can not be calculated directly from Equation 3 because the quantity Q_L is not known. As a result, an estimate of C_I is made by collecting a sample from inside the respirator cavity. The usual sampling strategy is to collect a sample over both the inhalation and exhalation phases of the respiratory cycle. This value will be designed as $\bar{\bar{C}}$ (the double bar designates sampling during inhalation and exhalation). This concentration estimate is a function of C_I and C_{EX}, the concentration present within the respirator cavity during exhalation and the inhalation and exhalation times t_I and t_{EX}. This functional relationship is expressed by the following equation:

$$\bar{\bar{C}} = k_1 C_I + k_2 C_{EX} \quad (4)$$

where k_1 and k_2 are respectively the normalized coefficients for time of inhalation and exhalation [*e.g.*, $k_1 = t_I/(t_I+t_{EX})$]. For the sampling estimate $\bar{\bar{C}}$ to be unbiased, the unbiased

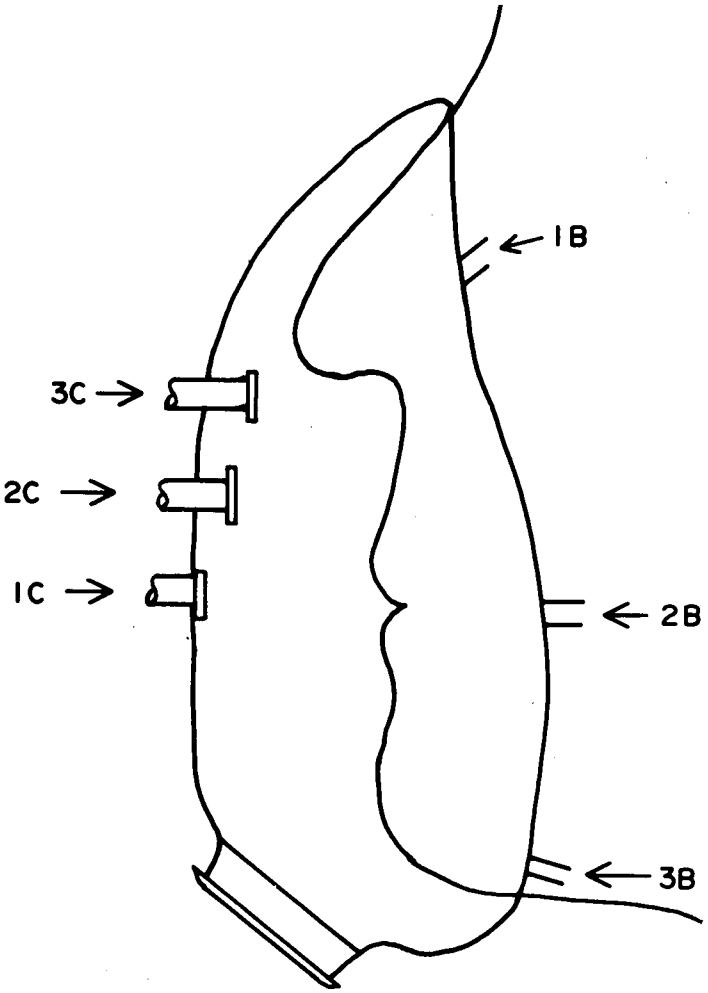

Figure 2 — Representation of probe mouth depths and leak sites on the face seal perimeter: leak sites 1B-nose; 2B-cheek, 3B-chin. Probe depths 1C-flush, 2C-.25 inch insertion, 3C-.5 inch insertion.

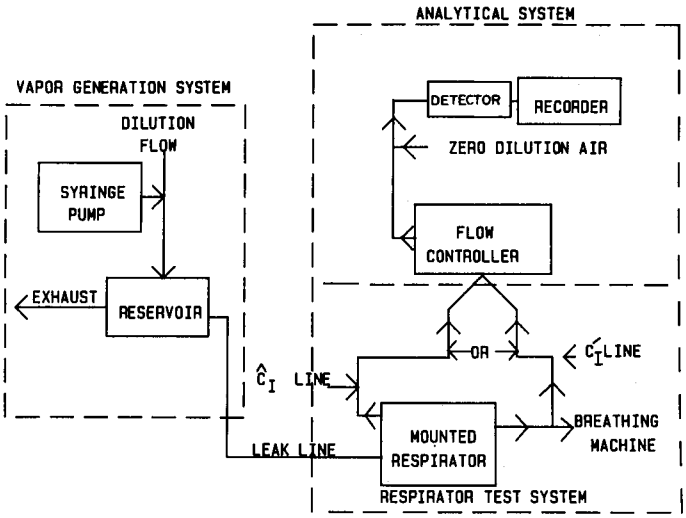

Figure 3 — Schematic of test system.

estimates of C_I and C_{EX} must be used. These estimates can be obtained as follows:

$$C_I = \xi_1 \hat{C}_I$$

and

$$C_{EX} = \xi_2 \hat{C}_{EX}$$

The values $\hat{C}_I$ and $\hat{C}_{EX}$ are the actual concentration estimates made by in-facepiece sampling. The values ξ_1 and ξ_2 are corrections for sampling bias experienced during the inhalation and exhalation phases of the respiratory cycle.

The difference between C_{EX} and C_I represents the loss in concentration due to lung retention. Lung retention is equivalent to lung collection efficiency, η_L; therefore, C_{EX} can be expressed as $(1-\eta_L)\, C_I$. By making the appropriate substitutions into Equation 4 and rearranging, the following expression is obtained for determining C_I based upon $\bar{\bar{C}}$:

$$C_I = \frac{\bar{\bar{C}}}{k_1\xi_1 + k_2\xi_2\,(1-\eta_L)} \quad (5)$$

From Equation 5, the calculation of the true inhalation exposure can be made based upon an estimation of exposure made over the inhalation and exhalation phases of the respiratory cycle given the duration time of inhalation and exhalation, inhalation and exhalation phase sampling biases, and lung retention characteristics for the specific contaminant. The given quantities required in Equation 5, however, are not known in general. For example, different aerosol size distributions or different gas/vapor contaminants have markedly different lung retention characteristics and, therefore, different values of η_L. Likewise, it is hard to determine k_1 and k_2 since these coefficients will most likely vary with respiration rate and individual. In addition, the corrections for sampling bias have not been determined.

An alternative approach that would greatly simplify the estimation of C_I would be to collect samples only during the inhalation phase of the respiratory cycle. The feasibility of using such an approach has been demonstrated by Fürst and Riediger[8] who have described a system for use in a labora-

tory setting, which collects samples from the respirator cavity only during inhalation. For this sampling scheme the concentration estimate obtained by in-facepiece sampling will be designated as $\overline{C}$. It is defined as:

$$\overline{C} = \xi_I \hat{C}_I \quad (6)$$

Experimental Design

This investigation was to provide an assessment of whether certain parameters of the man/respirator system may introduce bias into the sample estimates of the concentration collected from within the cavity of a negative pressure, half mask. If good mixing does occur inside the facepiece cavity, samples collected by in-facepiece sampling should closely approximate the theoretical level predicted from Equation 3. If good mixing does not occur, however, then samples collected by in-facepiece sampling would be different from theoretical levels. This difference can be expressed as sampling bias. As system parameters are varied between different levels, determination of any sampling bias caused by such variation would provide an indication of whether good mixing is occurring within the facepiece cavity.

The experimental approach taken was to conduct a screening experiment which utilized a fixed effect 3^k factorial design. This experimental design is a factorial arrangement with k variables (classes) each at three fixed levels of effect (levels).[9] With 5 variables the full 3^5 factorial design would have 243 treatment combinations. Since this was primarily a screening experiment, only main effects and 2-way interactions were considered important in the statistical analysis. As a result, a one-third factorial reduction was used to partition the full 3^5 design into three blocks having 81 treatment combinations. Each of the resulting blocks represent a 3^{k-1} or 3^4 fractional factorial design. The defining relation (I) used to partition the treatment combinations into each block was the interaction component $AB^2C^2D^2E^2$. Any one of the resulting three blocks of treatment combinations could have been selected for use.

Assumptions made with this design are that: 1) the variables (factors) are fixed; 2) the design is completely randomized; and 3) the usual normality and homogenity of variances assumptions are satisfied. For the initial statistical analysis of the data, a general linear model analysis was performed to determine which variables or 2-way interactions were significant causes of sampling bias.

The process of identifying and selecting factors for inclusion into the study was based upon a fault-tree analysis of the current technique for obtaining in-facepiece samples. That process identified many potential factors of the man/respirator system which could possibly introduce bias into the sample collection process. Based primarily upon professional judgment and experience, five factors were selected from the fault-tree analysis for study. Selection of those factors and their associated levels of effect are discussed as follows and are summarized in Table I.

Sampling Probe Location (PL)

The factor sampling probe location deals with the position of the probe on the midline of the resirator in an area between the nose and mouth. In practice the midline probe location on any given mask is fixed; however, its positional relationship to the nose and mouth will naturally vary between different wearers and also for an individual wearer during multiple donnings. The three probe locations selected for study were designated as follows: nose; between nose and mouth; and mouth. Selection was based upon the physical limits created by nose or mouth entry to the respiratory tract and a reasonable midpoint between the two (Figure 1).

Sampling Probe Depth (PD)

The factor probe depth deals with how deeply the probe mouth is extended into the cavity of the respirator. The three probing depths chosen for study were: flush (≤⅛ inch insertion); ¼ inch insertion; ½ inch insertion. These depths were chosen because experience indicated a half-inch probe depth

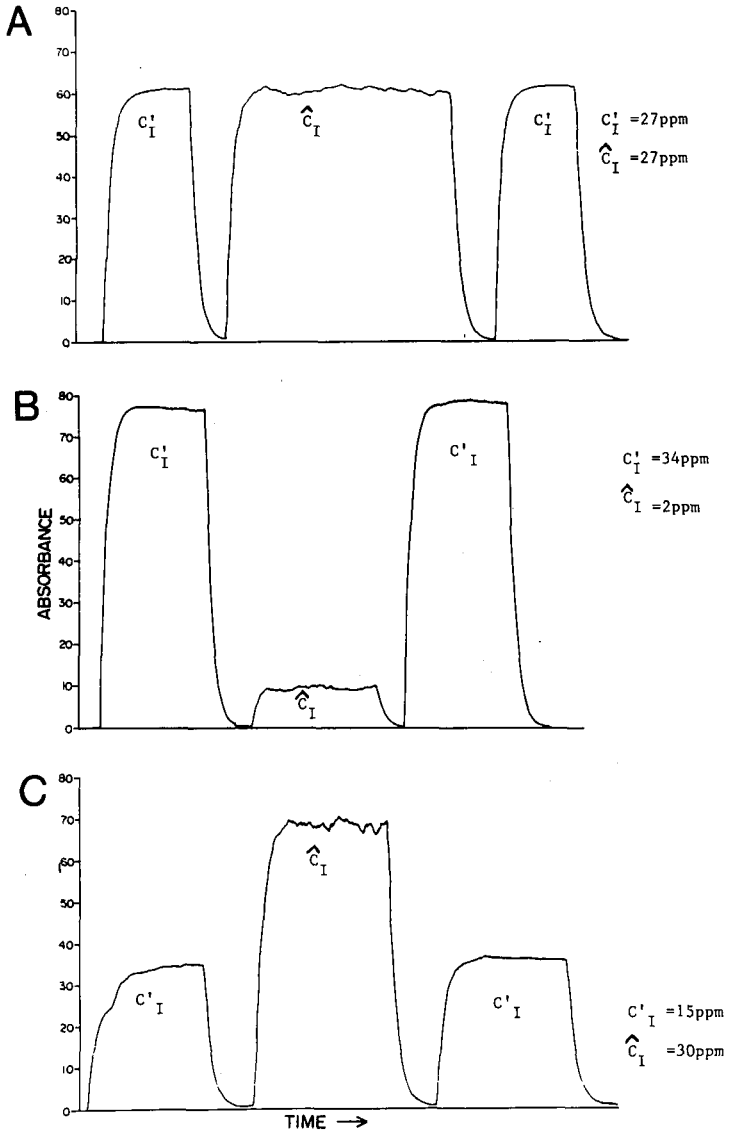

Figure 4 — Chart recordings of three test sequences demonstrating the relationship between C'_I and $\hat{C}_I$. Curve A shows no appreciable difference; Curve B, $\hat{C}_I$ underestimates the actual concentration by 89%; Curve C, $\hat{C}_I$ overestimates the actual concentration by 98%.

on a half-mask respirator could be practical on most people, while flush represents the physical limit of the mask and ¼ inch represents a midpoint (Figure 2).

Leak Site on Faceseal Perimeter (LS)

The factor leak site deals with the location of the leak on the faceseal perimeter. The three leak sites selected for study were: the nose, cheek and chin. These sites were selected based upon experience and professional judgment which indicates that nose, cheek and chin represent the most likely areas of faceseal leakage. Each leak site was created by inserting a piece of ⅛ inch internal diameter, circular tubing through the respirator body at the faceseal lip and was positioned such as to minimize deformation of the facepiece and faceseal. The circular geometry of such a leak may not provide a representative model of how other leak geometries may influence in-facepiece sampling; however, recent observations by Cohen from a study, in which a photographic technique to qualitatively fit test respirators was used, indicates that a circular leak geometry may be a reasonable model for a large percentage of the leaks he observed.[10] All three sites were located on the same side of the respirator. This was done based upon consideration of the symmetry of the respirator about its midline. In regard to the study, it should make no difference whether the leak occurred on the left or right hand side of the respirator (Figures 1 and 2).

Breathing Distribution Patterns (BP)

The factor, breathing distribution pattern, deals with the ratio of the inhalation flow volume that occurs through the nose and mouth. It was noted from questioning a number of respirator wearers that most would breathe through their nose during quantitative facepiece fit testing, but breathe through their mouth while working. As a result, the three breathing patterns chosen for study were as follows: inhalation flow evenly divided between nose and mouth; all inhalation flow through the mouth; all inhalation flow through the nose. These levels were selected because they represent the physiological limits (i.e., all nose or all mouth) and a reasonable midpoint.

Measurement Sample Rate (SR)

Measurement sample rate, the last factor studied, deals with the volumetric rate of sample through the sampling probe. The three sampling rates chosen for study were: 1 L/min; 2 L/min; and 3 L/min. The purpose of studying sample rate is to consider the sampling probe as an open duct with a capture zone that could be defined by velocity contours. Thus by varying the measurement sample rate and holding probe diameter constant, the effect of different sizes of capture zones on sampling efficiency can be evaluated. The rates of 1, 2 and 3 L/min were selected because currently employed in-facepiece sampling techniques most often use sample rates in this range.

Methods and Procedures

Test Apparatus

The complete test apparatus is shown schematically in Figure 3. It consists of three major subsystems: acetone generation and storage reservoir; respirator test setup; and sample collection and analysis.

The acetone generation and storage subsystem consisted of a syringe pump, a dilution air source controlled by flow controller and a vapor reservoir. The syringe pump and airflow controller were calibrated. The mean acetone deliv-

TABLE II
Data Summary of In-facepiece Sampling Bias Caused by Level of Effect for: Probe Location; Probe Depth; Leak Site; Breathing Pattern; and Sample Rate

Test Variable	Level of Variable	n	C_I±S.D.	$\acute{C}_I$±S.D.	$\hat{C}_I$±S.D.	Range $\hat{C}_I$ (ppm)	$\beta(\hat{C}_I)$±S.D.	C.V. for $\hat{C}_I$
	N	27	151±1.8	149±7.6	116±53.8	12 to 300	-22.3±35.6	46.4
PL	M	27	151±1.6	149±8.5	143±60.2	3 to 242	-3.4±41.9	42.0
	P	27	151±1.8	151±8.3	113±48.7	16 to 203	-24.2±34.0	43.0
	O	28	151±2.0	148±8.8	116±52.2	3 to 242	-21.0±38.5	45.2
PD	.25	30	151±1.7	150±7.9	121±54.0	12 to 236	-19.4±35.6	44.6
	.5	23	152±1.4	151±7.5	139±60.5	19 to 300	-7.7±40.7	43.7
	CH	30	151±1.7	148±8.5	154±34.8	93 to 242	4.6±26.1	22.6
LS	CK	26	151±2.0	151±7.5	133±34.9	77 to 208	-11.7±24.0	26.2
	N	25	151±1.5	149±8.0	78±63.8	3 to 300	-47.2±43.0	81.6
	EQ	27	151±1.7	149±9.2	130±44.5	58 to 237	-12.5±29.5	34.1
BP	M	29	151±1.7	149±7.0	126±47.2	50 to 300	-16.0±31.2	37.6
	N	25	151±1.8	150±8.2	116±73.3	3 to 242	-21.8±51.9	63.4
	1	28	153±0.87	149±7.1	126±66.8	3 to 300	-14.9±45.0	52.8
SR	2	28	151±1.3	145±7.4	124±52.1	21 to 242	-14.2±38.3	42.2
	3	25	150±1.4	155±6.6	122±46.4	16 to 236	-21.2±29.5	38.0
TOTAL		81	151±1.7	150±8.1	124±55.4	3 to 300	-16.6±38.1	44.7

ery rate was 0.191 mL/min and the mean dilution air flow rate was 4.9 L/min. Under normal temperature and pressure conditions the average vapor concentration of acetone, C_0 generated by the system was calculated to be 12900 ppm. On a daily basis the concentration of acetone was corrected for variation in temperature and pressure.

The acetone-air mixture was plumbed into a 22-L reservoir which helped dampen fluctuations in the concentration. The reservoir was allowed to exhaust to a hood and was maintained at less than ½-inch positive water pressure. Vapor was transported from the reservoir to the respirator test setup via tubing. This tubing was then connected, as appropriate, to each leak site on the faceseal perimeter.

The respirator test setup consisted of an MSA Comfo II half-mask respirator mounted on a headform by an airtight seal. The respirator was equipped with organic vapor cartridges. The pressure within the facepiece ranged between 0 and approximately 1-inch negative water pressure during inhalation. The sampling probe used for the study has been previously described.[11] The headform was plumbed to accommodate airflow breathing patterns occurring either simultaneously or separately through the nose and mouth. It was attached to a breathing machine operated with a 622 workrate cam. The tidal volume, $\dot{V}_I$, produced by the cam was 1.6 L. During testing, the frequency of the breathing machine was adjusted to correspond with each measurement sample rate to produce a flow of approximately 32 Lpm. This resulted in breathing frequencies of approximately 19.4, 18.8 and 18.1 cycles/min for the sample flow rates of 1,2 and 3 Lpm, respectively.

To allow measurement only during inhalation, the exhalation phase of the breathing cycle was routed directly to the atmosphere and not through the respirator.

Leakage into the respirator resulted from the negative pressure that occurred inside the facepiece cavity during the inhalation phase of each breathing cycle. The leakage rate was determined with a bubble flow meter to be 377, 370 and 363 mL/min respectively for 1, 2 and 3 Lpm measurement sample rates.

The true concentration of acetone existing within the facepiece cavity, C_I, for any given test is determined by Equation 3. In this equation, it is important to note that Q_R represents the total flow through the respirator, defined as $\dot{V}_I$ times the breathing frequency. During in-facepiece sampling, however, a sample volume is drawn out of the respirator at a specified rate Q_S independently of Q_R; therefore, the total flow through the respirator during in-facepiece sampling becomes $(Q_R + Q_S)$.

This means that C_I will be different for each sample flow Q_{Si} (i = 1, 2 or 3 Lpm) used in the study. As a result Equation 3 is modified as follows:

$$C_I = C_0\left(\frac{Q_L}{Q_R + Q_{Si}}\right) \qquad (7)$$

Based upon Equation 7 and an overall root mean square error analysis, the theoretical values of C_I (PPM ± 3 standard deviations) calculated for the 1, 2 and 3 Lpm sample rate conditions were respectively 148 ± 8 ppm, 145 ± 8 ppm and 142 ± 8 ppm. These predicted acetone concentrations were used as standard concentrations values.

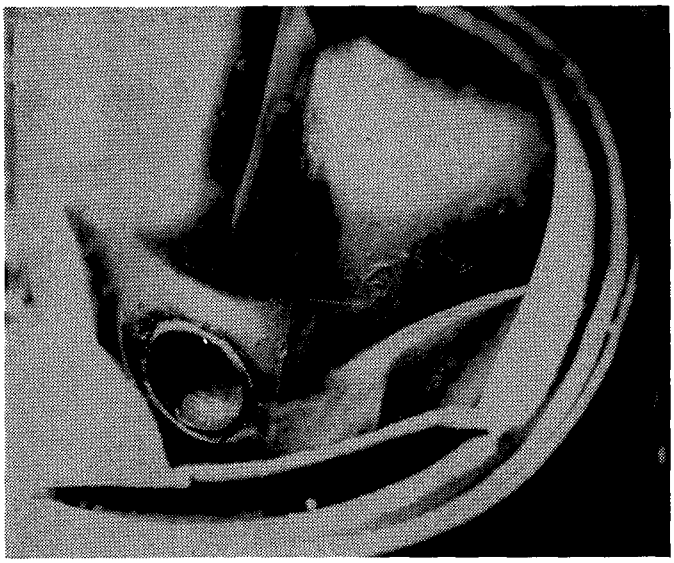

Figure 5 — Streamlines of faceseal leakage in a full facepiece respirator made visible by the presence of smoke.

The sample collection and analysis portion of the system consisted of a flow controller which controlled the sample flow rate and a Miran® 1A Infrared Analyzer calibrated for acetone. Use of a flow controller allowed easy control and adjustment of the measurement sample rate to 1, 2 or 3 Lpm. The collected sample was diluted with clean air to produce a final minute volume of approximately 10 L. The volume of dilution air was also controlled by a flow controller. The adsorbance response of the I.R. was recorded on a strip chart recorder for future data reduction and analysis.

The calibration data points; adsorbance units *vs.* ppm, were fit with a least squares regression line. The equation of the calibration line was -0.62 + 0.45X, where X is the observed adsorbance units. The coefficient of determination (r^2) on the regression was >0.99.

System Evaluation

While it was possible to predict the acetone concentration present in the facepiece cavity, it was desired to confirm this predicted value through experimental measurement. Such a measurement would require that an unbiased sample be collected from the system. Through experimental trial and error, a sampling location was selected immediately outside and behind the test head form in the plumbing leading to the breathing machine. The concentration of acetone measured at this probe location is identified as $\acute{C}_I$. For each test $\acute{C}_I$ was compared with the appropriate C_I value determined by Equation 7. The bias in the measurement of $\acute{C}_I$ was determined by Equation 8 using appropriate substitutions. Based upon 81 tests the mean bias was found to be -1.1% ($\acute{C}_I < C_I$). The close agreement between C_I and $\acute{C}_I$ indicates that the theoretical concentrations predicted by Equation 7 could be verified through experimental sampling and that $\acute{C}_I$ provided a good estimate of C_I. Since $\acute{C}_I$ could be obtained readily during each test, it was used as the concentration of acetone against which $\hat{C}_I$ was compared. In addition, it

served as an internal indicator of system integrity and operation.

Test Procedure

The concentration of acetone measured via the current technique for in-facepiece sample collection is directly analogous to the value $\hat{C}_I$ discussed previously.

From the concentration measurements $\acute{C}_I$ and $\hat{C}_I$, the sampling bias associated with in-facepiece sample collection could be determined. The sampling bias was calculated from the following expression:

$$\beta(\hat{C}_I) = (\hat{C}_I - \acute{C}_I)/\acute{C}_I \times 100 \quad \textbf{(8)}$$

All tests were conducted in the same general format which was to start the test by obtaining a measurement of $\acute{C}_I$ over a period of approximately 4 min. The analytical system was then flushed with acetone free air until adsorbance readings returned to zero. The analytical system was then connected to the sampling probe on the respirator to measure $\hat{C}_I$. This sample was collected over a period of approximately 6 min after which the analytical system was again flushed with acetone free air until adsorbance readings return to zero. Then a second $\acute{C}_I$ measurement was made for approximately 4 min.

Results and Discussion

The results of several test sequences are presented in Figures 4A, 4B and 4C. They represent typical test runs and demonstrate how the measurement of in-facepiece concentration was influenced by the factors under study.

Curve A of Figure 4 demonstrates the results of the test sequence where the probe location is at the level of the mouth; the probe depth is ¼ inch; the leak site is at the chin; the breathing distribution is all through the mouth; and the probe sample rate was 2 Lpm. The chart clearly indicates that this particular combination of test variables did not cause appreciable sampling bias.

Curve B of Figure 4 demonstrates the results of the test sequence where the probe site is between the nose and mouth; the probe depth is flush, the leak site is at the nose, the breathing distribution is all through the nose, and the probe sample rate is 3 Lpm. This combination of variables resulted in an estimation of the concentration of acetone which understimated the actual concentration of acetone inside the facepiece by 89%.

In Curve C of Figure 4 the probe site is at the nose; the probe depth is ½ inch; the leak site is at the nose; the breathing distribution is all through the mouth; and the probe sample rate is 1 Lpm. In this test setup, the combination of variables tested resulted in an estimation of acetone concentration, which over-estimated the actual concentration of acetone inside the facepiece by 98%.

A data summary of C_I, $\acute{C}_I$, $\hat{C}_I$ and $\beta(\hat{C}_I)$ for each level of test variable is presented in Table II. The level of variable represents the various states possible with each test variable. The sampling bias $[\beta(\hat{C}_I)]$ reported in the table represents the bias observed at each level of the 5 test variables. Several general observations can be made from the data. As previously mentioned, the first is the excellent agreement which exists between C_I and $\acute{C}_I$. The second is that the concentration measurements made via current in-facepiece sampling technique consistently, with one exception, underestimated the concentration of acetone within the facepiece cavity. This would lead one, on the average, to over-estimate the fit factor determined for a unique man/respirator combination. The third is that while values of $\acute{C}_I$ remained very stable around 147 ppm, values of $\hat{C}_I$ ranged from 3 ppm to 300 ppm. Statistical analysis of these data indicates that the following factors had significant contributions to the sampling bias observed with $\hat{C}_I$:

1) Varying the probe location on the midline between the nose, the area between nose and mouth, and the mouth;
2) Varying the position of the leak from between the nose, the cheek and the chin; and
3) An interaction between breathing distribution pattern and the site of the faceseal leak.

The coefficient of determination r^2 for the overall linear regression model was 0.8, which indicates that a large portion of the observed sampling error could be explained by main effects and 2-way interactions. Because of the very strong influence on sampling bias by leak site, sampling probe location, and the interaction between leak site and breathing pattern, any possible effects of the other main factors and interactions were overshadowed.

The variability in the estimate of $\hat{C}_I$ also demonstrates the wide range of uncontrolled sampling errors that may be occurring during quantitative facepiece fit testing and workplace protection factor testing on negative pressure half-mask respirators. The variability of quantitative facepiece fit test results has been demonstrated time and again and discussed at great length. The general conclusion most often put forward is that respirator fit is a function of several factors (*e.g.* subject variability, fit variability, *etc.*), which sufficiently explains the observed measurement variability. The results of this study, however, suggest that a portion of the variability associated with quantitative facepiece fit testing may actually be due in part to the large sampling bias in $\hat{C}_I$. This variability would result from the conditions created

TABLE III
Predicted and Actual Concentration Values from In-facepiece Sampling Over Inhalation and Exhalation

Observation	C_I	$\bar{\bar{C}}$	$\hat{\bar{C}}$	$\hat{\beta}(C)$	$\hat{\beta}(C_I)$
1	160	146	138	-0.14	-0.15
2	157	149	146	-0.07	-0.08
3	165	141	118	-0.28	-0.27
4	166	92	113	-0.32	-0.99
5	152	181	168	0.11	0.32
6	171	145	124	-0.27	-0.37

$\hat{\beta}(C) = (\hat{\bar{C}}-C_I)/C_I$

by randomly changing sampling probe locations, leak sites and breathing pattern interactions that are inherent with intra- and inter-subject fit testing. The effect of in-facepiece sampling bias on variability of quantitative facepiece fit testing results in perhaps more easily visualized by consideration of fit factors instead of sampling bias. The estimated fit factor, FF, corresponding to each of the 81 values of $\hat{C}_I$ measured in the study can be calculated from the following expression:

$$FF = C_0/\hat{C}_I \quad (9)$$

where C_0 is 12 900 ppm corrected for daily variation in temperature and pressure.

The true fit factor, FF_T is determined by $12\,900/C_I$ and is equal to 85 (C_I determined by Equation 7). The FF values determined by Equation 9 were found to range from 44 to 4728. Analysis of the resulting distribution of FF values indicated that they were not normally or lognormally distributed. The geometric mean was 124 with a geometric standard deviation of 2.1. The arithmetic mean value was 213 with a standard deviation of 539. The geometric mean of 124 overestimated the true fit factor (85) by 150% while the arithmetic mean overestimated it by 250%. In the last several years quantitative facepiece fit testing has been advocated as a means for assigning protection factors for specific man/respirator combinations. Because the sampling bias noted in this study resulted in large overestimates of true fit, the use of fit factors determined by current quantitiative facepiece fit testing to justify protection factors higher than those currently recognized by NIOSH and others should be cautioned.

Based upon the sampling biases noted with the measurement of $\hat{C}_I$, it is hypothesized that material coming through a leak on the faceseal perimeter is streamlining within the cavity of the respirator. Further evidence for this hypothesis was provided by visual observation made within the facepiece cavity of a full facepiece respirator during the inhalation phase of the respiratory cycle. A single leak was introduced into the facepiece cavity between the interface of the respirator faceseal and head form. Ventilation smoke was provided to the leak and made the streamlines clearly visible as shown in Figure 5. These streamlines may be more pronounced with a particulate aerosol, such as ventilation smoke or oil mist, rather than with a gas or vapor.

One noteworthy aspect of the methodology used in this research is that the sampling bias estimates have been made only when an inhalation volume was passed through the respirator. The accompanying exhalation volume was not routed back through the respirator. As a result, two important questions can be raised in regard to the data. First, does the cycling of both an inhalation and exhalation volume through a respirator increase the turbulence of airflow on inhalation and, therefore, decrease the sampling bias? Second, would sampling during exhalation, after presumably complete mixing has occurred in the lung, reduce the net effect of sampling bias during inhalation?

Visual observations, made of the leak streamlines in the full facepiece respirator setup previously discussed, demonstrated that routing an exhalation flow through the respirator did not appear to affect the leak streamlining produced during inhalation. In regard to the second question we need to consider the relationships expressed in Equation 3 and Equation 4. Very simply expressed, sampling over inhalation and exhalation can, to a varying extent, moderate the effect of sampling bias experienced during inhalation. The extent of the averaging would be dependent on the following: k_2; the sampling bias experienced during exhalation; and the amount of loss in concentration due to lung retention. On our test system C_I is known, and k_1, k_2 and η_L were determined to be 0.47, 0.53 and 0.05 respectively, if we assume $\xi_2 = 1$, then $\bar{\bar{C}}_I$ could be predicted and verified by actual sampling on specific test setups where ξ_1 has been determined. The predicted value of $\bar{\bar{C}}$ was calculated as follows:

$$\bar{\bar{C}} = k_1\xi_1 C_1 + k_2\xi_2 (1-\eta_L)C_I$$

The predicted concentration measurement, $\bar{\bar{C}}$, and the actual sampling measurement, denoted as $\hat{\hat{C}}$, associated with selected test setups are given in Table III. It can be seen from these data that sampling over exhalation does moderate, to a varying extent, the effect of sampling bias during inhalation. The somewhat large differences between $\bar{\bar{C}}$ and $\hat{\hat{C}}$ may indicate that the initial assumption of $\xi_2 = 1$ may have been incorrect for all specific test setups. This would suggest that some sampling bias may also be occurring during exhalation. It should also be noted that the moderating effect of exhalation sampling will vary substantially as η_L varies.

Conclusions

The magnitude of sampling bias observed under the conditions of this study, were from -99% to + 98%. The mean sampling bias was -17%. This research demonstrates that faceseal leakage is not mixing instantaneously and uniformly within the facepiece cavity.

It is hypothesized that faceseal leakage is streamlining within the respirator cavity during inhalation. The position of those streamlines relative to the location and depth of the sampling probe appears to be the major cause of the observed sampling bias. This is in contradiction to the assumption, often applied when doing in-facepiece sampling, that good mixing is occurring in the facepiece cavity during inhalation because of turbulent air flow in the mask. The sampling bias associated with in-facepiece sampling during inhalation may contribute to the variability often experienced with quantitative facepiece fit results.

If confirmed through additional research, these preliminary findings bring into critical question the interpretation and use of data obtained by the current in-facepiece sampling technique employed in the U.S. Other implications of this current research will be discussed further upon completion of research which is currently under way on two other brands of half mask respirators. We are continuing the

research to evaluate other variables such as differential leak rate, multiple leak sites, differential breathing rate, and leak site geometries and to develop an improved technique for in-facepiece sampling.

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