BIOLOGICAL MARKERS FOR FORMALDEHYDE EXPOSURE IN MORTICIAN STUDENTS

REPORT I, DOCUMENTATION OF MEASUREMENT METHODOLOGY FOR CHARACTERIZING EXTENT OF EXPOSURE

FINAL REPORT

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Prepared by:
Mark Boeniger, M.S., C.I.H.[1]
Patricia Stewart, M.S., C.I.H.[2]

[1]Industrial Hygiene Section
Industrywide Studies Branch
Division of Surveillance, Hazard Evaluations,
and Field Studies
National Institute for Occupational Safety and Health
Cincinnati, Ohio 45226

[2]Occupational Studies Section
Environmental Epidemiology Branch
National Cancer Institute
Rockville, Maryland 20892

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SUMMARY

Researchers at the National Institute for Occupational Safety and Health (NIOSH) and the National Cancer Institute (NCI) are conducting a study of embalming students who are exposed to airborne formaldehyde. The study will determine if exposure to formaldehyde in embalming practice is associated with the development of biological changes as measured by selected collection assays. This report presents an evaluation of the procedures used to characterize exposure to formaldehyde for this study. A companion report, subtitled "Extent of Exposure", provides the actual exposure monitoring results using the procedures described here.

A passive diffusion device (badge monitor) used in this study to monitor personal exposures to formaldehyde was compared to the NIOSH active air sampling method. Laboratory sampling in a dynamic vapor generation chamber using these two approaches, with exposure to freshly generated formaldehyde, indicated that the passive diffusion monitoring device provided results that were comparable to the results from a NIOSH active sampling method for formaldehyde with a total analyte loading of at least 8 ppm-hrs. Initial field testing in stationary sampling locations at an embalming laboratory revealed lower results and higher imprecision for the passive monitor versus the active sampling methods. It was suspected that this was due possibly to air starvation across the face of the passive monitors. An additional field sampling study was performed under more turbulent air conditions. However, the negative bias among the passive monitors relative to the active samplers still persisted, although the precisions were similar. In a final field evaluation, 50 sets of personal samples were collected using both the passive monitor and an active sampling method. The results indicate a grouped bias of -29% for the passive monitors. With the upper limit results removed from the data set, the overall bias was -25%. The cause of the field bias was hypothesized to be related to newly recognized forms of airborne formaldehyde. Polymeric forms of aged formaldehyde may be present in the atmosphere and could account for the sampling bias. Because polymeric forms of formaldehyde probably have lower diffusion coefficients through the diffusion barrier that covers the sampling reagent, passive monitors may produce lower measurement results if they were calibrated against monomeric formaldehyde. The active sampling methods, by comparison, collect all species of formaldehyde, including the polymers. Comparing the field results from each method by duration of use revealed no affect upon the passive monitors by this variable. However, plotting the bias against increasing concentrations of formaldehyde, as measured by the NIOSH tube method, did reveal increasing bias, which became noticeable when the sample loading exceeded 5 ppm-hours. For equivalence to measurements by the Occupational Safety and Health Administration (OSHA) and NIOSH air sampling methods for formaldehyde, results in the report entitled "Biological Markers for Formaldehyde Exposure in Mortician Students, Report II, Extent of Exposure" were adjusted for this bias.

Performance data for a continuous reading formaldehyde monitoring device are provided. Comparison of the continuous reading device to the NIOSH active sampling methods gave results that were in general agreement. It was demonstrated that this device could be used to monitor short-term elevations in formaldehyde concentration.

DISCLAIMER

Mention of company or product names does not constitute endorsement by the National Institute for Occupational Safety and Health or by the National Cancer Institute.

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INTRODUCTION

A collaborative study between researchers at NIOSH and the National Cancer Institute was initiated to study biological markers in mortician students at the Cincinnati College of Mortuary Science (C.C.M.S.) who are exposed primarily to formaldehyde during embalmments.[1] Detailed extent of exposure data is required for the correlation of exposure to the biological markers. Previous monitoring of these operations at C.C.M.S. indicated that the exposures ranged from approximately 0.3 to 8.7 ppm (geometric mean 1.9 ppm) and lasted from 1 to 2 hours on a given day.[2] The NIOSH investigators were informed that each student participates in at least one embalming (as an average) per week. However, to gain experience, students have the option of participating in more embalmments during the weekdays and may work on Saturday as well. In addition, many of the students may reside at a funeral home or have a part time job where they may participate in embalmments and have additional exposure to embalming solutions. Because of the irregular nature of exposures among this study population, a means was sought which would allow the students to perform some type of self-monitoring of their exposures.

The performance information provided by Air Quality Research, Inc. (present address P.O. Box 14063, Research Triangle Park, NC 27709) suggested that their passive monitoring devices met NIOSH requirements for accuracy, precision and specificity in a sampling method, and provided a practical means by which the students might perform self-monitoring of their exposures to formaldehyde. Support documentation provided by the company (Appendix I) indicated that the devices could be expected to be accurate to within 1% of the true concentration with an overall relative precision of 6%. The sampling range over which the PF-20 STEL monitor was considered by the manufacturer to be applicable was 0.2 to 8 ppm-hours. Among the many chemicals experimentally introduced to the monitors, none was determined to be an interference in the determination of formaldehyde.

A series of laboratory and field tests were conducted to determine independently the performance of these devices. The results of these tests were evaluated principally by comparing the results obtained from the passive monitors to the results of other, more established methods for quantitating formaldehyde in air. To be acceptable, the NIOSH Standards Completion Program (SCP) protocol requires that the monitors must be able to give a mean value that is within $\pm$25% of the reference value at the 95% confidence limit with a pooled relative standard deviation (CV) less than or equal to 10.5% at the target concentrations.[3] As part of this evaluation, blank values and sampler capacity were assessed in a laboratory study. Because of the need to quickly initiate this study to correspond with the academic school year at C.C.M.S, other parameters involving the performance of passive monitors were not evaluated, and

some data from the manufacturer were assumed representative of its performance. In a subsequent field evaluation, the performance of the passive monitor was assessed in the presence of the many chemical constituents found in embalming products.

METHODS

Laboratory Study

A laboratory study was undertaken which included the PF-20 STEL passive monitoring device and NIOSH method 2502.[4] The PF-20 STEL monitor was selected, rather than the PF-20 PEL, since the PF-20 PEL is incapable of determining less than 0.8 ppm-hours of exposure. For confidence in the analytical results, measurements should be taken which are several times above the limit of analytical detection (LOD). Because the sampling portal of the PF-20 STEL has a cross-sectional area which is 2.65 times larger than the portal in the PF-20 PEL monitor, it is capable of sampling significantly lower concentrations (about 0.2 ppm-hours). NIOSH Method 2502 was selected in this evaluation because of the ease of using a tube collection method. Both methods were used to sample the formaldehyde concentration in a dynamic exposure generating chamber that has been previously described elsewhere.[5] Two concentrations of formaldehyde gas were generated by injecting a solution (4.6 grams in 250 mL distilled water) of paraformaldehyde into an injection block heated to 130°C. The generated formaldehyde was then swept into the exposure chamber with a flow of dry nitrogen. Temperature and humidity were continually monitored within the chamber. All test runs were performed at a temperature of 74-75°F (23-24°C) and a relative humidity of 44-49%.

NIOSH method 2502 uses a specially treated solid sorbent medium contained in a glass tube to collect formaldehyde. These tubes were purchased from Supelco, Inc. (ORBO 22). The sampling rate, obtained by using Gilian® low flow personal sampling pumps, was approximately 40 mL/min. The flow rate for each pump was calibrated both before and after use. The sample tubes were connected to the inside of the exposure chamber through short lengths of 0.123" o.d. Teflon® tubing that extended into the same part of the chamber where the passive monitors were being exposed. A triplicate set of these samplers were used for the first two hours of sampling, and changed with fresh tubes for continuation into the second two hours of sampling.

The passive devices were exposed to formaldehyde over a range of time lasting 15 minutes to 4 hours. Since previous personal exposures at C.C.M.S. had been measured with a geometric mean of about 2 ppm that lasted one to two hours, a combination of times lasting from 0.25 hours to 4 hours and at a concentration level of 2 or 4 ppm would provide a full representation of the range of exposures expected to occur. A rack was constructed in the exposure chamber that could hold up to five sets of four badges. In contrast to the method 2502 approach, all 20 passive samples were placed simultaneously into the chamber at the beginning of the experiment. The

passive samples were clipped to a stainless steel bar in five sets of four which were then put onto the rack in the exposure chamber. At the end of each designated time period (0.25, 0.50, 1, 2, 4 hours) a sample set was removed from the chamber.

After sampling, the passive devices were returned to the manufacturer for analysis. The manufacturer's data printout gives a value of the concentration based on the amount of collected analyte and exposure time. According to the manufacturer, the concentrations reported are corrected for the laboratory blank values determined for each lot of badges. To assess field blank stability, badges were randomly selected from the lot of badges and given fictitious sampling times to serve as field blanks. They were treated in the same way as the chamber samples except that they were not exposed to formaldehyde.

Complete sample runs for each sampling duration and at two air concentrations of formaldehyde were collected. Because of problems that were encountered in operating a CEA 555 instrument for quick verification of the concentration of formaldehyde in the exposure chamber, a pair of direct reading Lion Formaldemeters (MDA Scientific) were used to sample the chamber environment for corroboration that the calculations concerning the expected air concentration were correct. Agreement between the direct reading instruments and the calculated concentration was obtained and two air concentrations of approximately 2 ppm and 4 ppm were generated for the duration of each run.

Field Study

a. Stationary Sampling

To determine if the passive monitors would perform adequately in the presence of other embalming chemicals, two separate efforts were made at the C.C.M.S. embalming laboratory to collect matched triplicate samples. In the first effort, a stationary sampling station was located adjacent to the embalming table on a bench top approximately 6-8 feet distant. Under these normal conditions of the laboratory room, the ambient air velocity in the vicinity of the sampling stations was non-detectable (<5 lfpm) as determined with a thermal anemometer. In the second effort, the sampling station was located in the same site, but a small portable fan was fixed above the site to provide 55 to 70 linear feet per minute (lfpm) of direct air movement across the face of the passive monitors.

During the first sampling effort, seven sets of samples were collected during seven embalmments at C.C.M.S. During these sampling periods the types of cases ranged from single, minimal preparation embalmments and anatomical preparations, to two autopsied cases being prepared simultaneously (considered to be a situation most

likely to generate the most intense exposures). For background information concerning the types of embalming chemicals used, details of seven individual cases are briefly described below:

Case 1 was a medium built man who had been refrigerated for 24 hours after death. Because this was an anatomical case (donated to medical training), a higher formalin concentration was used as well as 5 gallons of a special aqueous mixture containing 6% phenol, 4% methanol, 5.5% glycerin, and 32% ethanol. All injections were made into the carotid, axillary and femoral arteries. Hexaphene gel (containing formaldehyde) was applied to the extremities.

Case 2 was a slightly built older man who had been autopsied and had been refrigerated at the coroner's office for one week. For autopsied cases, in addition to the standard injection sites, formalin solution is added to the viscera bag and is hypo-injected in the side walls of the visceral cavity. Para-formaldehyde (2%) containing hardening agent powder was applied to the visceral cavity. "Dis-spray", a formalin and isopropanol containing disinfectant spray solution, was used for surface cleaning after embalming.

Case 3 was a autopsied adult female who had died from a severe head injury. Also being embalmed was a small 4 month old baby. Minimal quantities of embalming fluid were used on the baby. The embalming fluid used with the adult contained formaldehyde, methanol, and methoxymethanol as the listed ingredients. A granular hardening compound containing formaldehyde was added to the thoracic cavity walls.

Case 4 was a heavy set autopsied woman. This case was similar to case 3.

Case 5 involved two standard preparation corpses, both of which were older women. The second body was also being prepared for anatomical use and thus was injected with a special mixture containing phenol.

Case 6 was a medium built woman that was being prepared as an anatomical case. Hexaphene gel was applied to the hands and feet.

Case 7 involved two corpses which had been autopsied. Dis-spray was used in the nasal-mouth region. Granular hardening agent was used on both bodies. A detailed record of events that occurred during this case is presented with formaldehyde air concentrations in the Results section.

During the first sampling effort, each sample set included three passive monitors, and most included two independent methods for determining formaldehyde in air. Each independent sampling method also contained three sampling units per set. The two independent methods that were used were NIOSH Method 2502 (tube collection

method) and NIOSH Method 3500 (bisulfite impinger collection method).[4] The flow rates chosen for the NIOSH methods were about 50 mL/min., and 235 - 250 mL/min., respectively. The less sensitive method was Method 2502. The LOD in air calculated for this method, given a 110 minute sample, was 0.08 ppm of formaldehyde. This LOD is well under the level which has previously been measured by NIOSH/NCI researchers at this site.[2] In using the 3500 method, no prefilter was used so that both particulate as well as gaseous formaldehyde would be represented in the result. All impingers were inspected prior to use to determine that the stems were about 0.3 cm distant from the bottom of the flask.

In addition to the two independent NIOSH methods, an Interscan Series 4160 continuous reading formaldehyde meter with data logging capabilities was included in each set. This instrument is capable of recording all peak concentration episodes as well as the integrated time-weighted average concentration. More information on this instrument is provided in the following subsection of this report.

To determine concurrent concentrations of methanol, phenol, and glutaraldehyde, NIOSH Methods 2000, 3502, and 2531, respectively, were used.[4] Isopropanol was determined using both NIOSH Method 2000 and 1400. Methanol was collected in silica gel tubes, isopropanol was collected on both silica gel and charcoal tubes, phenol was collected in a bubbler, and glutaraldehyde was collected in specialty resin tubes. Quality assurance samples which contained a known amount of liquid spiked methanol and glutaraldehyde were submitted with the field collected samples. Unsampled field blanks were also submitted. All quality assurance samples were submitted blind to the laboratory with no special identification so that they could not be identified as spiked or blank samples.

Each sample collection set contained sampling media for formaldehyde and the other analytes and was attached to a wire test tube holder (approximately 4.5" by 10") and placed on a laboratory bench top adjacent to the two embalming tables in the embalming laboratory at C.C.M.S. The sampling station that included these sample collection media were located approximately six feet from the embalming table being used or midway if both tables were being used. Sample collection began simultaneously at a time just prior to beginning an embalming procedure. Sampling ended when the corpse was removed and the students left the laboratory. The embalming sessions monitored during this experiment were of a duration of between 100 to 170 minutes.

In the second field collection effort, five sample sets were collected. The sampling station was identical to that used in the first effort except that NIOSH Method 2541 replaced NIOSH Method 2502.[4] This replacement method has been determined to be superior by NIOSH researchers because it uses a collection tube media that has increased shelf life. As already stated, supplemental air movement was provided to benefit the passive monitors in case air stagnation was negatively biasing the results.

Finally, all impinger solutions for the sodium bisulfite impinger method were initially poured into their respective sample storage vials off-site to eliminate any possibility of field contamination of the sampling solution.

b. Personal Sampling

Personal sample collection was initiated immediately after the stationary sample results were analyzed. Using NIOSH Method 2541 as the reference method, the performance of the passive monitors were determined. The passive devices and sorbent tube media were attached within 5 inches of each other in the breathing zone of each wearer. At termination of the sampling period, the sampling pumps were stopped, both samplers were removed, and both were immediately capped and the end time recorded. Thirty-seven sample pairs were initially collected in work performed prior to the exposure monitoring study. Simply to expand this data set, an additional 13 sample pairs were obtained during the exposure monitoring study to supplement the earlier data, for a combined total of 50 sample pairs. There were no perceived differences between the two sampling periods.

The air flow rate for the sorbent tube method was about 50 mL/minute and the flow rate for each pump was checked with a primary air flow reference method (graduated cylinder) both before and after each use. Air flow calibrations tended to be extremely stable. After the sorbent tube and pump were attached to a student, the student was allowed, with supervision, to prepare and attach the passive monitor to himself or herself for sampling. This latter step allowed the investigators to observe the handling of these devices by persons unfamiliar with their use and was intended to assist the researchers in better anticipating any potential problems with their use during the actual exposure monitoring study.

Interscan Continuous Reading Monitor

An Interscan Portable Analyzer, Model 4160SP, (Interscan Corp., Chatsworth, CA) was purchased to allow continuous monitoring of the formaldehyde concentrations near the breathing zone of the mortuary students. The unit is a battery-operated device with an integral sampling pump which delivers air at 1 Lpm to an electrochemical voltametric cell inside the unit. The analog meter was factory installed to reflect a concentration range of 0-20 ppm formaldehyde. Response time as measured in our laboratory was very fast, being just a few seconds to full scale response. Interferences of potential concern based upon chemical usage at the C.C.M.S. laboratory are reported below. The ratio of responsiveness, on a ppm basis, by the instrument to chemicals other than formaldehyde is as follows: methanol, 624/1; isopropanol, 1100/1; glutaraldehyde, 120/1; and phenol, 6/1. Field samples for these compounds were collected in the C.C.M.S. laboratory.

In actual field use, a small diameter Teflon® tube was located at breathing level over the embalmer's table and run to the device. Because particulate formaldehyde could contaminate the sensor, a 0.5 um pore size Teflon® filter was attached to the sampling inlet. To continually record the measured response to formaldehyde concentration, the Interscan Portable analyzer was connected by cable to an electronic data storage device (Rustrak Ranger®, Gulton Co. East Greenwich, R.I.). The recorded data was later downloaded into a personal computer for later analysis and display.

RESULTS

Three out of four of the PF-20 STEL samples that were submitted as field blanks with the laboratory study samples indicated concentrations below the LOD (Table 1). The reason for the one exception could not be explained. Since a small number of field blanks were included in this phase of the evaluation, six additional field blanks were included in the later studies. These additional blank field values are reported in Table 2. All blank values were reported as below the LOD for formaldehyde. These data would suggest that the blank value is stable with time and that chemical artifacts are not present which would positively bias the results. Nor is there evidence that cross-contamination of these samples by actual samples occurred during shipping.

Laboratory Test Experiment

Results from the laboratory evaluation of the PF-20 STEL passive monitor and NIOSH Method 2502 are reported in Table 3. The two parameters which were varied were duration of exposure and concentration. In order to evaluate the results, the pooled coefficient of variation (CV) for the badge measurements and the bias relative to the independent method were calculated.

The bias calculation used here is not entirely valid since two-hour samples taken with the 2502 method were compared to passive monitors of varying lengths (15 minutes to 2 hours) of time. Shorter duration samples were not taken with the 2502 method since the calculated analyte loading at two hours was considered to be near the minimum necessary for confidence. In addition to bias and variation calculations, statistical probabilities were calculated using the paired t-test to determine whether the paired variances at each time period were equivalent.

The laboratory sampling results in Table 3 are listed by the period of time during which they were collected. Data Set 1 was collected at approximately 2 ppm, and Data Set 2 was collected at about 4 ppm. In addition to the individual sample period runs, grouped overall results are provided which compare the passive monitor results with the 2502 method for the period of 0-2 hours and 2-4 hours as well as "all sets" which include all time periods. Theoretically, the air concentration in the exposure chamber was constant during all periods, and allowed for grouping of different periods.

The results in Data Set 1 (Table 3) indicate individual passive monitor sample run variation in the range of 2.8 to 8.8% (group mean 6.6%) for the period 0-2 hours, with a bias range of +3.7 to -7.4% (group mean -3.3%). For the period 0-4 hours, the passive monitors have a CV of 2.6% and a bias of -3.9% (with one outlier removed). The imprecision in the passive monitor results compare favorably with the results from the 2502 method where the CV's were 4.8 and 1.4 for the 0-2 and 2-4 hour period samples, respectively.

The results in Data Set 2 (Table 3) indicate individual sample run variation for the passive monitors in the range 0.7 to 9.9% for sampling durations up to two hours, with a bias range of 0.8 to 14%. Sample Set 16, for period 0-2 hours, had a CV of 1.2 and a bias of +14%. The CV for the 2502 sampling set at 0 - 2 hours was 3.8%. For the period 0-4 hours, passive sampling set 17 has a CV of 32.3% and a bias of -34.5%. The CV for the 2502 sampling method was 4.4%. Overall, the passive devices produced results that were comparable to the NIOSH methods at 4 ppm for up to 2 hours of sampling. Beyond 2 hours of sampling at 4 ppm, apparently the passive monitors exceeded the limit of their sampling capacity (>8 ppm-hrs). The manufacturer of these devices supports the use of 8 ppm-hrs as a practical maximum exposure for field tests. (Written Communication, Air Quality Res., 13th Dec., 1989)

Field Study

a. Stationary Sampling

The results of the initial field sampling study shown in Table 4 indicate unacceptably high imprecision in the PF-20 STEL passive monitoring devices. In addition, there is a negative bias when compared to both the impinger (Method 3500) and tube (Method 2502) methods (Table 5). Unfortunately, the blank field samples for Method 3500 were positive, and an average value of 9 ug/sample was subtracted from the results. It is not known how such a high background occurred, but the same solution was used throughout the field study. The resulting average bias between the passive devices and Method 3500, adjusted for background, was -17%. Without the background adjustment, the bias was -42%.

The bias when comparing the results from Method 2502 to the passive monitor results was -28%. No adjustment of the 2502 method results was necessary because all blank sample results were less than the LOD.

Unexpectedly, Method 2502 did not agree well with Method 3500. The grouped bias when comparing Method 2502 to Method 3500, both adjusted and unadjusted for the blank value in Method 3500, was -8% and -18%, respectively. A closer inspection among the individual sets indicates that the individual biases ranged from -36% to -9% (unadjusted), and -58% to +32% (blank adjusted). One might expect that the 3500

method might give higher results than the 2502 method since it can collect both gaseous and particulate formaldehyde (without a prefilter). However, in studying the case descriptions, there is no appreciable difference in the bias between cases where particulate formaldehyde might be present - as in the preparation of autopsied cases, and those instances where only liquid forms of formaldehyde were used. The reason for the lack of better comparative performance is not known.

Methanol, phenol, and glutaraldehyde were not detected in any of the seven air sampling sets. The lowest concentrations that could have been determined under the conditions of this study were about 1.5, 0.2, and 0.15 ppm, respectively. Isopropanol was detected at low concentrations during the collection of most sample sets (Table 4).

A follow-up evaluation of the three sampling methods in a stationary location with a small fan produced results which are summarized in Table 6. All field blank values for both the tube and passive monitor methods were below the LOD. A trace concentration of formaldehyde was reported in the blank impinger samples. This blank value corresponds to less than 0.01 ppm in the air samples that were collected. The source of this blank was traced after analysis to the inappropriate use of high density polyethylene bottles.

In the second stationary evaluation involving 5 sets of samples, the results from NIOSH Method 3500 were 6% higher than the results from Method 2541 (Table 6A). Between the passive monitor and Method 3500 or Method 2541, the bias was -25 and -19%, respectively. The within set imprecision of the passive monitor was comparable to either of the NIOSH active sampling methods. However, using an *a posteriori* test of the differences of the results (Scheffe 95% confidence intervals), the results from the passive monitors were found to be significantly different from the results of either of the other two methods. Performing a two-way ANOVA, taking the methods and sample set results into account, the variation was highly significant at the $p<0.0001$ level. Figure 1 visually shows these differences.

b. Personal Sampling

The 50 individual paired results are provided in Table 7. Because in four pairs the measured amount of formaldehyde in the sample tube method (Method 2541) was below the limit of detection, and in two pairs, the passive monitor result was well over 100% of the active sampling tube method - suggesting a problem resulting from either the sampling flow rate through the tube or splashing of the monitor - data analysis was restricted to 44 sample pairs.

In the first set of 33 non-zero, non-outlier sample pairs, the passive monitors measured 37% less than the active sampling method. The passive monitors in the second set of 11 sample pairs produced an average result that was 5% less than the active sampling method.

The difference (using a paired t-test) between the two sets of personal sampling data was not quite statistically significant ($p = 0.07$). If the means of both sets of data were given equal weight, the pooled average was -24%. However, since the second data set was intended to supplement the first data set, and there was no reason to believe there should be a difference between the two sets, the data were combined. The combined overall average bias ($N=44$) was -29%.

These data are visually displayed in several figures. Figure 2 depicts the bias between methods as a function of sample duration. Sample duration, lasting from 80 to 170 minutes, was not seen to affect the extent of bias. Figure 3 shows the extent of bias, using the combined paired data, plotted against concentration as measured by the NIOSH tube method (note that the X-axis is not linear). A slight increase in bias with increasing concentration is suggested by this graph. Another way of viewing the data is to present the results from the two methods in terms of ppm-hours of sample loading. This is shown in Figure 4. In this figure, all fifty sample pairs are presented. Generally, a reasonable pattern of agreement appears between the sample loadings obtained by each method until the loading measured in the sorbent tube exceeds about 5 ppm-hours. After that a significant deviation occurs, although only a few data points exist at the higher loadings.

Simple linear regression analysis of the percent bias of the passive monitors against the NIOSH tube concentration data was performed. Excluding sample pairs where the sample loading was below the limit of detection, or where there was several times more analyte on the monitor than the tube (suggesting contamination), 44 data pairs were analyzed and plotted in Figure 5. The correlation coefficient was -0.53 and the slope of the regression line was highly significant ($p = 0.0002$). Again, the average bias for the passive monitor in this data was -29% (median = -30%; mode = -31%). A square root transformation of the percent bias (dependent variable) was performed to improve linearity. Performing a linear regression of the transformed data resulted in a

correlation coefficient of -0.63 and a probability level of 0.00001 on the slope. A plot of the residuals obtained with the square root transformed data appeared quite normal (not shown). A test of residuals from the transformed data using the Chi-square test and Kolmogorov-Smirnov tests of normality produced significance levels of 0.43 and 0.58, respectively, indicating that the residuals are normally distributed, and that the transformation of the data was acceptable.

However, it appears from Figure 5 that a few extreme data may be appreciably influencing the slope and driving the regression. Thus, five data pairs were excluded (N=39) where the tube loadings were greater than 5 ppm-hrs and the analysis was re-performed. Figure 6 indicates a reduction in the slope (nonsignificant, p = 0.11), and a reduction in the correlation coefficient to -0.26. The percent bias shown with sample loadings of about 1 ppm-hrs is about -20%, which increased to about 35% with sample loadings of about 4 ppm-hrs. The average bias of these data was -25% (Median = -28; mode = -29).

In a similar analysis, if only the total analyte loading was studied relative to the bias of the passive monitors, bias also is seen to decrease with decreasing analyte loading. For six sample pairs with a total analyte loading of greater than 5 ppm-hours, the average bias was -59%. If only sample pairs with between 2.5-5 ppm-hours are included, the average bias was -28% (N=15). Finally, if only samples with less than 2.5 ppm-hours are included, the average bias is -22% (N=23). The reason for this apparent analyte loading effect is not known. Because there are relatively small numbers of sample pairs at the higher loadings, it is not clear whether this is an effect due to analyte loading or just a random event. However, the data suggest that passive monitors may be more negatively biased at higher exposures, especially when the analyte loading exceeds 5 ppm-hrs.

Continuous Reading Monitor

An example of the type of output from the Interscan Monitor is shown in Figure 7. A summary of the activities being performed while sampling in the C.C.M.S. laboratory accompanies that figure. The output was corrected for a positive bias that was present in the instrument when initially received from the manufacturer (an electronic output signal was received from the unit when in clean air and the analog meter displayed zero). After an adjustment was made in the data recording for this bias, the cumulative output was taken to calculate the time-weighted average concentration as read by the device. This average result was then compared to the results of air samples collected simultaneously with NIOSH Method 3500 and NIOSH Method 2502 or Method 2541. The results are shown in Table 8. In the first field test comparison, the average result obtained by the Interscan unit exactly matched that obtained using NIOSH Method 2502 (0.72 ppm). The Interscan result was 18% higher than the blank adjusted 3500 method results (0.85 ppm). A second example of the output from this

device is provided in Figure 8. In this case, the Interscan unit recorded an average 0.61 ppm of formaldehyde while 0.79 ppm was measured with the 2502 method. The blank adjusted result from the 3500 method was 0.60 ppm.

To facilitate the direct determination of formaldehyde with this instrument, the device was sent to the manufacturer for re-zeroing and calibration. When it was returned to NIOSH, it was again taken to the CCMS laboratory for further evaluation of its performance.

Figures 9 and 10 show the output from stationary samples collected on the laboratory bench top after the Interscan device was re-zeroed and re-calibrated. The TWA concentrations measured with the Interscan unit in Figures 9 and 10 are 0.91 and 0.41 ppm, respectively. In comparison, NIOSH Method 3500 gave results that produced a TWA of 0.68 and 0.30, respectively. NIOSH Method 2541 gave results that produced a TWA of 0.66 and 0.22 ppm, respectively. These latter results suggest that the Interscan device was sensing more formaldehyde than the NIOSH methods. Measured concentrations of methyl and isopropyl alcohol, glutaraldehyde, and phenol were such that these compounds would not interfere with the formaldehyde measured by this instrument.

Overall, the Interscan unit produced TWA results that were as comparable to measurements taken by two NIOSH methods as could probably be expected, given the inherent typical lack of exact agreement often seen in matched field samples. Since the instrument seemed to respond well to formaldehyde and would at least be useful in determining the relative degree of exposure over time, no further effort was made to compare these methods in side-by-side stationary sampling for the purpose of determining the extent of quantitative agreement. However, additional information on the comparison of the stationary instrument results to the personal passive monitoring results are included in companion Report II, "Extent of Exposure" for this study. Thus, the accuracy of the device relative to this comparison were judged acceptable.

DISCUSSION AND CONCLUSIONS

Laboratory testing in a dynamic concentration generation chamber of the selected passive monitoring device produced results that generally compared favorably with NIOSH Method 2502. At an exposure level greater than 4 ppm for 2 hours a significant bias in the passive devices was observed, presumably due to over-loading the sampler. Such concentrations were not expected to occur in the C.C.M.S. laboratory. However, initial stationary field testing under relatively static air conditions, as present in the C.C.M.S. laboratory, produced results which indicated under-sampling of formaldehyde - compared to the results of both the 2502 and 3500 methods. This outcome was brought to the attention of the manufacturer of the passive monitors. They had previously performed studies that revealed that a minimum air turbulence velocity of about 25 cm/s (50 lfpm) is required for accurate performance. This air turbulence requirement is reportedly met when the samplers are worn as personal monitors, but was not met during this initial stationary field sampling investigation. Since the monitoring devices were initially evaluated under unusually static air conditions, the results of this evaluation will not be addressed further.

A follow-up evaluation of the passive devices and active sampling methods was performed at the C.C.M.S.. This time, a small electric fan was used to provide air turbulence around the stationary passive monitors. Air velocity measurements were taken to adjust the air velocity to between 55 - 70 lfpm. Because of the success obtained with the passive devices in the laboratory chamber study, it was anticipated that with adequate air turbulence the problems encountered in the first field study would be avoided. Unfortunately, the passive monitors produced results from five field trials that had a mean bias of -22% when compared to both of the NIOSH active sampling methods. The precision of the passive method was comparable to the NIOSH active sampling methods. Although these results are less than optimal, because the passive device showed equivalent precision relative to the NIOSH active sampling methods, the decision was made to continue to evaluate the monitors in the field by simultaneously monitoring personal exposures with the passive device and a NIOSH method. Such data allowed a final decision to be made concerning their utility to monitor personal exposures during this study on biological markers.

NIOSH Method 2502 has recently been replaced with Method 2541. The new method is identical to the old method except that a sampling tube with 10% (2-hydroxymethyl)piperidine is used on the resin matrix rather than (2-benzylamino)ethanol. This change is intended to improve sampler shelf life. Analyte stability during shipping and storage was not a problem in this study because our samples were always refrigerated and analyzed soon after collection. Nevertheless, the follow-up evaluation used the newer method (Method 2541). Media spikes that were included with the field samples to determine analyte recovery showed

no loss in recovery.

Although formaldehyde is the simplest of the aldehyde compounds with a carbonyl group, it is highly reactive and is seldom present in a pure state. The literature reports that aqueous formaldehyde solutions typically contains less than 0.1% free formaldehyde. Rather, the majority of aqueous formaldehyde is present as methylene glycol and polyoxymethylene glycols. Methanol is usually added to stabilize formaldehyde from extensive polymerization and will form monomethylethers of polyoxymethylene glycols.[6] Formaldehyde vapor in air polymerizes easily to a linear polymer.[7] It was shown in one experiment that increased relative humidity (RH) increases the rate of polymerization of formaldehyde. The rate of polymerization was rapid. At 10% RH, a 10% drop in formaldehyde concentration was seen in 15 minutes, while at 70% RH the drop was 82%.[8]

The negative bias found in the performance of the passive monitors relative to the active sampling method may be due to the species of formaldehyde in the air. The active sampling method would be expected to collect and retain any form of formaldehyde, provided it is reactive with the reagent. However, the personal monitors have a diffusion barrier through which the analyte must first pass. Laboratory performance of the passive monitor has been excellent in an environment where fresh formaldehyde is generated. Since polymeric forms of formaldehyde would be expected to have a lower diffusion coefficient, collection by the passive monitors of the total formaldehyde species present would be less than for formaldehyde gas. If this is correct, the question open to debate is which measure is more related to toxicological outcome. This question will not be addressed further here but may warrant further research.

A comparison of performance during personal sample collection using a NIOSH sorbent tube and a passive monitoring device method was performed. Since 90% of the personal sampling data collected with the sorbent tube method had sample loadings less than 5 ppm-hrs, it was concluded that the average bias calculated with the exclusion of data pairs with more than 5 ppm-hrs would be used to adjust the subsequent extent of exposure study data. The average bias with the exclusion of this data was -25%. This bias was very similar to the stationary sampling bias of -22%. Because of the comparable precision obtained during the stationary sampling, and the similar bias seen during personal sampling and the stationary sampling with a fan that suggested adequate air turbulence for personal sampling, it was decided to use the passive device for monitoring personal exposures during the upcoming study. To make the results obtained with the passive dosimeters comparable to results that may have been obtained by the active sampling methods, a +25% adjustment factor was used when reporting these results in Report II. An average bias value adjustment was chosen over a gradient value adjustment using the regression slope because the slope was nonsignificant and because of concern for the imprecision of the field bias response obtained from the passive monitor compared to the sorbent tube. The

imprecise bias response is probably due to environmental

concentration gradients and this presented concerns about using the latter adjustment approach. It was feared that adjusting field data any way other than by using a mean exceeded the confidence in the data and was not justified.

It was concluded that the passive monitor selected provides acceptable (adjusted) results, compared to more established active sampling methods, and provides a means by which students might monitor their personal exposures to formaldehyde, both in class and during outside embalmments. This conclusion was reached on the basis of the high precision found during replicate laboratory and stationary field testing of both the passive devices and the NIOSH methods. The relative pooled precision of the passive monitors was less than <10% in both types of sampling. Furthermore, the precision of the passive devices was at least as good overall as the reference NIOSH sampling methods. For example, during the second stationary field sampling study, the pooled relative precision for NIOSH Method 3500, NIOSH Method 2541, and the passive monitors was 8.4%, 9.7% and 8.6%, respectively. Comparison of personal sample results indicated that bias does not increase appreciably beyond -35% until sample loading exceeds 5 ppm-hrs. Fortunately, only 9 out of 150 samples (6%) in the exposure study reported in Report II exceeded this level. Often in these few cases, the level of loading was much greater than 5 ppm-hrs, suggesting that the monitor had been sprayed with embalming fluid or otherwise contaminated. Further adjustment of the few samples which exceeded 5 ppm-hrs loading was not attempted.

The continuous reading device selected provides a convenient means of obtaining continuous short-term readings of formaldehyde concentration in a manner that was not previously possible. Such data should be useful for describing the short-term fluctuations of formaldehyde exposure that embalmers experience.

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Table 1
Blank Passive Monitors From Laboratory Experiment
Results in ppm

Sample Number	Sampling Time (Fictitious)	Measured Concentration	Time Adjusted (a)
1	0.25	0.90	0.23
2	1.38	<0.11[b]	<0.15
3	2.07	<0.07	<0.14
4	4.00	<0.04	<0.16

(a) adjusted for one hour sampling time.
(b) "<" values reported are below the limit of detection.

Table 2
Blank Passive Monitors from Field Experiment
Results in ppm

Sample Number	Sampling Duration (Hrs.) (Fictitious)	Measured Concentration	Limit of Detection
113	1.67	<0.11	0.11
114	1.67	<0.11	0.11
010	2.17	<0.08	0.08
011	2.17	<0.08	0.08
012	2.08	<0.09	0.09
004	1.67	<0.11	0.11

Table 3
Summary of Laboratory Study
Comparison of Passive Monitors with NIOSH Method 2502 Results[1]

Sample Set	Method	Duration (Hours)	Concentration (ppm) ± SDD	CV (%)	Number Samples	Bias (%)
			Data Set 1			
1	2502	0 - 2	1.89 ± 0.09	4.8	3	
2	2502	2 - 4	2.18 ± 0.03	1.4	3	
3*	2502	0 - 4	2.04 ± 0.17	8.4	6	
4	Passive	0.25	1.96 ± 0.07	3.6	4	+3.7
5	Passive	0.50	1.78 ± 0.05	2.8	4	-5.3
6	Passive	1	1.82 ± 0.16	8.8	4	-3.7
7	Passive	2	1.75 ± 0.08	4.6	4	-7.4
8	Passive	4	1.84 ± 0.24	13	4	-9.5
9**	Passive	4	1.96 ± 0.05	2.6	3	-3.9
			Data Set 2			
10	2502	0 - 2	4.00 ± 0.15	3.8	3	
11	2502	2 - 4	3.76 ± 0.10	2.7	3	
12*	2502	0 - 4	3.88 ± 0.17	4.4	6	
13	Passive	0.25	4.19 ± 0.03	0.7***	4	+4.8
14	Passive	0.50	4.03 ± 0.40	9.9	4	+0.8
15	Passive	1	4.11 ± 0.34	8.3	4	+2.8
16	Passive	2	4.56 ± 0.06	1.2	3	+14.0
17	Passive	4	2.54 ± 0.82	32.3***	4	-34.5

[1]The sampling period for the 2502 method was sequential for the two 2-hour sets. The passive samples were all started simultaneously and removed at the designated time period.

* Summed result of two consecutive time intervals.
** Although rejection as outlier is not quite statistically indicated, this is the outcome if one low value in this set is removed.
*** Variances between two methods being compared are significantly different at $p<0.05$

Table 4
Results of First Field Sampling Study
Cincinnati College of Mortuary Science
(All results are in ppm with coefficient of variation in parenthesis)

Method 3500	Blank Adjusted[a]	Method 2502[b]	Passive Devices
		Sample Set 1	100 minutes
none collected		0.97	0.88
		0.98	1.02
		0.99	1.06
		0.98 (1%)	0.99 (10%)
3 ppm isopropanol detected.			
		Sample Set 2	125 minutes
1.37	1.14	none	0.82
1.46	1.23	collected	0.88
1.55	1.31		1.04
1.46 (6%)	1.22 (7%)		0.91 (12%)
24 ppm isopropanol detected.			
		Sample Set 3	165 minutes
0.58	0.40	0.68	0.35
0.64	0.47	0.70	0.37
0.65	0.47	0.75	0.46
0.62 (6%)	0.45 (9%)	0.71 (5%)	0.39 (15%)
		Sample Set 4	130 minutes
0.88	0.64	0.76	0.39
0.91	0.67	0.73	0.43
0.92	0.70	0.70	0.50
0.90 (2%)	0.67 (4%)	0.73 (4%)	0.44 (13%)
3 ppm isopropanol detected.			

Table 4 (Continued)

Method 3500	Blank Adjusted[a]	Method 2502[b]	Passive Devices
		Sample Set 5	110 minutes
0.52	0.26	ND (<0.08)	0.23
0.57	0.30	0.37	0.32
0.59	0.32	0.35	0.35
0.56 (6%)	0.29 (10%)	0.36	0.30 (21%)
		Sample Set 6	105 minutes
0.76	0.63	0.76	0.42
0.93	0.69	0.84	0.48
0.99	0.46	0.78	0.57
0.89 (13%)	0.60 (17%)	0.79 (5%)	0.49 (15%)
2 ppm isopropanol detected			
		Sample Set 7	170 minutes
0.67	0.48	0.32	0.47
0.83	0.65	0.89	0.52
0.88	0.70	0.94	0.59
0.79 (14%)	0.61 (19%)	0.72 (48%)	0.53 (11%)
3 ppm isopropanol detected.			

(a) The average Field Blank result was 9 ug per sample. Thus, the field results were adjusted by subtracting this quantity from each. The L.O.D. was 0.3 ug per sample.

(b) Field Blank results for Method 2502 were all nondetectable, thus the field results were not corrected. The L.O.D. was 0.5 ug per sample or 0.08 ppm in a 110 minute air sample.

Table 5
Summary of Field Study Bias (%) Between Methods[a]
First Field Evaluation

Sample Set	Method Bias[b] (B - A)/A	(B - AA)/AA	(C - A)/A	(C - AA)/AA	(C-B)/B
1					+1
2			-38	-25	
3	-15	-58	-37	-13	-45
4	-19	-9	-51	-34	-40
5	-36	-24	-46	+3	-17
6	-11	+32	-45	-18	-38
7	-9	+18	-33	-13	-26
Average:	-18 (CV=60)	-8 (CV=432)	-42 (CV=16)	-17 (CV=75)	-28 (CV=63)

(a) Method 3500 was used as the primary reference method, while Method 2502 was used as the secondary reference method in calculating the percent bias against the PF-20 STEL Monitor.

(b) A = 3500 method without blank adjustment.
AA = 3500 method with blank adjustment.
B = 2502 method.
C = PF-20 STEL passive monitor.

Table 6
Results from Second Stationary Field Evaluation[a]
Means and Coefficients of Variation
Cincinnati College of Mortuary Sciences

Set	Method 3500 (CV)	95% C.L.	Method 2541 (CV)	95% C.L.	Passive Monitor (CV)	95% C.L.
1	0.67 (7)		0.77 (7)		0.64 (9)	
2	0.90 (17)		0.92 (3)		0.50 (8)	
3	0.78 (2)		0.64 (0.9)		0.55 (6)	
4	0.30 (11)		0.22 (9)		0.23 (19)	
5	0.68 (5)		0.66 (10)		0.43 (27)	
Pooled Values	0.67 (8.4)	.63-.70	0.64 (9.7)	.61-.67	0.49 (8.6)	.46-.52*

[a] in the presence of a fan to increase air velocity during the tests.
* significantly different using 95% Scheffe multiple range analysis

Table 6A
Second Stationary Field Evaluation Results
Percent Bias[a]

Set	Percent Bias Between Methods B-A/A	C-A/A	C-B/B
1	15	-4	-17
2	2	-34	-36
3	-18	-29	-14
4	-27	-23	5
5	-3	-37	-35
Average Bias	-6	-25	-19

[a] Method A is NIOSH Method 3500
Method B is NIOSH Method 2541
Method C are PF-20 passive monitors

Table 7
Comparison of Personal Tube Sample Results with Passive Monitor Results

Date	Duration (mins.)	Tube Data Conc. (ppm)	Tube Data PPM-Hours	Passive Monitor Data Conc. (ppm)	Passive Monitor Data PPM-Hours	% Diff.
1-4-90	72	0.00	0.00	0.55	0.66	NA
1-5-90	100	0.00	0.00	0.27	0.45	NA
1-5-90	100	0.00	0.00	0.43	0.72	NA
1-10-90	120	0.47	0.94	0.12	0.24	-74
1-4-90	84	0.68	0.95	0.65	0.91	-4
1-12-90	132	0.71	1.56	0.73	1.61	3
1-10-90	98	0.71	1.16	0.48	0.78	-32
1-11-90	149	0.72	1.78	0.51	1.27	-29
1-10-90	95	0.73	1.15	0.53	0.84	-27
1-10-90	134	0.75	1.67	0.56	1.25	-25
1-4-90	81	0.77	1.03	0.55	0.74	-28
1-17-90	128	0.80	1.70	0.62	1.32	-22
1-11-90	158	0.87	2.29	0.6	1.58	-31
1-17-90	135	0.88	1.97	2.49	5.60	184
1-4-90	80	0.96	1.28	0.54	0.72	-44
1-17-90	130	1.01	2.19	0.58	1.26	-43
1-11-90	150	1.02	2.55	0.65	1.63	-36
1-8-90	155	1.06	2.74	0.83	2.14	-22
1-9-90	170	1.07	3.02	0.68	1.93	-36
1-8-90	156	1.09	2.83	0.63	1.64	-42
1-17-90	119	1.09	2.16	0.69	1.37	-37
1-4-90	92	1.18	1.81	0.84	1.29	-29
1-11-90	140	1.22	2.85	0.56	1.31	-54
1-11-90	170	1.29	3.66	0.85	2.41	-34
1-8-90	167	1.33	3.69	1.44	4.01	9
1-17-90	124	1.35	2.80	0.69	1.43	-49
1-8-90	110	1.37	2.52	1.1	2.02	-20
1-9-90	135	1.38	3.11	1.16	2.61	-16
1-12-90	90	1.57	2.36	1.04	1.56	-34
1-8-90	162	1.85	4.98	0.85	2.30	-54
1-9-90	122	2.33	4.74	1.21	2.46	-48
1-9-90	90	2.35	3.53	0.93	1.40	-61
1-8-90	111	2.82	5.22	1.91	3.53	-32
1-8-90	103	3.23	5.54	0.96	1.65	-70
1-10-90	75	3.24	4.05	1.65	2.06	-49
1-8-90	157	4.94	12.94	0.83	2.17	-83
1-8-90	108	4.98	8.97	1.57	2.83	-68

Date	Duration (mins.)	Tube Data Conc. (ppm)	PPM-Hours	Passive Monitor Data Conc. (ppm)	PPM-Hours	% Diff.
2-27-90	135	0.00	0.00	0.76	1.71	NA
2-27-90	140	0.34	0.80	0.36	0.84	6
2-21-90	110	0.48	0.88	0.43	0.79	-10
2-27-90	103	0.50	0.86	0.53	0.91	5
2-21-90	110	0.56	1.03	2.25	4.13	299
2-27-90	80	0.65	0.86	0.54	0.72	-16
2-27-90	95	0.67	1.06	0.56	0.89	-16
2-21-90	133	0.73	1.61	0.71	1.57	-2
2-20-90	128	0.82	1.76	0.77	1.64	-6
2-20-90	138	0.93	2.13	0.81	1.86	-13
2-20-90	133	1.40	3.10	1.97	4.37	41
2-20-90	143	1.51	3.61	1.47	3.50	-3
2-21-90	135	2.69	6.04	1.49	3.35	-45

Table 8
Results from Interscan Continuous Reading Monitor, NIOSH Method 3500, and NIOSH Method 2502/2541.

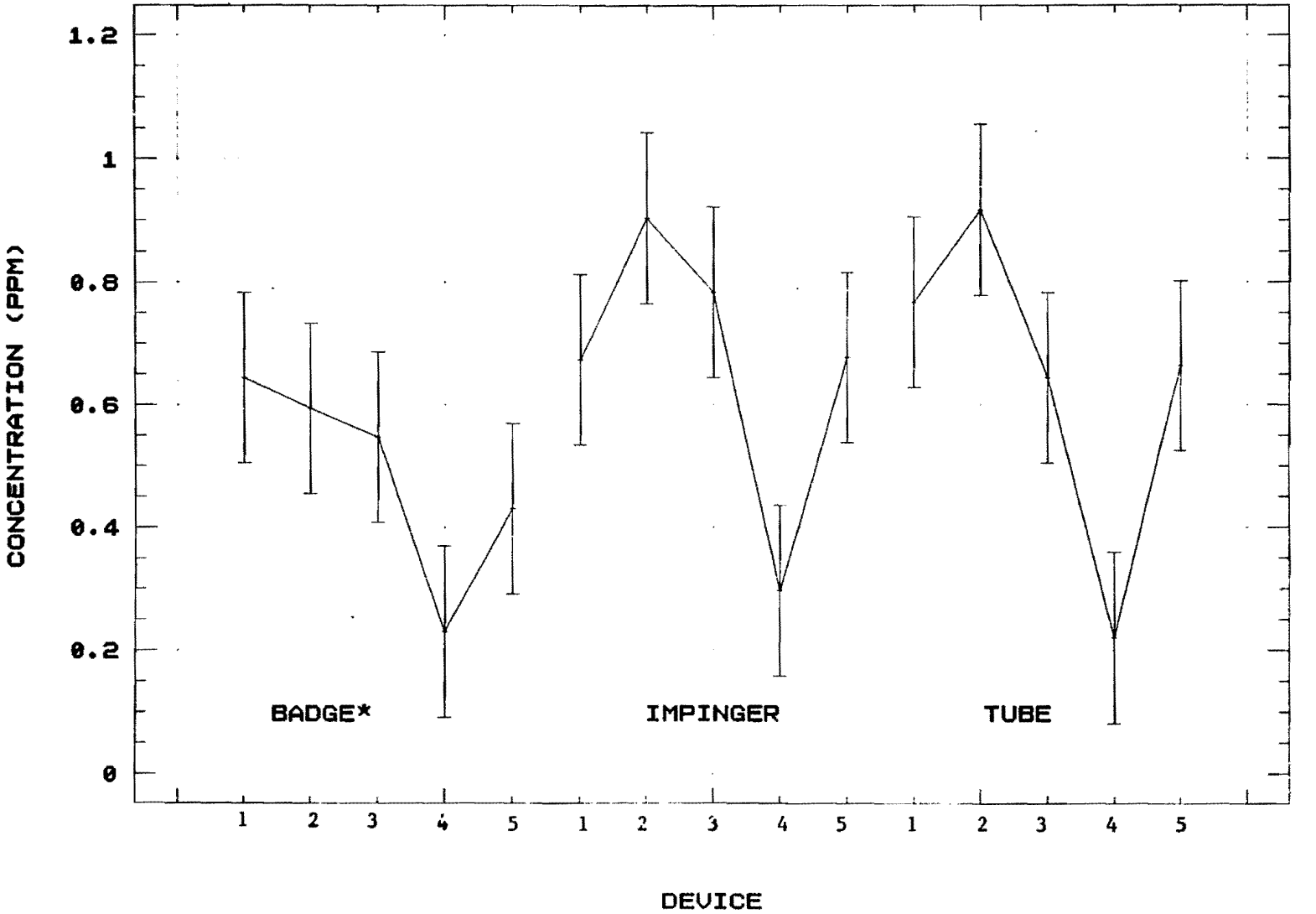
	Test Comparison			
Method	1	2	3	4
Interscan	0.72	0.61	0.91	0.41
Method 3500	0.85*	0.60*	0.68	0.30
Method 2502 or 2541	0.72	0.79	0.66	0.22

* Blank corrected result

FIGURES

Figure 1

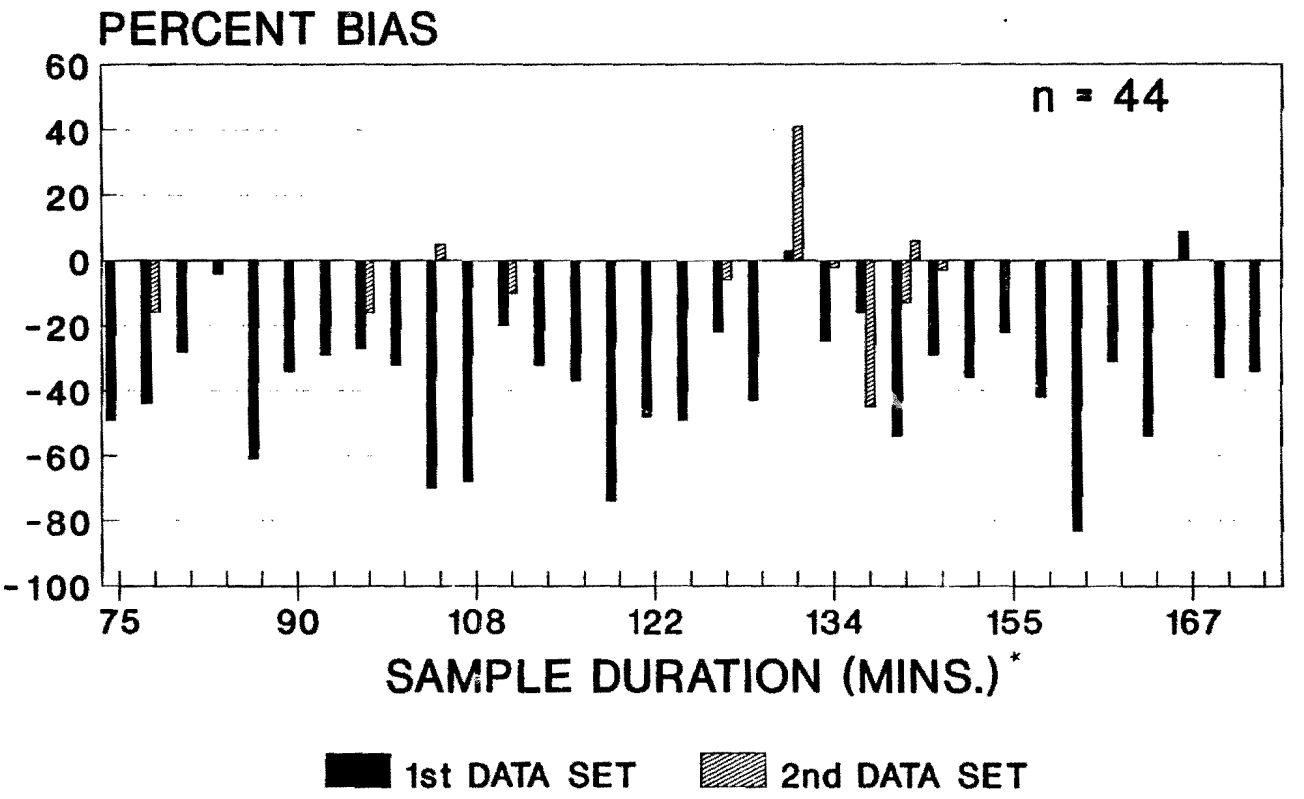
RESPONSE OF THREE METHODS TO AIRBORNE FORMALDEHYDE FROM EMBALMING SOLUTION



* Significantly Different

Figure 2

Percent Bias of PF-20 Monitor Against NIOSH Sorbent Tube Method by Duration

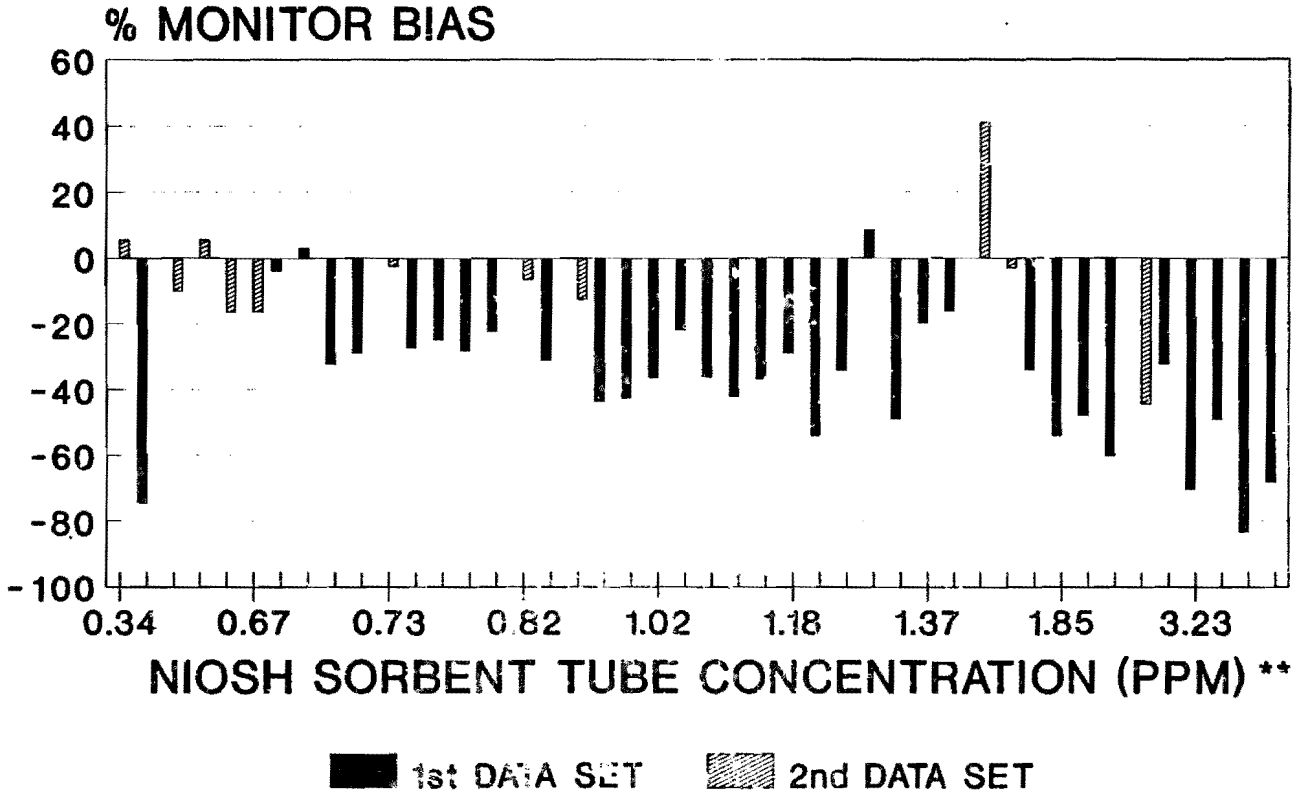


Personal Sampling Results

* Scale is not linear

Figure 3

Percent Bias of PF-20 Monitor Against NIOSH Sorbent Tube Concentration Result*

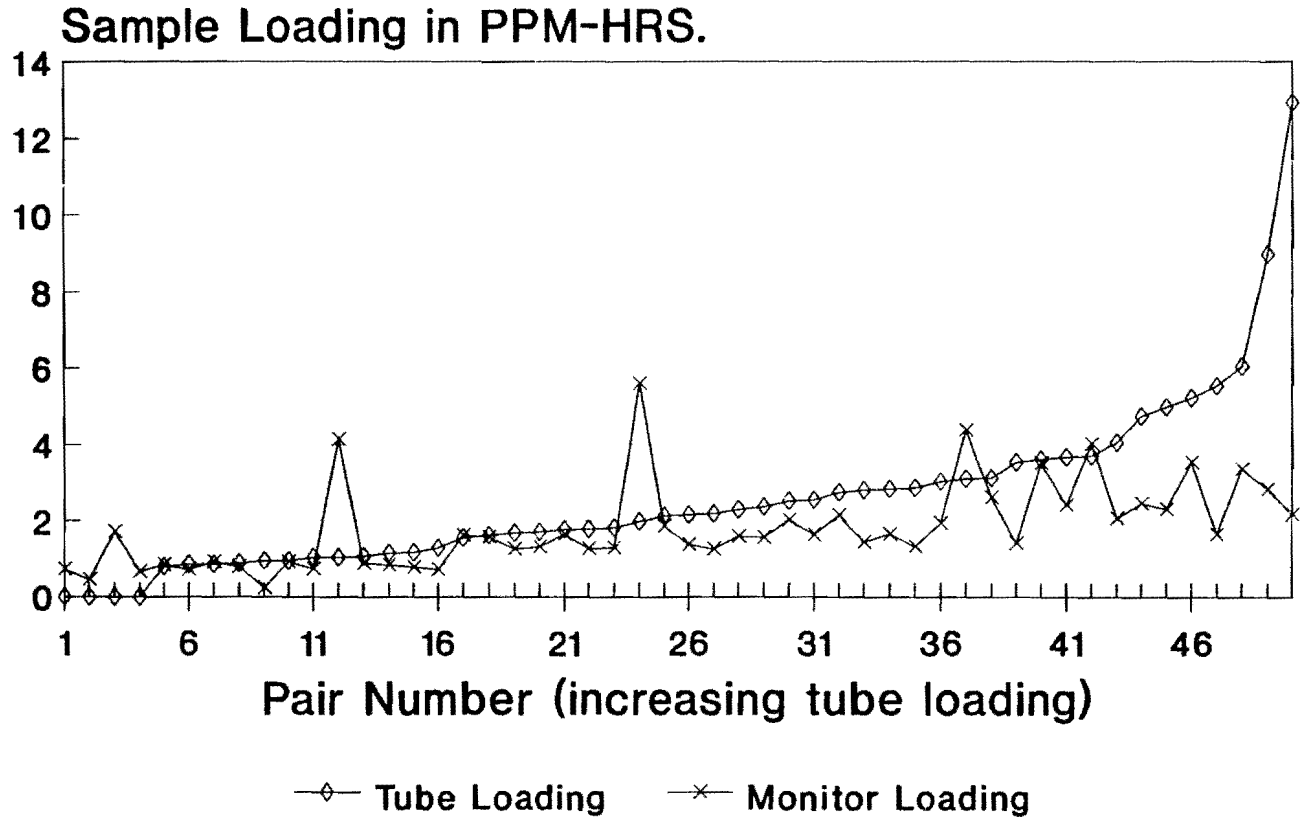


* plotted by increasing concentration

** X-Scale is not linear

Figure 4

Relationship Between Tube Loading and Passive Monitor Loading*



*Fifty personal samples

Figure 5

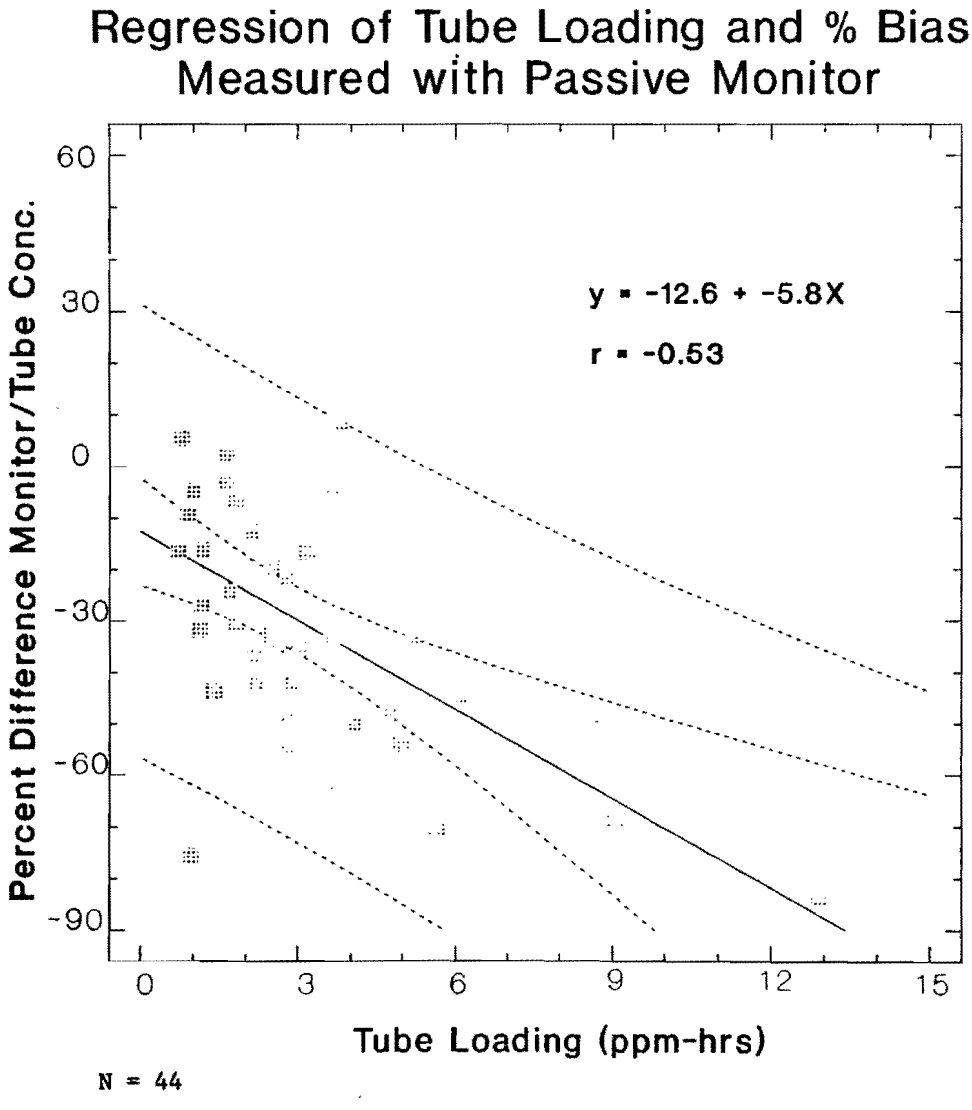

Regression of Tube Loading and % Bias
Measured with Passive Monitor
y = -12.6 + -5.8X
r = -0.53
Percent Difference Monitor/Tube Conc.
60
30
0
-30
-60
-90
0
3
6
9
12
15
Tube Loading (ppm-hrs)
N = 44

Figure 6

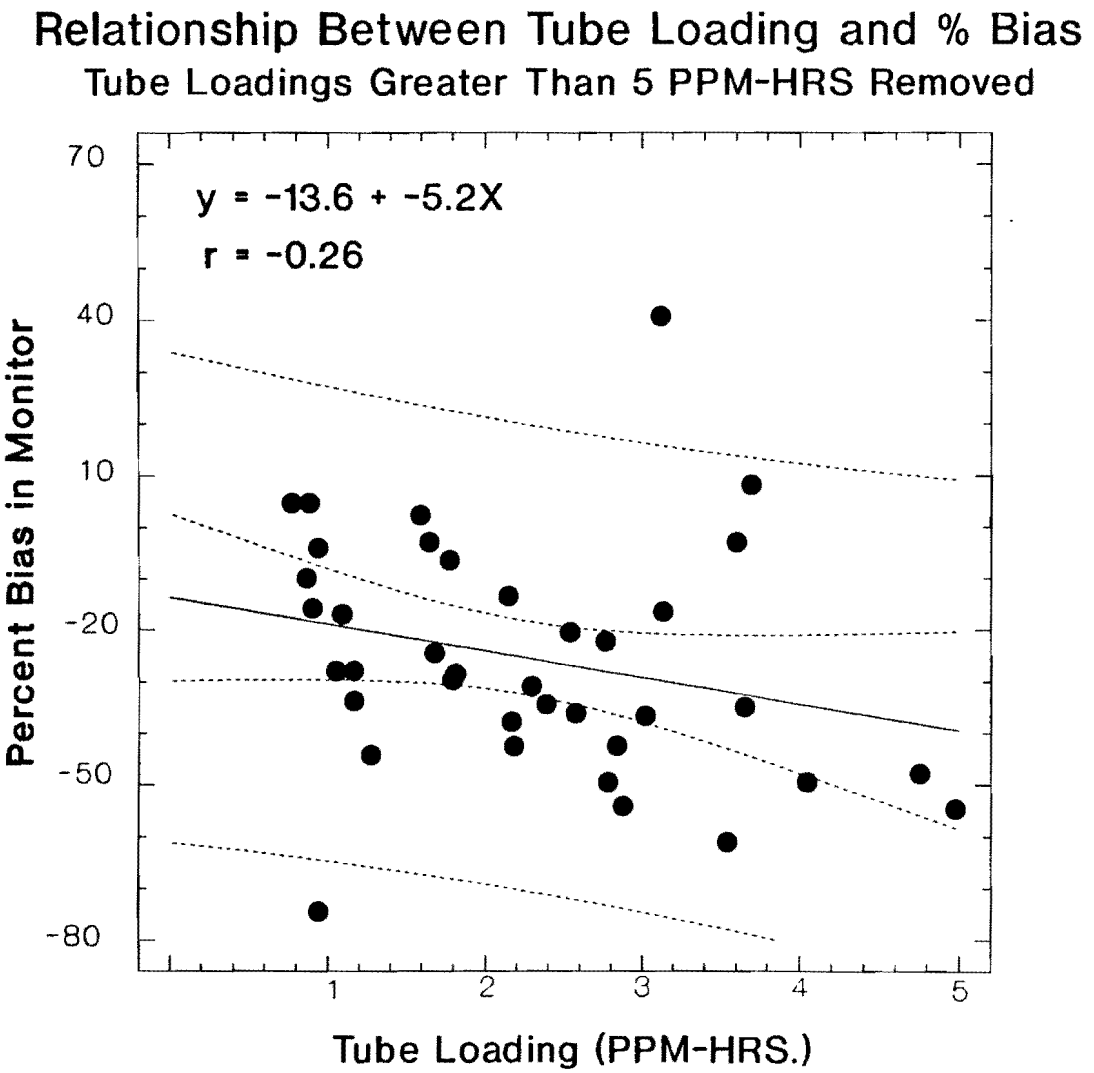
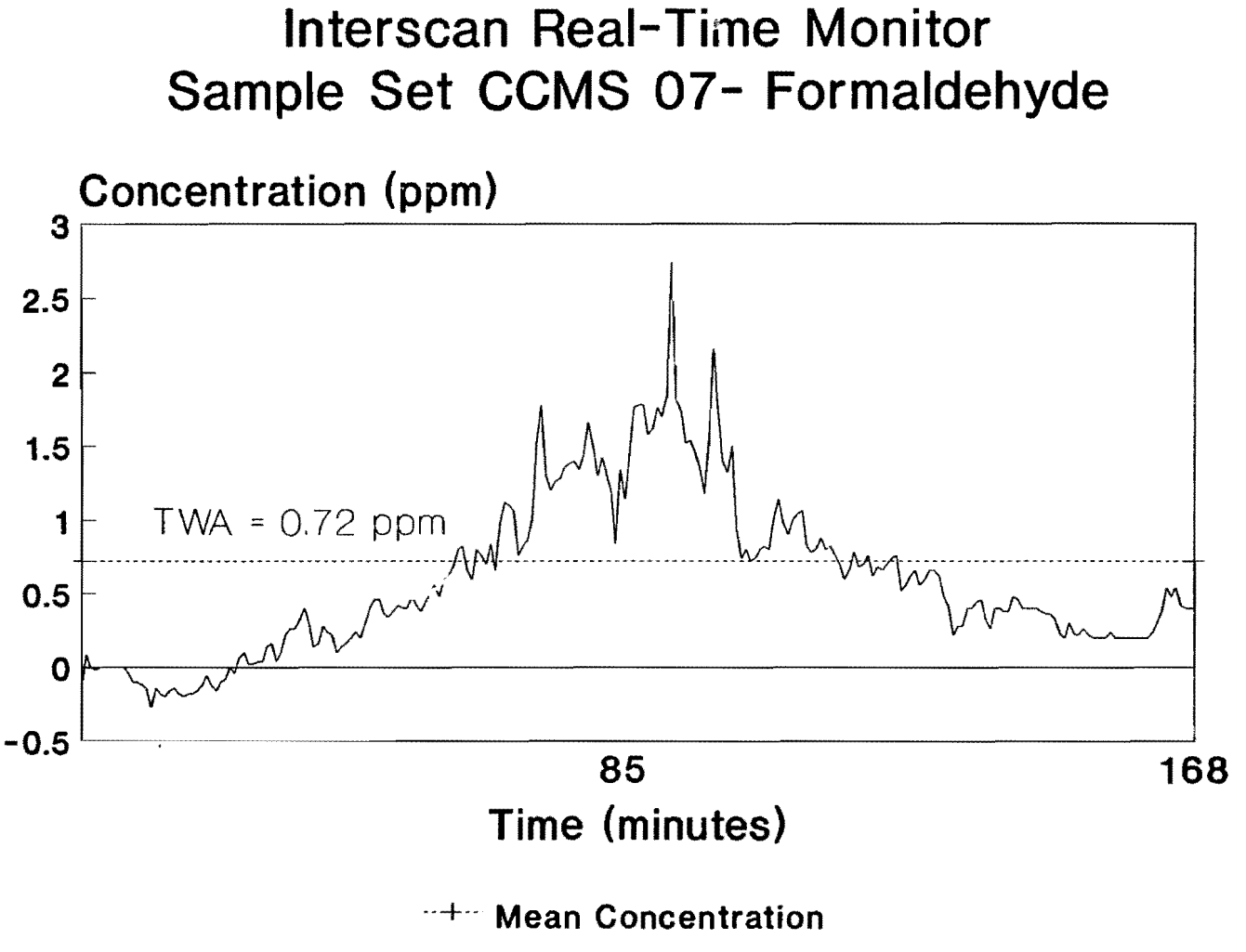

Relationship Between Tube Loading and % Bias
Tube Loadings Greater Than 5 PPM-HRS Removed
y = -13.6 + -5.2X
r = -0.26
Percent Bias in Monitor
70
40
10
-20
-50
-80
1
2
3
4
5
Tube Loading (PPM-HRS.)
N = 39

Figure 7

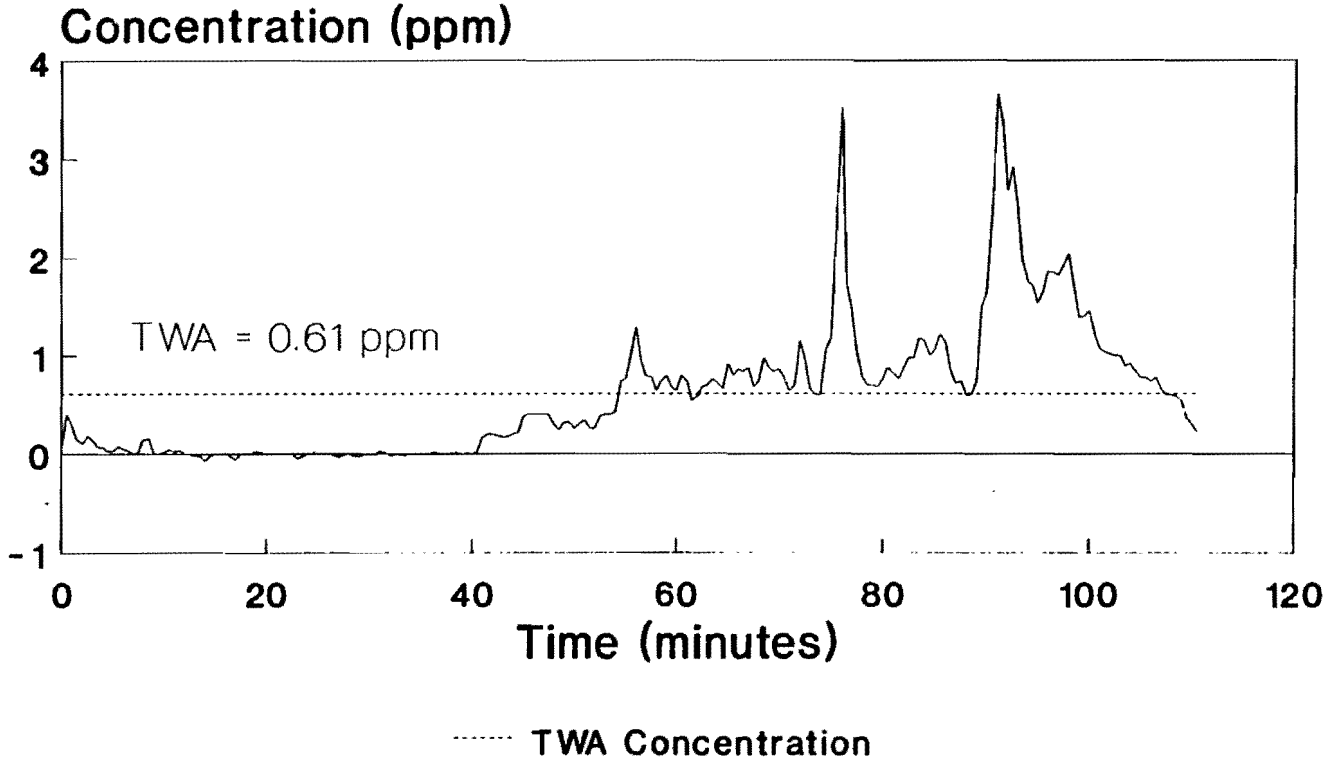

Interscan Real-Time Monitor
Sample Set CCMS 07- Formaldehyde
Concentration (ppm)
3
2.5
2
1.5
1
0.5
0
-0.5
TWA = 0.72 ppm
85
168
Time (minutes)
Mean Concentration

Supplement to Figure 7
Time Sequence Events During Collection of Air Sample
Cincinnati College of Mortuary Science

Summary: Two autopsied bodies, one adult man and one adult female, were simultaneously embalmed. The C.C.M.S. Case Numbers were 333 and 332. Tissue Firm #30 Index with co-injection with Disan-Glutaldehyde was used to make up the embalming fluids used in the first case. Two bottles of HAR were used to treat viscera. The second case was injected with Triton #28 Index and 2 bottles of HAR were added to the visera bag.

Time	Description of Operation
0	Started removing stitches and opening body, mix solutions, treat viscera, begin air sampling.
25	Started injecting legs Case 333.
30	Prepared additional embalming solution for Case 333.
33	Started injecting legs Case 332.
45	Started injecting arms both cases.
55	Sprayed nasal, mouth region with Dis-Spray on Case 333.
60	Prepared additional embalming solution for Case 332.
70	Started hypo-injecting side regions of Case 332, leakage from head region in Case 333.
75	Opened granular hardening agent for Case 332 and applied.
82	Started hypo-injecting side regions of Case 333, aspiratng viscera bag for Case 332.
95	Applied granular hardening agent to Case 333. Replaced viscera bag and aspirate.
130	Complete sewing up both bodies, begin wash.
165	Removed both bodies from room.
168	Terminate air sampling.

Interscan Real-Time Monitor
Sample Set CCMS 06 - Formaldehyde*



* single anatomical case

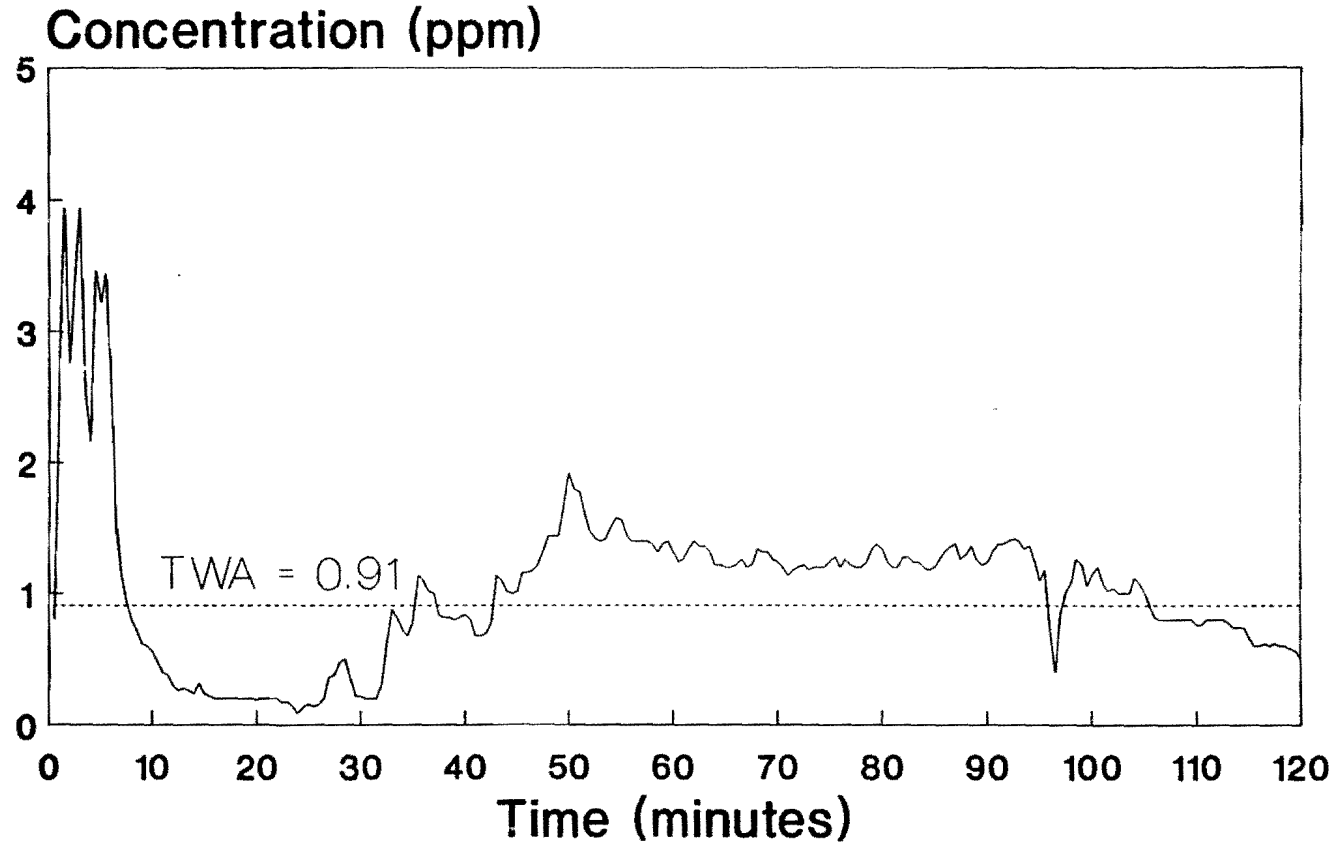
Supplement to Figure 8
Time Sequence of Events During Collection of Air Sample
Cincinnati College of Mortuary Science

Summary: One anatomical case, a medium size woman was embalmed by four students and the instructor on Table #1. The embalming solution initially consisted of two bottles of Esco Firm Arterial, Chemical Index 35 diluted to 2 gallons.

Time	Description of Operations
0	Begin body preparation & finding arteries.
10	Mixed embalming solution.
30	Started injecting axillary.
35	Mixed two more gallons embalming fluid.
50	Five gallons of phenol solution injected, required 10 minutes.
65	Hypo-injected legs, mixed another gallon of embalming solution.
75	Flushed toilet. Applied formaldehyde gel over hands and feet.
90	Transferred body out of embalming room.
110	Stopped sampling.

Figure 9

Interscan Continuous Reading Monitor
Data Set CCMS12*



*Two autopsied bodies

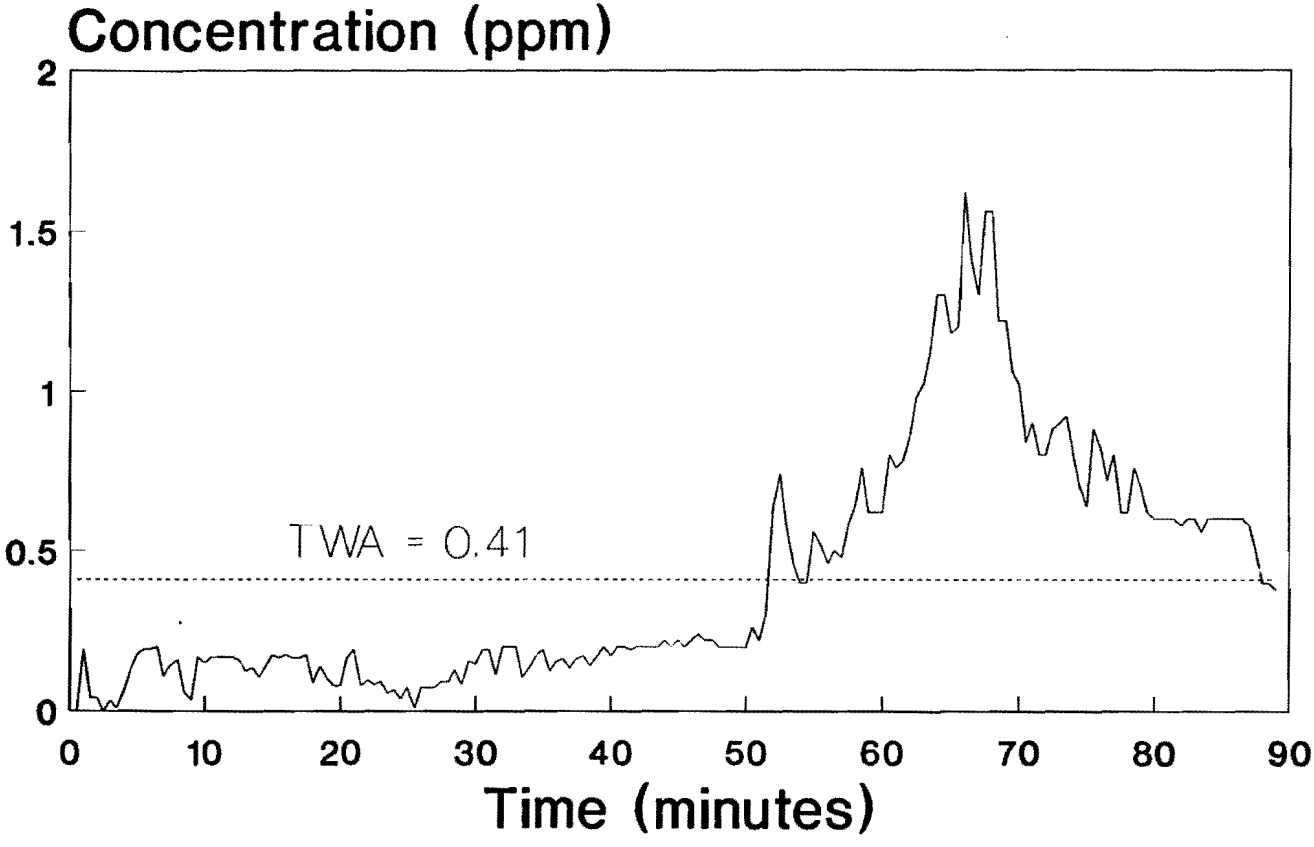
Supplement to Figure 9
Time-Activity Log for Data Set CCMS012
Interscan Continuous Monitor

Summary: Two victims of a automobile crash were embalmed after being autopsied. Each corpse was embalmed with six bottles of Triton 28 Arterial Sporacidal fluid.

Time	Description of Activities
0	Started Monitoring.
1	Poured 2 bottles of HAR into both visera bags.
8	Opening stitches on each body to open thoracic cavity.
18	Isolating arteries.
26	Prepared 3 bottles Triton 28 concentrate to "freeze" each head.
30	Injected head of corpse #1, there was leakage from opene skull cavity.
42	Injected head of corps #2, massive initial leakage.
47	Started injecting femoral arteries of corpse #1.
48	Added 3 more bottles Triton 28 to #2 reservoir.
53	Started injecting femoral arteries of corpse #2.
60	Injecting Axillary arteries of corpse #1, then corpse #2 - there was lots of leakage.
71	Started hypoinjecting side walls of both corpses. Applied Dodge Dryene (contains phenol) to skull and then Dodge Inner-seal.
76	Applied Granular Hardening Compound to corpse #2.
83	Applied Granular Hardening Compound to corpse #1.
85	Replaced viscera bag into corpse #2, aspirated bag, added more hardening compound.
89	Replaced viscera bag into corpse #1, aspirated bag.
133	Completed restitching both corpses.
158	Applied Hexaphene Gel to hands and feet of corpse #2, removed body.
166	As above to corpse #1.
173	Stopped monitoring.

Figure 10

Interscan Continuous Reading Monitor
Data Set CCMS11*



*one anatomical body

Supplement to Figure 10
Time-Activity Log for Data Set CCMS011
Interscan Continuous Monitor

Summary: This was a female corpse prepared for anatomical study. Embalming was preformed using 2.5 bottles of Vitaflex 20 and the special phenolic solution.

Time	Description of Activity
0	Started Monitoring
2	Prepared embalming solution
35	Started to inject
43	Flushed toilet
48	Started injecting phenolic solution
50	Started hypoinjecting legs
53	Ended phenolic injection
78	Zipped up body inside plastic body bag
86	Ended monitoring

AIR QUALITY RESEARCH, INC. INTERNATIONAL

(415) 644-2097

901 Grayson Street, Berkeley, California 94710 USA

VALIDATION DATA FOR PF-20 FORMALDEHYDE MONITOR

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Introduction

The PF-20 is a passive (diffusion-type) monitor designed to measure occupational exposures to formaldehyde. Two configurations are available which differ only in the rate at which formaldehyde is collected. The PF-20(PEL) operates at a sampling rate which is suitable for monitoring over periods of 1-8 hr; this is the configuration which should be used for full-shift monitoring relative to the current OSHA Permissible Exposure Limit (PEL). The PF-20(STEL) operates at a faster sampling rate than the PF-20(PEL); this configuration is intended for monitoring relative to the current OSHA Short-Term-Exposure Limit (STEL) of 2 ppm (15 min).

Each PF-20 monitor employs a dry proprietary collector which converts formaldehyde into a chemically stable product prior to analysis. A permeable plastic membrane, which separates the collector from the atmosphere, governs the rate of sampling (formaldehyde uptake). The cross-sectional area of the membrane which is used for the PF-20(STEL) is 2.65 times that of the PF-20(PEL) and is therefore responsible for the increased uptake of the STEL configuration.

Formaldehyde is regenerated from the collector during analysis by the chromotropic acid method. The particular combination of the selective trapping agent and the analytical procedure allows formaldehyde to be measured free of interference by other substances including phenol, other aldehydes and aromatic hydrocarbons. There are no known interferences to airborne formaldehyde determined by the PF-20 monitor.

AQR conducted extensive tests to assure the efficacy of the PF-20 for the routine monitoring of airborne formaldehyde exposures. The following discussion summarizes the results of these experiments.

I. Effect of Formaldehyde Air Concentration and Environmental Factors on Uptake

Since the PF-20 operates via molecular diffusion, it is important that the uptake rate be maintained constant during the period of sampling and not be influenced by either the air concentration or environmental factors such as temperature, humidity, air velocity and orientation to air flow. Thus, a series of tests were performed to determine the effect of these variables upon uptake rate. Controlled test atmospheres of formaldehyde were prepared from the catalytic depolymerization of trioxane as described by Geisling et al. [Anal. Chem. 54: 140-142 (1982)]. Air was maintained at the desired temperature and humidity by a Miller-Nelson Model HCS-201 air generator. (Subambient

temperatures required a refrigerated test chamber as well). Air velocities were controlled in two ways. Velocities of 3.6-63 cm/s were obtained by varying the dimensions of an acrylic exposure chamber and/or the volumetric flow rate of air through the chamber. PF-20 monitors lay on the floor of the chamber as air passed above them under laminar-flow conditions. Higher velocities were obtained by placing a fan at the bottom of a cube-shaped exposure chamber (1 ft. x 1 ft. x 1 ft.) and varying the fan speed to obtain an average air speed of 84 cm/sec as measured with a thermal anemometer at 10 locations in the chamber. In this case the PF-20s were mounted at the periphery of the chamber with the collecting elements oriented toward the center of the chamber.

I.A. Formaldehyde Concentration and Humidity

Groups of 10 PF-20(PEL) monitors were exposed for 8 hr to airborne formaldehyde at an air velocity of 30 cm/s and at a temperature between 21 and 24° C. The air concentration (0.1-2.7 ppm) and relative humidity (19-88% RH) were varied from run to run as shown in Table I. The uptake rate of formaldehyde (ug/ppm-hr), which measures the performance of the PF-20 under these different conditions, was unaffected by the changes in air concentration and humidity over the indicated ranges. This lack of effect is illustrated further in the graphical displays of data shown in Figures 1 and 2, which show the mean uptake rate of each group of monitors vs. the level of air concentration or humidity.

I.B. Temperature

Groups of 8 to 10 PF-20(PEL) monitors were exposed for 6-7 hr to airborne formaldehyde at concentrations between 0.7 and 1.7 ppm at an air velocity of 70 cm/s. The temperatures of the three runs were 15, 26, and 35° C. The results of the tests are shown in Table II. The mean uptake rates for the three groups were 1.36, 1.26, and 1.51 ug/ppm-hr at 15, 26, and 35° C, respectively. A one-way analysis of variance indicated that the mean uptake rates at the three temperatures were significantly different ($p=0.002$). Inspection of Table II indicates that this difference was caused by an increase in the uptake rate at 35°C as compared to the rates observed at 15 and 26°C. Thus, the specifications for the PF-20(PEL) indicate a validated range of no effect between 15 and 26° C (59 and 79° F). However, since the increase in uptake rate at 35° C was only 14% greater than the mean uptake rate observed at the lower two temperatures (1.32 ug/ppm-hr), relatively little error should result from use of the PF-20 at temperatures up to 35° C (95° F).

I.C. Air Velocity

Groups of 8 to 10 PF-20(PEL) monitors were exposed for 6-8 hr to formaldehyde at ambient temperature (23-28° C) and at air velocities between 3.6 and 84.3 cm/sec (Table III). The uptake rate was less than expected at low air velocities in the range of 3.6-13.8 cm/s. In this range of air velocities it appears that there was insufficient air flow over the monitor to replenish

formaldehyde at the inlet and, thereby, maintain the necessary concentration gradient. At velocities in the range of 24-84 cm/sec, the rate of uptake was uniform indicating that the concentration gradient was maintained. These results indicate that the air velocity at the inlet should be at least 24 cm/sec to maintain the desired rate of uptake. Since the PF-20 is a personal monitor designed to measure occupational exposure, the range of air velocities encountered should be well in excess of 24 cm/sec; thus no difficulties should be encountered as the result of insufficient air movement at the inlet to the membrane. The PF-20 should not be used as a stationary air monitor in positions of stagnant air flow, since undersampling of formaldehyde may occur in certain circumstances.

I.D. Effect of Orientation to Air Flow

The effect of orientation of the monitor relative to the direction of air flow was tested by simultaneously exposing two groups of 10 PF-20(PEL) monitors to formaldehyde in the large chamber operated at an average air velocity of 84 cm/s. The orientation of Group A was parallel to the direction of air flow while that of Group B was perpendicular. The exposure was conducted for 8.4 hr with 0.91 ppm of formaldehyde at 27°C and 58% RH. The following uptake rates (mean $\pm$ s.d.) were observed for the two groups: Group A, 1.20$\pm$0.14 ug/ppm-hr and Group B, 1.17$\pm$ 0.07 ug/ppm-hr. These means were not statistically different as determined by a t-test at a significance level of 0.05. This indicates that the orientation of the PF-20 to the direction of air flow does not significantly affect its uptake.

II. Accuracy and Precision

II.A. PF-20(PEL) Monitors

Seven runs were performed to determine the accuracy and precision of the PF-20(PEL) monitors over a range of formaldehyde concentrations. Between 10 and 19 monitors were exposed in each group for 7.5-8.5 hr at 21-24° C, 65-88% RH and at an air velocity of 29-32 cm/s. The range of formaldehyde concentrations was between 0.1 and 1.8 ppm.

The results are given in Table IV. In each case the expected mass of formaldehyde is given (based upon the empirically determined uptake rate of 1.20 ug/ppm-hr for the period sampled) as well as the mean mass observed for each group. The relative bias, determined as (Obs.-Exp.)/Exp., ranged between -8.8% and 10.7% with a mean of -0.9%, indicating no significant bias in the uptake of the monitors. The coefficients of variation for the 7 runs ranged between 4.2% and 15.7%. The latter value of 15.7% was significantly different from the other values as determined by a Chi-square test at the 0.05 level of significance. This CV was observed at the lowest air concentration of 0.1 ppm where some loss of precision would be expected. Since the CVs from the other six runs were not significantly different, they were pooled to yield an estimated CV of 6.1% over the range of 0.2-2 ppm for 8 hr.

II.B. PF-20(STEL) Monitors

Four runs were performed to determine the accuracy and precision of the PF-20(STEL) monitors over a range of formaldehyde concentrations. Groups of 10 PF-20(STEL) monitors were exposed for 15 min at 25-27° C, 50% RH and at an air velocity of 84 cm/s. The range of formaldehyde concentrations was between 0.55 and 5.87 ppm. At each of the two highest air concentrations (3.85 and 5.87 ppm) groups of 10 PF-20(PEL) monitors were exposed side by side with the STEL monitors. This was done to predict the theoretical uptake of the PF-20(STEL) as follows:

Uptake (STEL) = 2.65 x Uptake (PEL),

where the factor 2.65 represents the ratio of the cross-sectional areas of the porous membranes of the STEL and PEL monitors. Since the uptake behavior of the PF-20(PEL) had been well characterized, this allowed the expected uptake of the PF-20(STEL) to be determined.

The results are given in Table V. At the two highest concentrations (Runs 32 and 33), the observed uptake rates of the STEL monitor were within 4.8% and 0.8% of the expected rates. This indicates that the increased uptake of the PF-20(STEL) results from the increased surface area of the porous membrane as predicted by theory and is not influenced by the rate of reaction of formaldehyde with the collector over the range of air concentrations between 0.55 and 5.87 ppm. The precision (CV) of the STEL monitor over the same range of air concentrations was between 2.9 and 7.4%. The pooled estimate of the CV obtained from the four values is 6.3% which is essentially the same as observed for the PF-20(PEL) monitor.

III. Shelf Life

A group of 70 PF-20(PEL) monitors was prepared for repetitive testing over a period of 18 months. The monitors were stored in the original packaging at room temperature in an office. After various lengths of time had elapsed groups of 10 of the monitors were exposed to formaldehyde in the test chamber for 6-8 hr at a nominal concentration of 0.5 ppm at 50% RH and 24-27°C, and at an air velocity of 84 cm/sec. Additional groups of 5 monitors were analyzed without exposure to formaldehyde to determine the blank concentration.

The results are shown in Table VI. Although the uptake rates and blank values of the monitors appeared stable over the first 11 months of the experiment, some deterioration was observed in the monitors stored for 18 months, notably in an increase in the blank value of about 50%. AQR suggests that monitors not be stored for periods longer than one year prior to use.

TABLE I

Uptake of Formaldehyde by the PF-20(PEL) Monitor at Different Air Concentrations and Relative Humidities

(Groups of 10 monitors exposed for 8 hr at 21-24° C at a face velocity of 30 cm/s)

Run	Air Conc. (ppm)	Rel. Hum. (%)	Uptake Rate (ug/ppm-hr) Mean	Std. Dev.
1	0.1	70	1.18	0.19
2	1.7	20	1.26	0.08
3	2.7	40	1.21	0.05
4	1.8	82	1.20	0.06
5	2.0	19	1.10	0.05
6	0.8	88	1.15	0.05
7	1.8	70	1.10	0.05
8	0.2	65	1.33	0.09
9	0.4	72	1.19	0.08
10	0.6	72	1.30	0.18
11	1.0	88	1.16	0.05
12	0.6	82	1.25	0.12

TABLE II

Uptake of Formaldehyde by the PF-20(PEL) Monitor at Different Temperatures

(Groups of 8-10 monitors exposed for 6-7 hr at a face velocity of 70 cm/s and a relative humidity between 40 and 60%)

Run	Air Conc. (ppm)	Temp. (C)	Uptake Rate (ug/ppm-hr) Mean	Std. Dev.
13	0.7	15	1.36	0.14
14	1.7	26	1.26	0.17
15	0.6	35	1.51	0.11

TABLE III

Uptake of Formaldehyde by the PF-20(PEL) Monitor at Different Air Velocities

(Groups of 8-10 monitors exposed for 6-8 hr at 23-28°C)

Run	Air Conc. (ppm)	Rel. Hum. (%)	Air Vel. (cm/s)	Uptake Rate (ug/ppm-hr) Mean	Std. Dev.
16	0.6	32	3.6	0.80	0.08
17	0.6	32	7.7	0.94	0.06
18	0.2	74	10.0	0.95	0.08
19	0.1	68	13.8	1.05	0.14
20	0.4	70	24.3	1.19	0.11
21	1.2	60	60.7	1.21	0.09
22	0.6	65	62.9	1.20	0.08
23	0.9	58	84.3	1.20	0.13

TABLE IV

Accuracy and Precision of the PF-20(PEL) Monitor at Different Formaldehyde Concentrations

(Monitors exposed for 7.5-8.5 hr at 21-24°C, 65-85% RH at a face velocity of 29-32 cm/sec)

Run	Air Conc. (ppm)	n	Exp. Mass (ug)	Obs. Mass (ug)	Rel. Bias* (%)	CV (%)
24	0.1	10	0.82	0.80	-1.89	15.7
25	0.8	19	7.35	7.00	-4.72	4.7
26	1.8	19	17.37	15.85	-8.79	4.2
27	0.2	18	2.14	2.37	10.73	6.7
28	0.4	10	4.59	4.56	-0.65	6.9
29	1.0	10	9.08	8.70	-4.15	4.5
30	0.6	10	4.99	5.17	3.48	9.7

* (Obs.Mass-Exp.Mass)/Exp.Mass

TABLE V

Accuracy and Precision of the PF-20(STEL) Monitor at Different Formaldehyde Concentrations

(Groups of 10 monitors exposed for 15 min at 25-27°C, 50% RH and face velocity of 84 cm/sec)

Run	Air Conc. (ppm)	Uptake (ug/ppm-hr) Expected*	Observed	Rel.Bias** (%)	CV (%)
31	2.17	---	4.11±0.27	---	6.5
32	3.85	3.93±0.10	4.12±0.12	5.8	2.9
33	5.87	3.82±0.03	3.79±0.25	-0.8	6.6
34	0.55	---	4.23±0.31	---	7.4

* Expected Uptake = PF-20(PEL) Uptake x 2.65.

** (Obs.Uptake-Exp.Uptake)/Exp.Uptake

Table VI

Shelf Life of PF-20 Monitors Following Storage at Room Temperature

(Groups of 10 monitors exposed for 6-8 hr to 0.5 ppm of formaldehyde at 50% RH, 24-27°C and face velocity of 84 cm/sec. Groups of 5 blank monitors analyzed without exposure.)

Run	Storage Time (Months)	Uptake (ug/ppm-hr)	Blank Conc. (ug/mL)
35	0	1.14±0.08	Not Det.
36	1	1.11±0.09	0.323
37	3	1.24±0.07	0.291
38	11	1.04±0.09	0.275
38	18	0.99±0.06	0.458

Figure 1

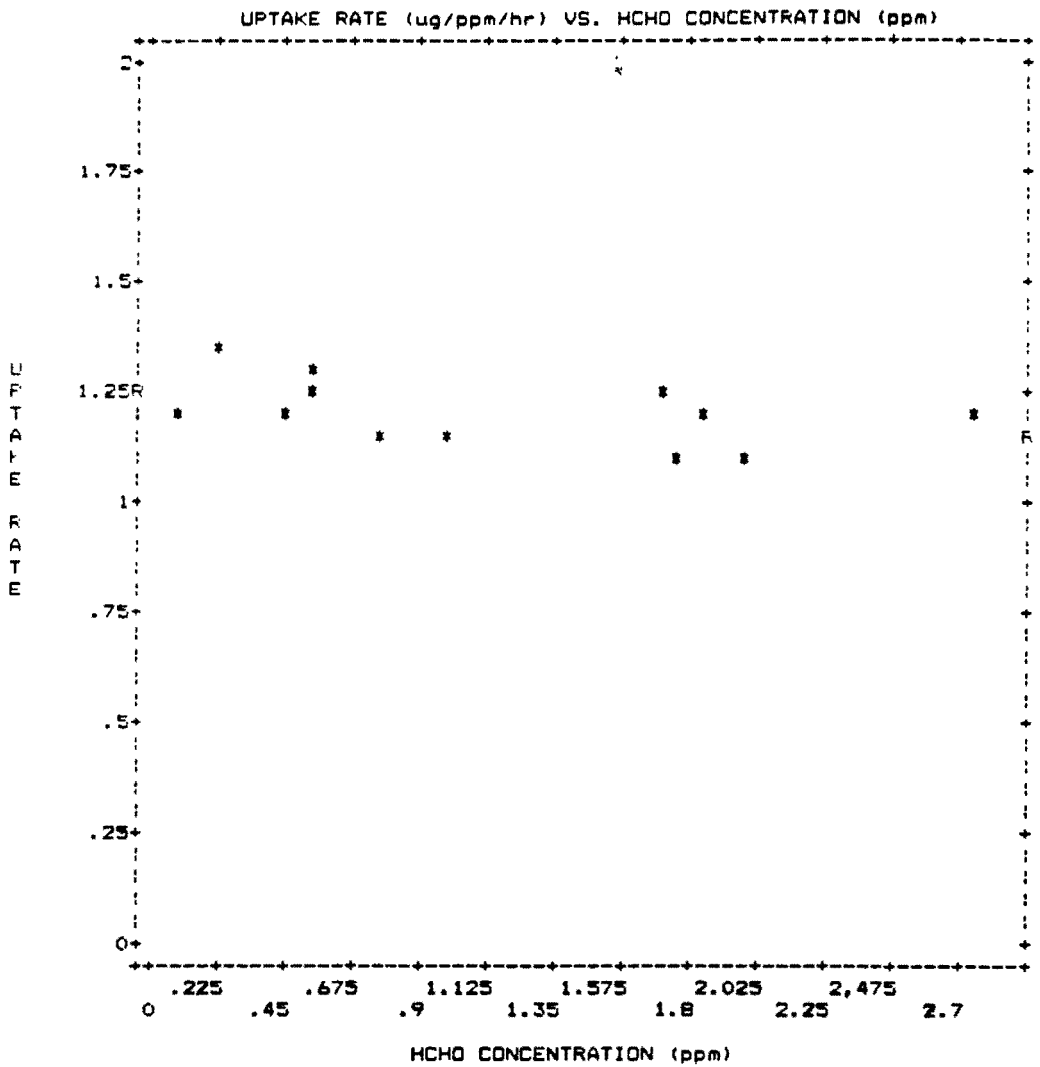
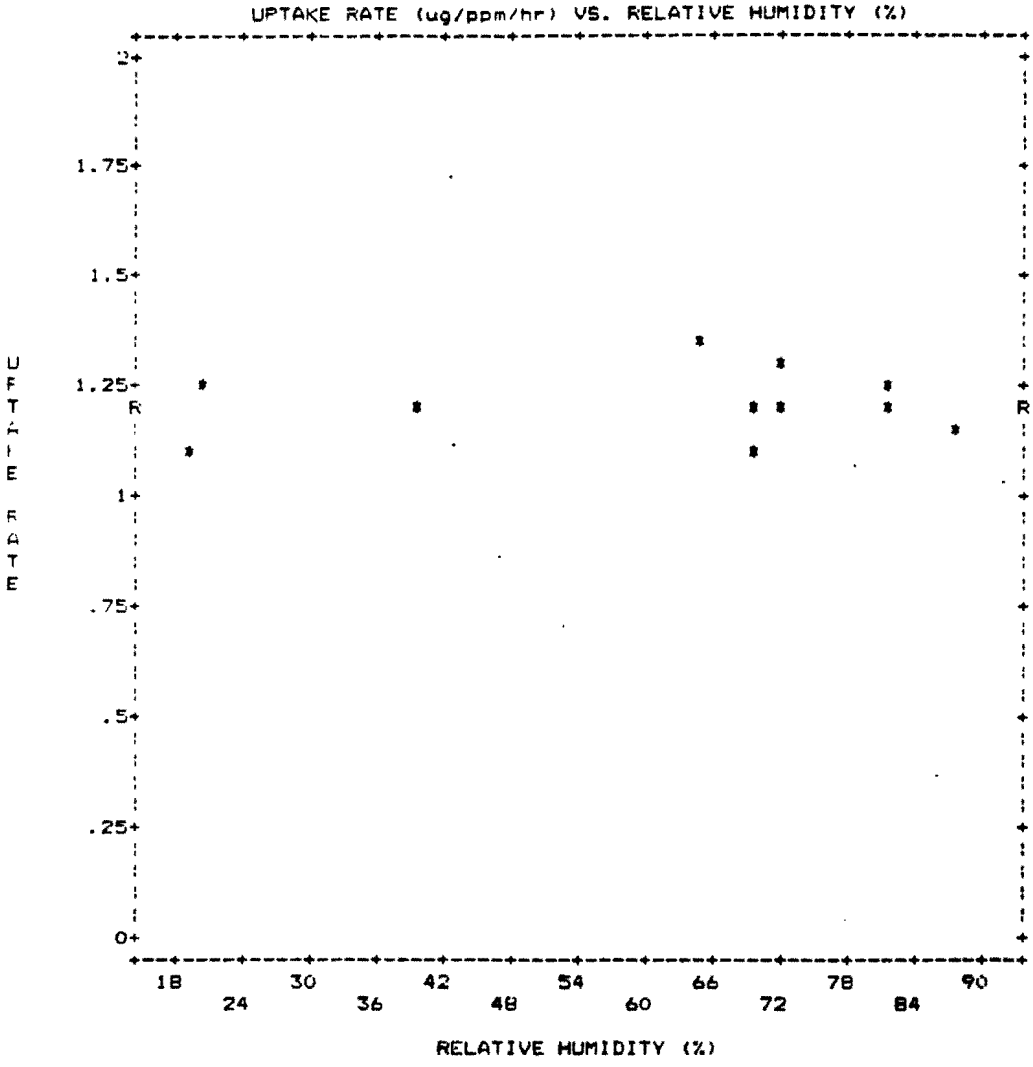

UPTAKE RATE (ug/ppm/hr) VS. HCHO CONCENTRATION (ppm)
UPTAKE RATE
2
1.75
1.5
1.25
1
.75
.5
.25
0
.225
.675
1.125
1.575
2.025
2.475
0
.45
.9
1.35
1.8
2.25
2.7
HCHO CONCENTRATION (ppm)

Figure 2


UPTAKE RATE (ug/ppm/hr) VS. RELATIVE HUMIDITY (%)
2
1.75
1.5
1.25
1
.75
.5
.25
0
UPTAKE RATE
18
24
30
36
42
48
54
60
66
72
78
84
90
RELATIVE HUMIDITY (%)