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### ASSESSMENT OF POTENTIAL BIASES IN THE APPLICATION OF MSHA RESPIRABLE COAL MINE DUST DATA TO AN EPIDEMIOLOGIC STUDY

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# ASSESSMENT OF POTENTIAL BIASES IN THE APPLICATION OF MSHA RESPIRABLE COAL MINE DUST DATA TO AN EPIDEMIOLOGIC STUDY\*†

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*Systematic errors in exposure data will result in biased estimates of the exposure-response relationship derived from epidemiologic analyses. Thus, adjustment of exposure data to account for identified errors may provide for a more accurate assessment of effect. In preparing to apply respirable coal mine dust exposure data collected by the Mine Safety and Health Administration (MSHA) to a study of the pulmonary status of underground coal miners, an assessment of potential systematic errors was undertaken. Potential errors stemming from adjustment of controls during sampling, concentration-dependent sampling, truncation of sampling results, identified sampling equipment problems, and a disproportionate number of low concentration samples in mine operator-collected samples were identified and evaluated. Methods to account for these errors and adjust mean exposures by mine, occupation, and year are given.*

**T**he National Institute for Occupational Health's (NIOSH's) National Study of Coal Workers Pneumoconiosis (NCS) was started in 1970 to assess the degree of respiratory morbidity in U.S. underground coal mines.<sup>(1,2)</sup> No quantitative exposure data have been collected explicitly for this study, because the Mine Safety and Health Administration (MSHA) has been systematically monitoring exposure to respirable coal mine dust in underground coal mines as part of its health standards compliance program since 1970.

The data collected under the MSHA program may be used to construct detailed estimates of exposure for the NCS cohort.

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Because the MSHA exposure data are obtained under a program designed to collect compliance information, certain biases may be present when the data are applied to epidemiologic analyses.

Numerous potential biases have been identified in the data set. Some of these cannot be fully evaluated but are briefly described. Potential biases for which corrections may be made are described in more detail, and a procedure for correcting estimated mean exposures by mine, occupation, and year is developed. These corrected means will then be used in conjunction with miners' work histories to calculate lifetime cumulative exposure indices for epidemiologic analysis. In this presentation, the mean connotes the arithmetic mean of the exposure distribution, which has been shown to be the primary parameter for the assessment of chronic hazards.<sup>(3,4)</sup>

## DATA DESCRIPTION

The sampling strategy for the collection of the air samples is complex, but follows a uniform protocol. In brief, the strategy includes sampling by both mine operators and by MSHA inspectors at specified intervals on miners in particular occupations. Operators obtain several samples bimonthly on highly exposed occupations at the mine face, and once bimonthly in other designated areas of the mine. MSHA inspectors sample face occupations for up to 5 days and other occupations as deemed necessary at each inspection.

The data set used for the analysis presented in this paper includes only full shift personal respirable dust samples collected between 1970 and 1987 from 36 underground coal mines. The 36 mines are those from which the NCS cohort was originally selected. It includes 314 118 samples, of which 2.8% were obtained by MSHA inspectors and 97.2% by mine operators. Parameters of the overall distribution are given in Table I and the distribution is presented in Figure 1. Analyses conducted to assess the degree to which the distribution is lognormal indicate

**TABLE 1. Parameters of the Distributions of Operator and Inspector Data from 36 Underground Coal Mines**

	<i>n</i>	Arithmetic Mean <sup>A</sup>	SD <sup>B</sup>	Geometric Mean <sup>A</sup>	SD
Operator	306 849	1.41	1.67	0.72	3.48
Inspector	7269	1.61	2.76	1.06	2.53

<sup>A</sup>In milligrams per cubic meter.

<sup>B</sup>SD = standard deviation (milligrams per cubic meter).

that the distribution is reasonably close to lognormal, but not uniformly so in each mine, occupation, and year category. A complete description of the sampling strategy and these analyses has been prepared.<sup>(5)</sup>

### Assessment of Potential Systematic Errors

To make an unbiased estimate of mean exposures, one would ideally take a random sample of workers within each occupational category and sample each on randomly selected days.<sup>(6)</sup> Because the MSHA data are collected under specific compliance-oriented protocols, the data do not have these characteristics and may be biased. Several potential biases resulting from these rules and other aspects of the sampling program are discussed below. However, without significant additional experimental study, the overall magnitude of the first three of these errors cannot be accurately estimated or accounted for. These errors include:

1. Negative bias introduced by infrequent pump calibration. MSHA requires calibration of operator sampling pumps only every 200 hr (25 shifts) and no postshift calibration. Thus, as the airflow is reduced across a shift, the volume of air collected may be overestimated and the resulting concentration underestimated.
2. Positive or negative bias introduced by MSHA voiding of samples with oversized particles. MSHA rejects samples that are found to have a significant number of particles over 10  $\mu\text{m}$  in diameter on the theory that this indicates a failure of the cyclone separator.
3. Random and systematic error resulting from the British Medical Research Establishment (MRE) conversion factor. The MSHA exposure standard is based on data collected with a horizontal elutriator that conforms to the MRE respirable dust sampling criteria. MSHA employs a

uniform conversion factor to compute the MRE-equivalent concentration from the data collected with the 10-mm cyclone.<sup>(7)</sup> Bartley et al.<sup>(8)</sup> have shown that the correct conversion factor will be dependent on the particle size distribution of the dust cloud sampled.

An additional set of five systematic errors that are amenable to analysis and control have been identified. These errors are described below.

### Adjustments on Controls during MSHA Inspections

MSHA inspectors conduct health compliance inspections at least once each year in every underground coal mine. The inspector arrives unannounced and collects personal and area dust samples in each section of the mine. Personal samples are collected on the "designated occupation" (DO), which is the miner with the highest expected exposure, and four or five additional occupations at the coal face. The primary purpose of the inspector sampling is to evaluate the effectiveness of the mine operators' written plan for control of dust. The sampling also is used to indicate if the occupation assigned DO is in fact the highest exposed occupation on the mine section. On the basis of the results of the first day's inspection, a decision is made

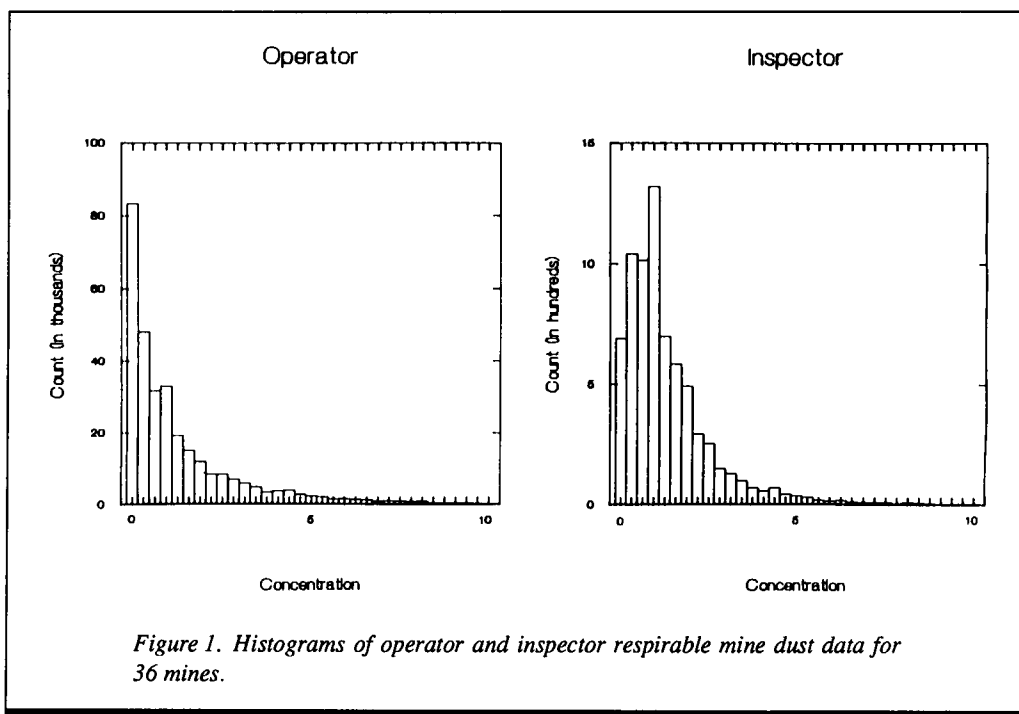


Figure 1. Histograms of operator and inspector respirable mine dust data for 36 mines.

according to specified rules<sup>(9)</sup> as to compliance status or whether additional sampling, for up to 5 days, must be done to make a compliance determination.

In estimating the true mean exposure for a category of miners, two potential errors in the inspector data for face occupations must be considered. First, because the primary purpose of inspector sampling is to evaluate the adequacy of the mine's dust control plan, the controls operating on the section under evaluation may be adjusted to conform to the dust control plan during the day of an inspection. Adjustments may be made to the

ventilation, water spray pressure, or other specified controls, thus either increasing or decreasing exposures from the levels normally found on that section. Thus, the concentrations determined by the inspector may not be representative of exposures on other workdays.

Second, controls may be added by the mine operator after the first day of an inspection to avoid potential citation in the event that the inspector returns for additional sampling. An analysis of this issue conducted by MSHA on a series of 100 inspections found that on the 18 inspections requiring more than 1 day of sampling, concentrations observed on the first day were approximately twice those observed on the subsequent days of the same inspection.<sup>(10)</sup>

These observations call into question the usefulness of inspector samples on face occupations for exposure estimation. Estimates of the magnitude of these effects cannot be simply determined with the available data.

Although it is possible that control parameters are adjusted similarly during operator sampling, it is not explicitly required. Because operator sampling takes place on a frequent and routine schedule, repeated adjustment of controls and production levels would be costly and thus, less probable. While operator data for face occupations is not thought to be completely unbiased, it is probably more reliable than inspector data.

On nonface occupations, the same potential biases may be reflected in inspector data, however, to a lesser degree. In addition, because the number of samples collected by operators on nonface occupations is small, inspector data are frequently the only source of information about exposure levels for these occupations.

### *Concentration-Dependent Sampling*

The MSHA sampling strategy used from 1970 through 1980 required mine operators to sample miners in highly exposed occupations at each mine section 10 times monthly. If exposures at the section were found to be in compliance, the sampling schedule was gradually reduced—first to five samples monthly and if compliance continued, then to five samples bimonthly.<sup>(11)</sup> Thus, the frequency of operator sampling on these jobs was dependent on concentration.

Inspectors are required to sample face occupations at least once during each year; however, where levels are high, additional days of sampling, up to 5, are more likely to be required. Thus, for both operator and inspector sampling, a mean concentration calculated from all samples for an individual mine is likely to be positively biased with respect to the average concentration that might be measured if random sampling was conducted.

To determine if this expected bias was actually present in our data, a smaller data sample was taken from seven large mines. The analysis was only conducted for one high-exposure job, Continuous Miner Operator, which is most commonly the DO, because there were an insufficient number of samples to conduct the analysis for other occupations. The number of samples and the mean were calculated for each mine section and year. A correlation of the number of samples with the mean was conducted. Because both number of samples and concentration are strongly time-dependent, a separate correlation was calculated for each year. Of the 17 correlation coefficients obtained, 14 were positive with a mean of

0.167 for operator data, and 12 were positive with a mean of 0.147 for inspector data. Thus, for both operators and inspectors, there is generally a slightly positive association between number of samples obtained and exposure levels.

This potential bias may be avoided, however, by estimating the mean exposure for each mine and occupation combination with a two-stage sampling procedure. First, the mean for each occupation within each mine section can be calculated. Then, the mean of the section means for each occupation can be obtained. Because there is generally one miner in each occupation on each section, the mean of mine section means for that occupation is an unbiased estimator of the occupation and mine's mean. This method of estimating the mean is independent of the number of samples taken on each mine section and will largely eliminate the potential bias introduced by concentration-dependent sampling.

### *Truncation Error*

MSHA weighing procedures call for weighing to an accuracy of 0.1 mg. However, because the weighing program is conducted in a legally controversial atmosphere, the weights are truncated to the first decimal place rather than rounded up or down. For instance, both 0.30 and 0.39 mg are truncated to 0.3 mg. The concentration observed for any particular sample is obtained by first calculating the filter weight gain by subtracting the pre-sampling filter weight from the postsampling weight. Because these two weights are truncated in the same manner, the resulting weight gain is, on average, unbiased.

To obtain the Mine Research Establishment (MRE) equivalent concentration, the weight gain is divided by the number of cubic meters sampled (generally 0.96 for an 8-hr shift at 2.0 L/min), and then multiplied by a constant factor (originally 1.6,<sup>(12)</sup> after December 15, 1973, 1.38<sup>(13)</sup>). This final result is then truncated down to the nearest 0.1 mg/m<sup>3</sup>. (If the concentration is less than 0.1, the sample is assigned a result of 0.1 mg/m<sup>3</sup>.) Thus, there is a systematic reduction of the results overall.

The effect of the truncation over the whole data distribution was estimated. For each possible weight gain, the concentration was calculated based on a full shift sample volume of 0.96 m<sup>3</sup> for both the 1.38 and 1.6 conversion factors. The concentration was then truncated to the first decimal place and the difference between the "true" concentration and the truncated concentration calculated. To calculate the effect of this bias on the data as a whole, the difference between the true and truncated concentrations was weighted by the distribution of operator sampling data and the weighted mean difference computed. The overall bias thus calculated is -0.03 and -0.05 mg/m<sup>3</sup> for the 1.6 and 1.38 conversion factors, respectively.

### *Filter Cassette Weight Loss*

In 1975, the National Bureau of Standards (NBS) issued a report of an investigation of Mine Enforcement Safety Agency's (MESA, the predecessor of MSHA) dust weighing program.<sup>(14)</sup> The report includes a description of problems with filter cassettes manufactured by both MSA and Bendix, the two primary suppliers of sampling equipment to the mining industry at that time. The NBS reported that Bendix cassettes weighed repeatedly from July, 1974 (manufacture date) to February, 1975 had an average weight loss of 0.26 mg. Problems in the design and

manufacture of the Bendix cassettes that might have accounted for this weight loss are reported. As noted in the report, the Bendix cassette was subsequently decertified and thus removed from use by mid-1975.

About 40% of the market at that time was represented by Bendix and most cassettes were used on average approximately 1 month after the manufacturer obtained the preweight.<sup>(15)</sup> Assuming a linear loss of weight over the 7-month test period (this is a conservative assumption, because one would expect weight loss to slow over time), a cassette used 1 month after manufacture would have lost approximately 0.04 mg before use and reweighing. When adjusted for 40% market share and converted to an MRE equivalent concentration (using a sample volume of 0.96 m<sup>3</sup> and the 1.6 conversion factor), this weight loss represents an average underestimation of -0.03 mg/m<sup>3</sup>.

### Unexpected Low Values in Operator Data

Normally, one would not expect occupations at the mine face to have exposures less than about 0.3 mg/m<sup>3</sup>.<sup>‡</sup> Previous investigators have noted a large number of low-concentration samples on face occupations in operator data when compared to the anticipated lognormal distribution or to the distribution of inspector-collected samples.<sup>(16,17)</sup> The authors' data have a similar pattern. If these data represent falsely low concentrations in operator data, it may significantly bias an exposure estimate.

To examine this issue in the authors' data, a comparison was made of the fraction of samples comprised by low values ( $\leq 0.1$ ,  $\leq 0.2$ ,  $\leq 0.3$  mg/m<sup>3</sup>) in the operator and inspector data. The data were stratified by mine section, occupation, and year and limited to strata containing greater than five operator and inspector samples. Strata totaling 260 were identified in 35 mines and 21 occupations. The fractions in operator and inspector data are shown in Table II. The difference in the fractions is highly significant for all three levels tested. Of the 12% difference in the fraction of samples with concentrations less than or equal to 0.3 mg/m<sup>3</sup>, two-thirds (8% of 12%) of the difference is accounted for by samples with concentrations of 0.1 mg/m<sup>3</sup>. Because the greatest difference was found at 0.1 mg/m<sup>3</sup>, and it is these 0.1 mg/m<sup>3</sup> samples that are least expected to be found at the mine face, this fraction was used for subsequent analyses.

To determine how uniformly these differences occur across mines and occupations, the average fraction of operator and inspector samples occurring at 0.1 mg/m<sup>3</sup> was determined for each mine, and then for each occupation (Figures 2 and 3). The fractions at 0.1 mg/m<sup>3</sup> for operator data are consistently greater than those for inspectors across all mines, although the difference is much greater in some mines than others. As shown in Figure 3, the same is true for all face occupations. For the two nonface occupations for which strata with sufficient samples were identified (underground laborer and surface laborer), the inspector

**TABLE II. Paired Comparisons between Fraction of All Dust Samples Collected for Operator and Inspector Data Found at  $\leq 0.1$ ,  $\leq 0.2$ , and  $\leq 0.3$  mg/m<sup>3</sup>.<sup>A</sup>**

Fraction of Samples $\leq$ :	Operator Samples	Inspector Samples	Mean Difference <sup>B</sup>
0.1 mg/m <sup>3</sup>	0.11 (0.01) <sup>C</sup>	0.03 (0.01)	0.08 (0.06, 0.09)
0.2 mg/m <sup>3</sup>	0.17 (0.01)	0.06 (0.01)	0.11 (0.10, 0.13)
0.3 mg/m <sup>3</sup>	0.19 (0.01)	0.07 (0.01)	0.12 (0.10, 0.14)

<sup>A</sup>Based on 260 occupation, year, and mine section strata with  $\geq 5$  operator and inspector samples from 36 NCS mines.

<sup>B</sup>95% confidence interval.

<sup>C</sup>Fraction (standard error of the mean).

fraction is greater than that for operator data. These mean fractions, however, are quite unstable, being estimated from only four and one fractions, respectively.

In order to determine the importance of the observed differences in fractions of low samples to the estimation of means, a sensitivity analysis was done. The number of operator samples expected at 0.1 mg/m<sup>3</sup> based on the fraction found in inspector data was calculated. The arithmetic and geometric means of the distribution of operator samples were then recalculated using this expected number of low samples.

The fraction of the overall distribution at 0.1 mg/m<sup>3</sup> for inspector data was 0.043, while the fraction for operator data was 0.171. Thus, given a distribution similar to the inspector data, only 25% ( $0.043/0.171 \times 100\%$ ) of the operator 0.1 values would be expected.

The arithmetic and geometric means for the operator distribution were recalculated to demonstrate the effect of discounting these low values. When 75% of the 0.1 values are discounted the arithmetic mean is raised from 1.41 to 1.60 mg/m<sup>3</sup>. The geometric mean is raised from 0.72 to 0.96 mg/m<sup>3</sup>. The results of these analyses show that across both mines and face occupations there is a larger proportion of very low samples obtained by operators than inspectors. Taken along with the previous analyses<sup>(16,17)</sup> and expert judgment (see Footnote <sup>‡</sup>) on low samples in operator data, there is strong evidence that these low samples do not well represent actual exposure conditions. The bias estimated in the arithmetic mean is -0.19 mg/m<sup>3</sup> ( $1.41 - 1.60$ ), or 13% of the mean of 1.41 mg/m<sup>3</sup>.

### SUMMARY AND IMPLICATIONS OF EVALUATED BIASES

Five potential biases that may affect the estimation of mean exposures for underground coal mines using MSHA compliance data have been evaluated. Adjustments made by inspectors or mine operators during MSHA inspections make data obtained by inspectors on face occupations unreliable for exposure estimation. Concentration-dependent sampling by both operators and inspectors on face occupations may yield a positively biased mean; however, this problem may be avoided by estimating exposures as the mean of mine section means. Truncation of sample concentrations to the nearest decimal place will yield, overall, a bias of -0.03 or -0.05 mg/m<sup>3</sup>, depending on the conversion factor used at the time. Problems with Bendix filter

<sup>‡</sup>This observation is based on several personal communications: T. Tomb, Chief, MSHA Dust Division, Pittsburgh, Pa.; G. Niewiadomski, MSHA Coal Mine Safety and Health, Health Division, Arlington, Va.; and R. Thaxton, I.H. Supervisor, MSHA District 4, Mt. Hope, W.Va.; and the observation that dust concentrations in intake air are commonly as great as 0.2 mg/m<sup>3</sup>.

cassettes yield an estimated  $-0.03 \text{ mg/m}^3$  bias in the results. Finally, disproportionate low samples in operator data yields an estimated bias of  $-13\%$ .

In estimating mean respirable dust exposures by mine, occupation, and year, one must account for the five biases that have been evaluated. For face occupations, only operator data will be

used. The data collected before July, 1975 will be adjusted up  $0.03 \text{ mg/m}^3$  to account for cassette weight loss and up either  $0.03$  or  $0.05 \text{ mg/m}^3$ , depending on the collection date, to account for errors resulting from truncation of the results. The mean of the section means by mine, occupation, and year will then be estimated. The mean values will then be adjusted upwards by  $13\%$  to account for disproportionate low samples in operator data.

Because inspector data should be more reliable on non-face jobs, both operator and inspector data will be used to estimate mean exposures for these occupations. As for face occupations, the data will be adjusted upwards by  $0.03 \text{ mg/m}^3$  and  $0.03$  or  $0.05 \text{ mg/m}^3$  to account for cassette weight loss and truncation errors. Because the concentration-dependent sampling and disproportionate low samples in operator data are not found in nonface data, the means calculated for these occupations will not be further adjusted.

## DISCUSSION

The meaningful association between exposure to an environmental or workplace agent to a specific health outcome relies on precise and accurate information for both. Both random and systematic errors in exposure information may bias the exposure-response relationship derived.<sup>(18)</sup> Random errors will tend to decrease the exposure-response relationship while systematic errors, if equally distributed to subjects with high and low cumulative exposures, will result in a shift in the exposure-response curve. Overestimation of exposure will shift the curve to the right, resulting in an underestimation of the effect at a given exposure level, while

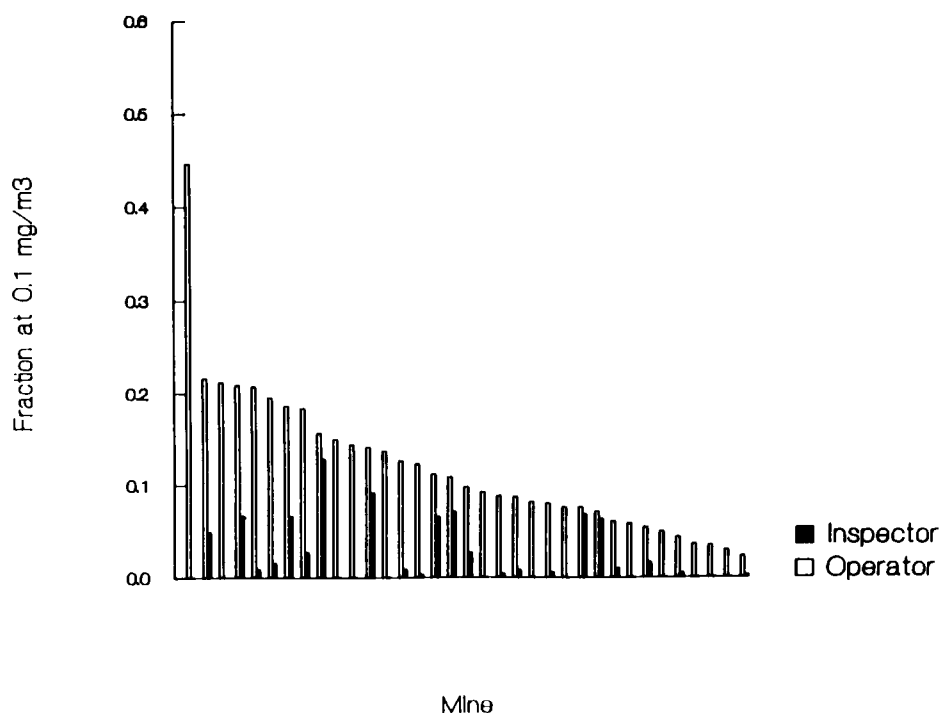


Figure 2. Fraction of operator data at  $0.1 \text{ mg/m}^3$  by mine.

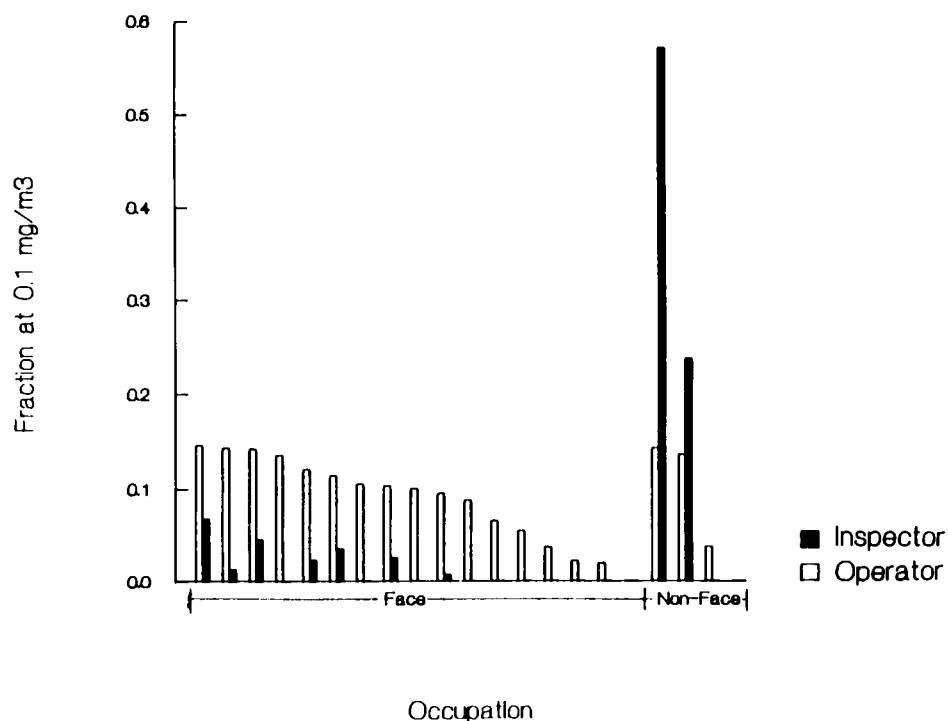


Figure 3. Fraction of operator data at  $0.1 \text{ mg/m}^3$  by occupation.

underestimation of exposure will provide the opposite effect. Systematic errors, which affect subjects with high and low cumulative exposures differentially, may have various effects on the observed relationship. Control of biases will minimize possible distortions of the exposure-response relationship.

When applying compliance data to an epidemiologic study, one must assess the adequacy of the data for the purpose at hand. Ulvarson has presented a list of possible biases that may exist in exposure data.<sup>(19)</sup> In the data and analyses presented here, several examples of these types of errors have been identified and estimates of the effects quantified.

The nonrepresentative nature of samples collected by inspectors limits the usefulness of these data. Because the inspector data make up a relatively small proportion of the data, it is possible to discard it without a great loss of precision.

Concentration-dependent sampling on face occupations requires that means are estimated as means of mine section means. Because each mine section or mechanized mining unit (MMU) has one miner in each occupation, the mean of section means is an unbiased estimator of the mean for the whole mine.

Small errors in the way the measurements are made—truncation of the results and weight loss in the sampling cassette—have been identified and quantified. The adjustment of the data using the average effect of truncation, rather than the effect for each individual result, may result in small errors in any particular case but should be, on the whole, unbiased. The estimate of the effect of cassette weight loss is based on only one experiment on a limited number of cassettes and uncertain assumptions about the shape of the weight loss curve and the time from manufacture to cassette use. However, the most probable error introduced by both assumptions is to minimize the potential error. If, as might be expected, weight loss is greater just after manufacture and slows down with time, our estimate based on a linear weight loss over 7 months is low. And, if the cassettes were used several months after manufacture rather than only 1 month, the estimate is again on the low side. Thus, the estimate given for cassette weight loss,  $-0.03 \text{ mg/m}^3$ , is the smallest that might be expected.

The analysis of the occurrence of a disproportion of low samples in operator data adds to the evidence present in the literature that these samples do not adequately represent true exposure conditions. The analysis was conducted with a highly specific stratification—by mine, mine section, occupation, and year, and it does not rely on distributional assumptions. The results indicate that the phenomenon is present across all mines and face occupations—although not on nonface occupations.

Boden<sup>(17)</sup> suggests, on the basis of economic theory, that the incentives to the operator of underreporting dust concentrations provide an explanation for the low concentrations in operator data. If the main reason for the low samples were purposeful falsification to reduce penalties associated with noncompliance on the part of the mine operators, one might expect it to be present in only certain mines. The analysis has shown that it is true in all mines examined, although to different extents. This observation suggests that there may be additional factors responsible for the presence of the low samples that act across all mines.

In interviews with miners and mine operators, Sharpe<sup>(16)</sup> has presented a number of reasons for the occurrence of these samples. He cites several comments by miners that suggest that

they do not always believe that accurate dust sampling will lead to dust level reduction or prevention of disease. Sharpe noted that miners at times attempt to obtain falsely low concentrations for fear of later disqualifying themselves for black lung benefits and in order to avoid having to repeatedly wear the cumbersome sampling equipment.

On the basis of the analysis of this issue, it is only possible to conclude that there is an unusually large proportion of low samples in operator data. Sufficient rationale for these data have been given by previous investigators to allow the conclusion that they are unlikely to accurately reflect exposure concentrations to face workers.

Two basic methods were used to evaluate potential biases present in this data set. The rules and procedures under which the data were collected were analyzed for potential bias and the data distributions were examined to detect departures from those predicted by another segment of the data. These general approaches may be used whenever a set of exposure data collected for one use, such as legal compliance, is used for an epidemiologic analysis. Although the estimates that one obtains of the magnitude of the biases are somewhat uncertain, to ignore the recognized biases would be to allow greater uncertainty in the final exposure-response estimates than to account for them using the best information available. The exposure-response relationship derived using these adjusted data will be as unbiased an estimate as possible and will help guide future public health interventions in the mines.

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