GUIDELINES FOR STATISTICAL ANALYSIS OF OCCUPATIONAL EXPOSURE DATA

FINAL

by

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DISCLAIMER

This report was developed as an in-house working document and the procedures and methods presented are subject to change. Any policy issues discussed in the document have not been subjected to agency review and do not necessarily reflect official agency policy. Mention of trade names or products does not constitute endorsement or recommendation for use.

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INTRODUCTION

The purpose of these guidelines is to establish a consistent approach to handling the wide variety of occupational exposure data available for preparing occupational exposure assessments in support of risk assessments. It provides guidance in the characterization of broad ranges of job groups with similar exposures, calculation of descriptive statistics (where appropriate) and treatment of uncertainties, assumptions, and biases in the data. It is designed to be used by engineers in the Office of Pollution Prevention and Toxics (OPPT), with some assistance from industrial hygienists and statisticians. The procedures described provide a systematic methodology for performing an occupational exposure assessment based upon the types of data which are most commonly available for such analyses. Methods used by OPPT's Chemical Engineering Branch (CEB) to prepare assessments of occupational exposure and environmental release are presented in the CEB Engineering Manual (IT, 91). These guidelines are a supplement to the CEB Engineering Manual intended for use with recently collected data. It should be noted that these guidelines are not intended to provide recommendations for performing additional monitoring of exposure or for determining compliance with regulatory standards. If this is the goal, the reader should consult other references such as Hawkins (91) and Patty (81), etc.

A. <u>Types of Occupational Exposure Monitoring Data</u>

Monitoring data usually consist of area samples, personal inhalation samples or dermal samples. Area samples are collected to represent the airborne concentration of a chemical in a specific location at a facility. Personal samples are collected to represent a worker's inhalation exposure during a specified time period; for example, peak, ceiling, short-term, and full-shift samples. Peak or ceiling samples are typically collected instantaneously through continuous monitoring or for 15 minutes or less. Short-term samples are collected over a designated period, typically less than 2 hours. Full-shift samples are collected to represent a worker's inhalation exposure over an entire work shift and may be composed of a single sample or consecutive short-term samples. Dermal samples are collected to represent a worker's dermal exposure to a given chemical over a portion of the body which has been in contact with the chemical. Exposure data collected for each type of exposure should be separated and statistical analyses conducted separately.

Biological monitoring may also be used to determine an employee's overall exposure to a given chemical by measuring the appropriate determinant in biological specimens collected from exposed workers at the specified time. While biological monitoring provides information complementary to air monitoring, interpretation of data can be difficult due to variability in the physiological and health status of the individual, exposure sources, individual life style, analytical errors, etc. If biological monitoring data are available, this fact should be noted in the exposure assessment. This report does not address biological monitoring but focuses on air monitoring data collected to assess inhalation exposure.

For the purposes of this report, three broad categories of occupational exposure data are considered:

- Type 1 data consist of measurements for which all important variables are known. The data consist of studies that contain individual measurements and include all backup and ancillary information (e.g., analytical method, limit of detection, sampling duration, type of sample taken, job tasks, etc.).
- Type 2 data consist of measurements where important variables are not known but for which assumptions can be made for their estimation. The data consist of individual monitoring measurements, but backup and ancillary information are inconsistent.
- Type 3 data consist of measurement summaries, anecdotal data, or other data for which the important variables are not known and cannot be estimated. Individual monitoring measurements are typically not available.

These categories were developed for use with these guidelines; judgment is used in determining the type(s) of data available. Examples and additional information on the categories are provided beginning with Step 10.

Once satisfied that the data have been properly collected for the objective of the study, the primary determinant of the confidence one can place in the analysis is the sample size. Every effort should therefore be made to collect and analyze every available piece of data. Because the size of the data set being analyzed has a large effect on the confidence that can be placed in the analysis, the methodology set forth in these guidelines allows the combination of similar data sets based on statistical tests. The traditional categorization of data by the industrial hygienist or engineer is supplemented by statistical analysis of the categorization; the goal is identification of groups of data that are as large as possible and describable by standard statistical distributions (lognormal and normal).

B. <u>Types of Occupational Exposure Assessments</u>

There are various types of exposure assessments performed by OPPTs' CEB. The main distinction between them is the level of effort expended in collecting data. Regardless of what type of data are obtained, however, the CEB engineer should review the level of detail required in the exposure assessment and try to provide the best and most complete analysis of the available data.

The following are examples of the program areas and types of exposure assessments performed by CEB:

- <u>New Chemicals Program</u>. An initial screening assessment is performed with a goal to determine the high end and central tendency exposures, generally using available information and information submitted in the Premanufacture Notification (PMN). In reality, these estimates are more likely to be bounding (e.g., overestimates of) exposure, due to lack of information. If there are concerns for worker exposure, the initial assessment is refined as the case progresses through the review process. However, due to lack of data on these new chemicals which have not yet been commercialized, this often involves the use of modeling or surrogate data, rather than analysis of actual data on exposure to the substance of concern.
- <u>Chemical Testing</u>. A preliminary exposure assessment is completed to determine the bounds of potential occupational exposure for chemical testing candidates. This exposure assessment is refined as the case progresses and additional information is gathered. Since these are "existing" chemicals, there may be some exposure data available on the specific substance. These chemicals may be referred to CEB through the Interagency Testing Committee (ITC).
- <u>Existing Chemicals</u>. An exposure assessment may be an initial screening which is used to help determine if further work is needed on the case. If so, a more detailed exposure assessment including the range of potential exposure, measure of central tendency, uncertainty, etc. is completed for the population(s) of concern. A risk assessment is performed; if risk management action will be taken the exposure assessment may be revised to include additional information or to cover additional uses, etc. For some cases monitoring studies will be conducted to determine workplace exposure levels. An evaluation of controls may also be needed.

C. <u>Variability in Occupational Exposure Data</u>

It is rare to find studies of occupational exposure based on a statistical approach to providing representative information for an individual facility; it is even less likely to find such a study that represents a particular industry subsector or group of facilities. While random sampling (i.e., monitoring exposure to a group of workers in a random fashion) is preferred, "worst-case sampling" (i.e., monitoring the individual with the highest exposure) during a 1- to 3-day sampling campaign is common industrial hygiene practice for compliance with regulatory standards. However, sampling programs are being used that promote exposure monitoring and periodic surveillance (Damiano, 89; Hawkins, 91).

Even in statistically-selected, well-done studies, there may be high variability in the characterization of worker exposure. Measurements at a plant made over a period of no more than a few days may be all that are available to characterize exposures over an entire year or a period of years. Seasonal variability, interday and intraday variability, and changes in the process or worker activities can cause the exposure to vary from that measured on a single day. Temperature changes can affect evaporation rates, and seasonal changes in natural ventilation affect exposure. Sampling methods and time periods can also vary. Seldom can all these variables be measured and accounted for. However, if

important variables are identified and quantified, it is hoped the influence of less important variables on the overall measure of central tendency will be minimized. Variables that may not be obvious may also affect variability among plants in the same industry category. Variables such as the age of the plant, the age of the control equipment, whether the plant is in a volatile organic compound (VOC) nonattainment area, and operation and maintenance (O&M) practices at the plant should be investigated.

When analyzing sample data, it is important to understand the sources of variation in exposure sample results that combine to create the observed variability (Patty, 81). The size of the variation may be a function of both the exposure levels and the measurement method. Both random and systematic errors should be considered.

Random variations in workplace exposure levels can result in intraday variations, interday variations, or variations in exposures of different workers within a job group or occupational category (Patty, 81). Variability in the measurement procedure can be caused by random changes in pump flow rate, collection efficiency, or desorption efficiency. It is important to realize that random variation in real workplace exposure levels will usually exceed measurement procedure variation by a substantial amount, often by factors of 10 or 20 (Patty, 81; Nicas, 91).

Systematic variations in the determinant variables affecting workplace exposure levels will lead to systematic shifts in the exposure results. Variability in worker exposure levels reflects changes in worker job operations during a work shift or over several days, production process changes, or control system changes. Systematic errors in the measurement procedure can result from mistakes in pump calibration, use of sampling devices at temperatures or altitudes substantially different from calibration conditions, physical or chemical interferences, sample degradation during storage, internal laboratory errors, and interlaboratory errors (Patty, 81). These errors may be identified and their effects minimized with the use of quality assurance programs (EPA, 92). Specific variables (parameters) that can affect occupational exposure measurements are more fully discussed in Step 4.

It is also important to ascertain the objectives of the monitoring study to identify potential biases in the data. For example, if the objective was to sample only well-controlled facilities, then the results would probably not represent the exposure in the industry as a whole. If the monitoring resulted from worker complaints, then exposures may not represent typical exposures. If the monitoring was conducted to evaluate engineering controls or as a preliminary screening of exposure, the results may not represent actual employee exposure. It is important that all potential variables be identified and evaluated.

D. Organization of This Report

Following the introduction is a 19-step procedure for statistical analysis of occupational exposure data. Figures 1 to 3 present flow diagrams outlining these procedures. Each numbered step in these figures is explained separately. Steps 1 through 6 are presented in Figure 1 and give the actions necessary to prepare a preliminary exposure matrix. Steps 7 through 14 are presented in Figure 2 and give the actions necessary to prepare a completed exposure matrix from the preliminary exposure matrix including preparation of a non-statistical report on Type 3 data. Steps 15 through 19 are presented in Figure 3 and

relate to the statistical analysis of Type 1 and 2 data and the presentation of the results. An example is used throughout the 19 steps to better explain the techniques used in the guidelines. The data used in the example are based on real data, but have been altered where necessary to emphasize particular points in the guidelines.

These guidelines present rather sophisticated approaches for statistical analysis of occupational exposure data. Nonstatisticians may require training or the assistance of a statistician in order to properly understand and use the guidelines. The development of software as a companion to the guidelines could be useful in guiding the user through the analyses and in incorporating more complex calculations for certain nondefault procedures discussed in Appendix B.

A bibliography of references pertinent to occupational exposure analysis is also provided. Appendix A presents a spreadsheet matrix for the example data set. Appendix B presents background information on the methodology available to statistically analyze the data. Appendix C presents a listing of currently available computer software for the statistical analyses.

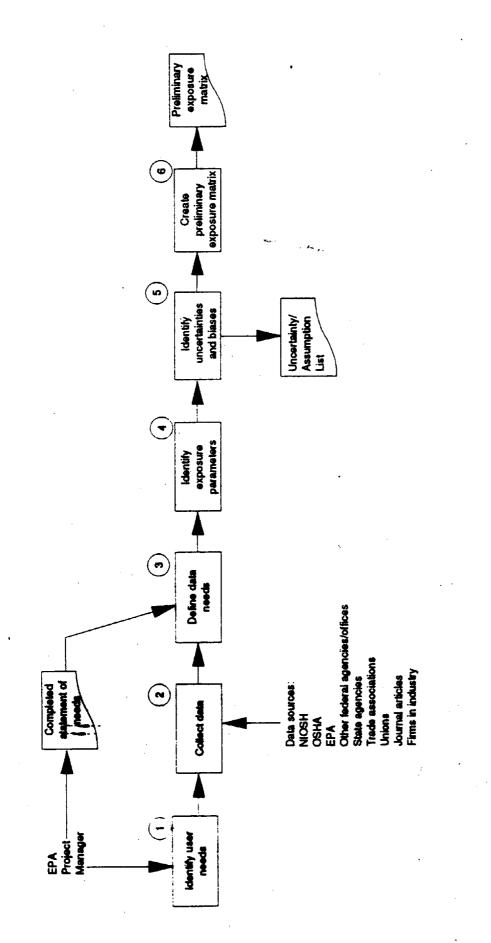


Figure 1. Flow Diagram for Creation of Preliminary Exposure Matrix.

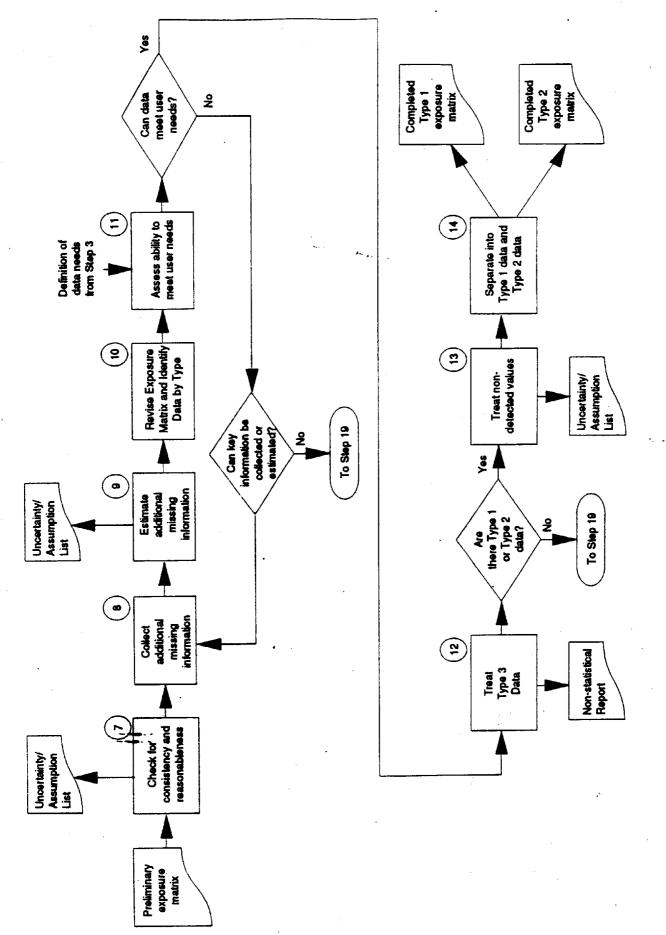


Figure 2. Flow Diagram for Creation of a Completed Exposure Matrix.

ć

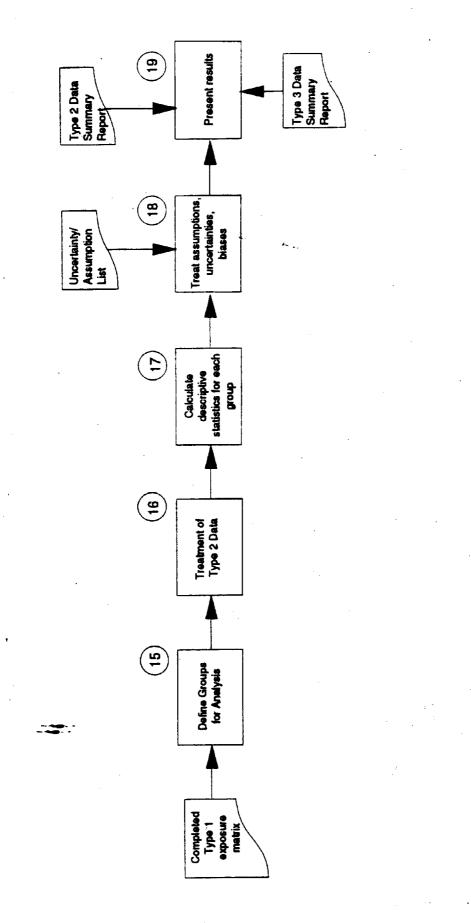


Figure 3. Flow Diagram for the Statistical Analysis of Type 1 and Type 2 Data.

STEP 1: IDENTIFY USER NEEDS

The first step in an exposure assessment is to identify the needs of those using the information, usually in some form of risk assessment activity. The user is typically the project manager for the chemical under review. This step initially identifies the data requirements of the assessment so that resources can be used most effectively to collect pertinent data.

The level of detail required in an exposure assessment depends on the scope of the risk assessment activity it supports (EPA, 87). If the purpose of the analysis is merely to screen a new chemical for potential problems, a much less rigorous bounding estimate of exposure will often be prepared. These analyses are useful in developing statements that exposures are "not greater than" the estimated value. However, to support a detailed risk assessment, an in-depth presentation of potential exposures must be prepared. It is also necessary to know if the end user is interested in a particular demographic group, route of exposure, frequency and duration of exposure, industry, exposure period, or other variable. For example, if the chemical is of concern because of possible reproductive effects for women of childbearing age, then every effort should be made to gather information on the exposure of this demographic group. Information needs also depend on the specific health hazards identified for the chemical. Some of the information needs that may be identified include:

- Mean, standard deviation
- Geometric mean, geometric standard deviation
- Range of exposures, confidence intervals
- Duration of exposure (hr/day and days/yr)
- 8-hour time-weighted average (TWA)
- Peak exposures
- Time period (i.e., particular year, 1989)
- Cumulative exposure over time, lifetime average daily exposure (for possible use in risk assessment)
- Probability of excursions or exposure during upsets or emergency release
- Uncertainties associated with the data and assumptions used in analyzing the data

The objectives of the exposure assessment must be defined using information obtained from the "user," typically the project manager for the chemical under review. To assist in this process project managers should be contacted initially to discuss the data requirements of the assessment and asked to complete a "statement of customer needs" form for exposure assessments which are not typical new chemical-type assessments. When this form (shown in Figure 4) is returned, it will be of value in Step 3 to more completely define user needs.

Since health effects data are often gathered to prepare the hazard assessment in parallel to the occupational exposure assessment, good lines of communication with the project manager and those preparing the hazard assessment will facilitate information exchange regarding potentially changing assessment needs. For example, as new health effects are defined, the exposure data classification or level of detection required of the analytical methods used may need to be changed. For example, if chronic

health effects are identified, generally long-term exposures are of interest, while peak or short-term exposures are of interest for acute health effects. Timely communication will minimize the changes that need to be made as well as the need for further data collection.

EXAMPLE

The example shown below will be used throughout this report to illustrate how the statistical analysis proceeds.

The example chemical is a colorless gas whose primary use is polymerization to make various elastomers. Recent chronic oncology studies indicate that the chemical is carcinogenic in mice. The present OSHA Permissible Exposure Limit (PEL) is 1,000 ppm as an 8-hour TWA, but the American Conference of Governmental Industrial Hygienists (ACGIH) recommended a revised Threshold Limit Value (TLV) of 10 ppm as an 8-hour TWA.

The project manager identified two general needs for the exposure assessment. First, the exposure assessment was needed to do a preliminary risk assessment for all worker exposures to the chemical. Second, it was needed as a baseline to estimate the technological feasibility and cost of reducing worker exposure to target levels of 10 ppm, 1 ppm, and 0.1 ppm. An example statement of needs form for the example chemical is shown in Figure 4.

Figure 4. Statement of Needs

Statement of Customer Needs for CEB Engineering Assessments

Requester: Sally Jones, Project Manager Date of Request: 2/20/94

The purpose of this form is to gather information on customer needs to be used in developing a CEB engineering assessment. Please note that all identified needs may not be met due to data limitations, resource constraints, etc. What with multiple customers of CEB assessments, it is suggested that the form be completed by the individual who will be using the specific type of information provided by CEB.

Return completed form to: <u>John Smith, CEB Engineer</u> Phone: <u>260-1234</u>

Section 1. General Information

A. Please indicate the origin of the case and chemical/use cluster, etc. (e.g. RM 2 analysis for hydrazine): <u>RM2 analysis for example chemical</u>.

B. What are the purpose and goals of the CEB assessment and the project? Develop assessment of occupational exposure to the example chemical.

C. What are the approximate completion dates for the CEB assessment and for the project? <u>CEB</u> assessment is due April 4, 1994

D. Please identify the health effects of concern (e.g. carcinogenicity, neurotoxicity, liver effects, reproductive effects, sensitization, etc.): Carcinogenicity

E. Please identify the environmental effects of concern : <u>NA</u>

F. Please identify any specific data, sources, references, or personal contacts you would like CEB to research: <u>NIOSH and OSHA data.</u>

G. When do you need to have an estimate of CEB extramural resources (if any) for this project? <u>NA</u>

Section 2. Occupational Exposure Assessment

 \Box Not Needed

A. CEB will estimate number of workers exposed for each industry segment of interest. Identify any special population characteristics of interest (e.g. gender, etc.): <u>Total number of workers potentially</u> exposed, and population potentially exposed during monomer and polymer production.

С.	Indicate ✓ which types of ex	cposure are of interest:		
✓ □	Inhalation exposure Other (e.g. ingestion):		Dermal exposure	
-				

D. Identify which worker activities are of interest (e.g. the assessment need only address textile dye weighers): All worker activities associated with monomer and polymer production.

E.Indicate \checkmark the preferred characterization for duration and frequency of exposure:

- □ Short-term exposure (e.g. peak exposure, maximum 15-minute exposure, etc.), for acute health effects. Identify specific requirements: ______
- ✓ Long-term exposure (e.g. annual average exposure, lifetime average daily dose, etc.), for chronic health effects. Identify specific requirements: <u>annual average exposure and lifetime average daily</u> dose.
- $\checkmark \qquad \text{Frequency of exposure (days/yr)}$
- ✓ Cumulative exposure over time (e.g. days, months, years): <u>days, months, and years are of interest</u>
- □ Other: _____

G. CEB will attempt to provide a measure of central tendency, and a high end Potential Dose Rate (PDR), identify assumptions made, and characterize uncertainty, as data and methodologies allow. Identify any specific needs (e.g. specific statistical descriptors, etc): Statistical descriptors of geometric mean, arithmetic mean, geometric standard deviation, arithmetic standard deviation, the distribution of the data, and a graphic presentation of the data are preferred.

H. Please identify any other special needs for the occupational exposure assessment: Estimate of the technical feasibility of controlling exposure to 10 ppm, 1 ppm and 0.1 ppm.

Section 3. Process Information

A. Are there specific industrial segments (e.g. manufacture, processing into a coating, end use as a paint in automotive application) you would like process information for?

Please specify the information you	would like C	EB to provide:
Please specify the information you we Number of sites	would like C	<i>EB to provide:</i> Days/yr
	would like C.	-

Section 4. Environmental Release Assessment

✓ Not Needed

A. CEB will provide estimates of environmental release (i.e. kg/site-day or kg/yr) for manufacture, processing and end use operations. Indicate any specific industry segments of interest or special data needs:

B .	Indicate ✓ which types of re	eleases are of	f interest, and indicate any special needs:
	Water releases		Air releases
	Landfill releases		Incineration releases
	Other:		
Spe	cial Needs:		
-			

C. CEB will attempt to provide descriptors for release assessments, identify assumptions made, and characterize uncertainty, as data and methodologies allow. Identify any specific needs:

Are there specific industrial segments you would like CEB to provide an assessment of pollution prevention opportunities and/or occupational exposure reduction for?

	□ PPA	□ OERA	□ Both	
1.				
2.				
3.				

Section 6. Other Information Needs

✓ Not Needed

Please identify other information, analysis or data needed, and the rationale for requiring the information:

Customer Contact (e.g. Project Manager):

Sally Jones, Project Manager CCD 260-2345 2/20/94

(Name) (Division/Branch) (Telephone) (Date)

STEP 2: COLLECT DATA

Once the data requirements of the assessment are preliminarily identified, the next step is to collect the monitoring data that will be used in the analysis. It is important to obtain information on all variables relating to the measured values, such as the collection method, number of workers exposed, duration of the sampling, etc. Step 4 contains a listing of parameters that may affect exposure. The more data that are identified and collected, the better the analysis will be. Therefore, it is important to ascertain at the beginning of the project that all possible sources of data have been checked.

Typical sources of exposure monitoring data include the National Institute for Occupational Safety and Health (NIOSH), the Occupational Safety and Health Administration (OSHA), the Environmental Protection Agency (EPA), other federal agencies or departments, state agencies, trade associations, unions, journal articles, and individual companies in the industry.

A. Obtaining Data From NIOSH

For existing chemicals that have been studied by NIOSH, Health Hazard Evaluations (HHEs) and Industry Wide Surveys (IWSs) usually represent the largest body of complete and extremely well documented data. NIOSH reports usually include most of the information necessary to fully classify data. In cases where the chemical of interest was not the primary reason for the NIOSH report, but rather only measured as a secondary chemical, information may have to be filled in by direct contact with the inspector. In addition, it may also be necessary to confirm the presence of the chemical in all areas monitored if a large quantity of nondetected values are recorded. Since HHEs are generally done in response to a complaint regarding a specific chemical, the data may not be random in selection. IWSs tend to be well selected to represent an industry, but may be biased if only well controlled facilities were monitored. NIOSH Control Technology Assessment reports are developed to identify and evaluate appropriate control measures and may be biased toward facilities that are well-controlled. Contact with NIOSH can usually identify any potential biases. NIOSH tends to take many samples per visit as contrasted with OSHA which typically only takes a few measurements.

In general, NIOSH inspectors are easy to locate and will have worked on more than one of the surveys, so that multiple information can be gathered from each contact. Where contact cannot be made, it is usually acceptable to assume that the NIOSH collection and analytical method recommended at the time was used to collect the data. NIOSH may also have unpublished data or studies that are in progress; contact with NIOSH personnel who have been or are working on the chemical can thus result in additional unpublished monitoring data. The best source of NIOSH reports is the NIOSHTIC data base, which is available through DIALOG or on computer disk. In addition, the NIOSH Publications Catalog can be manually reviewed to identify useful reports. It may also be useful to obtain up-to-date published and unpublished information available on microfiche and hardcopy from NIOSH. Data may be obtained from:

U.S. Department of Health and Human Services National Institute for Occupational Safety and Health Robert A. Taft Laboratories 4676 Columbia Parkway Cincinnati, Ohio 45226 (800) 35-NIOSH

B. Obtaining Data From OSHA

The largest number of measurements for an existing chemical is generally located through accessing the OSHA National Health Sampling Results by Inspection (OSHA report: OHR 2.6). These data can be obtained by written request to:

U.S. Department of Labor
Occupational Safety and Health Administration
Director, Office of Management Data Systems
Room N3661
200 Constitution Ave., N.W.
Washington, D.C. 20210
(202) 219-7008

Information provided for each facility includes company name and address, SIC code, inspector code, OSHA office, date and reason for visit, job title, exposure value, number of similarly exposed workers at the time of the inspection, and type of exposure (peak/8-hour TWA, personal/area). No information is provided on controls, type of process, monitoring method, concentration of chemical in process, or demographics of the exposed workers. The sampling and analytical method and limit of detection may not be available. Where the sampling and analytical method cannot be ascertained, it is usually acceptable to assume that the method used is that specified by OSHA in the OSHA Technical Manual at the time the survey was used (OSHA, 90). The methods specified in this publication are in most cases from either the NIOSH Manual of Analytical Methods (NIOSH, 84) or the OSHA Manual of Analytical Methods (OSHA, unpublished). Unlike NIOSH, OSHA usually collects only one or two samples per chemical during each inspection. In many cases, the job title or SIC may uniquely define the use of the chemical (e.g., degreaser operator or SIC 7216, Dry Cleaning Plants), but most data require that some assumptions be made for categorization. In addition, the data may include large quantities of nondetects and SIC codes may be inconsistently applied. If time and budget permit, it is best to contact the OSHA inspector. Because the inspector at the local OSHA office must be called and few summaries are from the same inspector, this process can be time consuming. Also, inspectors may be difficult to locate, files may be stored away, or the inspector may not remember details of the facility. Many states (23 to date) operate their own OSHA State Programs which must be "at least as effective as" the federal program. However, these State plans have historically not had data in this OSHA data base. OSHA's Publication Catalog can also be reviewed, and up-to-date information (including NIOSH studies) may also be available from:

OSHA Technical Data Center Department of Labor 200 Constitution Avenue, N.W. Room H-2625 Washington, D.C. 20210 (202) 219-7500

C. Other Sources of Data

Monitoring data may also be available from previous and ongoing EPA studies. Previous reports done by OPPT (formerly OTS) may contain occupational exposure data. Usually the data will have been summarized and the primary data will have to be obtained separately. It is important to obtain primary data to avoid the duplication of data from other sources. Information submitted under Sections 4, 8(a), and 8(d) of TSCA may be useful in preparing the exposure assessment. Non-confidential information submitted under TSCA may be obtained through the TSCA Non-Confidential Information Center at (202) 260-7099. The Office of Air Quality Planning and Standards (OAQPS) may have collected some exposure data through the use of Section 114 letters. Information about OAQPS Section 114 letters can be obtained by contacting the Emissions Standards Division at (919) 541-5571.

Other federal agencies or departments may have collected exposure data. For example, the Army and Air Force have monitoring data on workers in a wide variety of job categories. These data may be obtained by contacting the following departments:

Army:	Assistant Secretary of the Army (Installations, Logistics and Environment) Attn: SAILE (ESOH) 1 110 Army Pentagon Washington, D.C. 20310-0110 (703) 614-8464
Air Force:	HQ AFMOA SGPA (BEES) 170 Luke Avenue Bolling AFB Washington, D.C. 20332-5113 (202) 767-1731
MSHA:	Mine Safety and Health Administration Metal/Nonmetal, Division of Health 4015 Wilson Blvd. Arlington, VA 22203-1984 (703) 235-8307

Mine Safety and Health Administration Coal, Division of Health 4015 Wilson Blvd. Arlington, VA 22203-1984 (703) 235-1358

State environmental and occupational safety agencies concerned with both environmental protection and worker health may have monitoring data. This is especially true if there is a concentration of the industry under study in a state.

Trade associations often collect and evaluate monitoring data from their members. In many cases the association may not allow access to the primary data and will provide only summaries of the data, thus limiting its usefulness. Even if the data cannot be incorporated in the direct analysis, however, it can be used for comparison with the results of other analyses. An extensive listing of trade associations is contained in the Encyclopedia of Associations (Koek, 88).

Unions often are the driving force behind the investigation of a particular chemical. In such cases they may have obtained exposure measurements from companies with which they have contracts. Direct contact with the union in question is the best method to obtain these data.

Data may also be identified from journal articles. On-line data bases that can be useful to identify exposure data include BIOSIS, CA Search, EMBASE, Enviroline, Medline, NIOSHTIC, NTIS, and Pollution Abstracts. These sources almost never present the primary data and the necessary ancillary information, so the author will usually have to be contacted if primary data are necessary.

Finally, if plant visits are being conducted or plants are being contacted to provide information for the study, they may also be asked to voluntarily provide monitoring data. Such contacts are of course limited by Office of Management and Budget (OMB) oversight under the provisions of the Paperwork Reduction Act. Plants may also be surveyed in the form of OMB approved questionnaires or telephone surveys.

EXAMPLE

For the example chemical, worker exposure data were obtained from NIOSH, OSHA, a previous contractor report for EPA, and the union representing workers at several facilities. The data were generally not primary monitoring results but only summaries of the data giving means and number of samples for ranges (i.e., Type 3 data). The user needs identified in Step 1, however, called for the types of results only available by analysis of Type 1 data. Therefore, new monitoring data had to be collected for the industry. The available and new data form the basis for the analyses shown in the example in the following steps.

STEP 3: DEFINE DATA NEEDS

By the time the initial data collection has been finished, the completed "statement of needs for occupational exposure assessment" form (Figure 4) should have been received from the project manager. This form and any other information provided should be used to formally define the data needs of the assessment. A preliminary determination should be made by the CEB engineer as to whether the existing data are "in the ball park" or if significant changes in data collection resources or expectations of the project manager are needed. A more detailed assessment of whether the user needs can be met will be made in Step 11.

If it is apparent that the exposure data are inadequate to meet the needs set forth in the statement of needsy form, then the CEB engineer should inform the project manager that expectations should be modified to match the existing data or outline approaches and resource implications to meet those needs.

It is important to be responsive to requests for specific statistics in the assessment. For instance, it is typical for exposure data to be summarized by calculating the geometric mean. Exposures tend to follow a lognormal distribution and the geometric mean is the value that represents the most "middle" value in such a distribution. However, if the concern of the end user is with total dose rather than with typical exposure levels, the arithmetic mean may be a more appropriate measure of central tendency, and should be provided with the assessment.

EXAMPLE

For the example chemical, several key issues were identified in the information supplied by the end users:

- Exposure of workers in the industry was of more interest than exposure of the general population.
- Worker exposure in the monomer industry was of more interest than worker exposure in the polymerization process. Worker exposure in handling of the finished polymer was of least interest.
- EPA was considering risk management options under TSCA. Since exposure may be limited to workers, a referral to OSHA was also possible. OSHA had no ongoing activities for the chemical at this time.
- Only inhalation exposure was of interest at this time.
- Only long-term exposure was of interest at this time.
- Specific descriptive statistics were requested.

Because the only data available were of Type 3, it was therefore necessary to conduct a monitoring program to obtain sufficient Type 1 data to conduct the types of analyses necessary to meet these needs.

STEP 4: IDENTIFY PARAMETERS AFFECTING EXPOSURE

Prior to statistical analysis, monitoring results must be classified into categories containing sufficient and reliable data so that meaningful analyses can be conducted (EPA, 87). The classification and organization of occupational exposure monitoring data are extremely important to the analysis and to the usefulness of the data for the end user. The classification and organization processes can be seen as the result of a compromise between two competing goals.

The first goal is to completely define the data set. If this were the single goal, the only data included would be those for which all parameters that can influence worker exposure were known, thus allowing definition of categories based on differences induced by all of these variables. For example, each category could be uniquely defined by process type, job title, worker activities, ambient control type (e.g., carbon adsorber), occupational control type (e.g., local exhaust ventilation), collection method, concentration of chemical in the process, demographics of the exposed worker, date the sample was taken, and any other parameter that could affect exposure or risk. The categories so defined would yield groups of exposure measurements (or groups of individual workers) expected to have the same or a similar exposure profile. Stated another way, the first goal is to define subsets of the data such that data within each subset are measuring the same thing, i.e., the subsets define homogeneous categories. Categories that are defined based on too few categorizing variables may lump together data that are not homogeneous.

The second goal, however, is to get categories with sufficient numbers of observations to allow meaningful statistical analyses. The power of any statistical analysis is greatly affected by sample size; large uncertainty can result when data sets are too small. The ability to make generalizations (extrapolations) is also limited when sample sizes are small. The number of observations within categories is inversely related to the number of categories (which is directly related to the number of parameters used to define the categories). Sample size is also reduced if observations have to be excluded from consideration because the values of variables potentially affecting those observations are missing or unknown.

The approach to balancing these two conflicting goals presented here has an industrial hygiene (qualitative) component and a statistical component. The industrial hygiene component is described in Step 4. The statistical component, described in Step 15, verifies the results of the industrial hygiene-based component and suggests possible re-categorization.

Thus, Step 4 consists of the critical process of identifying those parameters that are important in influencing worker exposure to the chemical under study. These exposure parameters will be used to define the categories (subsets or subpopulations) into which the exposure data will be classified.

CEB often develops categories of individuals with the same or similar exposure by first identifying the industrial process or unit operation during which exposure to the substance occurs, then identifying specific work activities or tasks associated with exposure, and identifying (or estimating) those workers associated with the activity or task, incorporating other information as appropriate. If monitoring data are available and job descriptions or job titles are given for the data, the engineer will need to evaluate whether the job description or job title can be directly linked to a specific work activity or task. There are cases where the job title or description does reflect the work activity, but the converse is also true where job titles or job descriptions may be broader than the activities linked directly to the monitoring (Hawkins, 91).

If the job title is associated with a specific work activity, the engineer may determine that creating categories by industrial process/unit operation/job title/work activity/control type/etc. is appropriate. If the job title or description is not associated with a certain task or work activity, the engineer should try to obtain information on work activities associated with a personnel job title or description. If appropriate, an alternative is to make assumptions about the activities associated with the job title, based on knowledge of the process, professional judgment, etc. These assumptions should be fully documented and evaluated with other assumptions made during the assessment (see Step 5). It should also be noted that the identification of important exposure parameters is often refined as additional information is gathered during the exposure assessment.

Occupational control type is a variable that may affect worker exposure and which should often be considered when defining a classification scheme for exposure data.

The categories should also be designed with user needs in mind. This may include consideration of parameters that relate to risk assessment and regulatory considerations. All potential parameters will be used to create the preliminary exposure data matrix in Step 6.

A distinction may sometimes be made between exposure parameters that can be considered "explanatory" as opposed to those that are merely "blocking" factors. For example, it may be the case that exposures differ from one company to another, across plants, or with time. Although a statistical analysis may determine that plant-to-plant differences are significant, the factor, plant, does not "explain" why the exposures are different. Plant is not an explanatory parameter, it is what can be referred to as a blocking factor; the plant-to-plant differences may be present because of differences in occupational or ambient controls or other unknown factors that are directly related to exposure concentrations. Blocking factors are merely parameters within which exposures are expected to be similar. The factors that contribute to plant-to-plant differences, for example, may not be known or identified, and so it may sometimes be the case that such blocking variables need to be retained to account for differences in exposure levels. Nevertheless, the engineer is encouraged to identify explanatory parameters for the purposes of categorization. Retention of some blocking variables may be suggested, but their importance (as well as the importance of the proposed explanatory variables) will be tested statistically in Step 15.

The engineer should also consider the relative importance of the exposure factors considered for the classification. Based on his or her knowledge of the industry and the processes entailing exposure, he or she may be able to suggest that a small set of explanatory (and, perhaps, blocking factors) will be the most important for determining exposure. Parameters identified by the end user as important should be considered for the categorization, although, as discussed in Step 11, the expectations of the user may have to be modified in accordance with the availability of pertinent data. Job title, work practices, occupational controls, and production levels are typical examples of important parameters. One purpose of ranking the variables is to prioritize collection of additional information in these areas where necessary (see Steps 8 and 9).

Ideally, for risk assessment purposes, the exposure profiles for each exposed subpopulation defined by the parameters identified in this step should include the size of the group, the make-up of the group (age, sex, etc.), the source of the chemical, exposure pathways, the frequency and the intensity of exposure by each route (dermal, inhalation, etc.), the duration of exposure, and the form of the chemical when exposure occurs. Assumptions and uncertainties associated with each scenario and profile should be recorded and clearly discussed in the results presentation (EPA, 87).

The following parameters are presented as guidance to the CEB engineer as typical variables that can affect exposure and may be important in determining categories of similarly exposed individuals. They are presented in general order of their typical importance, but the actual importance of the parameter must be determined by the CEB engineer for the specific chemical and use.

•	Type of sample	- Sample type such as personal, area, ceiling, peak, etc. should be defined. In general, different sample types are not combined.
•	Process type	- Process should be defined by all characteristics that are likely to affect exposure. Examples include machine type (e.g., open-top vs. conveyorized degreaser), age of equipment, usage rate, and product (e.g., printing on paper vs. plastic).
•	Job title	- Job title is usually given with the monitoring data and may require combination of similar job descriptions (e.g., printer, letterpress operator, and press operator could be combined into a single category).
•	Worker activities	- Within a given job title, activities performed by the workers may vary in a significant way that can directly affect exposure.
•	Worker location	- The approximate location of the worker with respect to the source of the exposure is an important factor.
•	Occupational control type (workplace practices)	- Controls such as local exhaust ventilation (LEV) or general ventilation directly affect measured exposure. Other controls such such as respirators do not generally affect measured exposure but do affect actual worker exposure.
•	Exposure period	- The time period the worker is exposed to the chemical in a workday directly affects exposure. Frequency and duration of exposure are also important factors.

Production - Exposure can relate directly to the volume of production at the facility.

- Operating Total exposure relates directly to these variables. frequency and duration
- Concentration of chemicals in the process
 The concentration of the chemical can directly affect the exposure of the workers. Such information is seldom available, however.
- Sampling strategy The duration of the sampling and the sampling strategy can affect the accuracy of the measurements in characterizing the exposure.
- Ambient control type
 Although such controls are installed primarily to reduce release of the chemical to the ambient air (e.g., refrigerated condenser, carbon adsorber, or baghouse), they may also increase or decrease occupational exposure.
- Company and location
 Variables such as local regulations, differences between large and small companies, and regional differences in processes can affect worker exposure.
- Date of measurement
 The date the measurement was taken can be indicative of the measurement method, the controls in use, and the effect of natural ventilation or other factors.
- Sample collection Different collection methods, sampling times, validated range of the method, or method analytical techniques can affect the accuracy of the measurement and the detection limit.
- Source of data
 Analysis by source of the data can help to identify potential biases in the data. Biases that are not evident in the review of data in Step 5 may be identified in Step 16.
- Demographics of the exposed worker
 If health effects data show that a particular demographic group is susceptible (e.g., women of childbearing age), then whenever possible data should be categorized using this information. While this is not typically needed in an exposure assessment, it may be needed for a later health risk assessment.
- Industry While four-digit SIC is preferable to two-digit SIC, OPPT assessments often focus on individual companies and/or facilities.
- Other Depending on the process, controls implemented primarily for other substances may also reduce exposure to the substance of concern (e.g., LEV at the raw material transfer operation).

EXAMPLE

For the example data set, the following were identified as potentially important parameters:

- Sample type
- Job title
- Process type
- Occupational control
- Company
- Sample collection method
- Industry

While data were collected for other parameters discussed in this section, emphasis was placed on verifying information on these seven parameters. Note that the "blocking" variables, company and industry have been retained. Industry, in particular was retained because the end user had specified that the monomer industry needed to be considered separately from the polymer industry.

STEP 5: IDENTIFY UNCERTAINTIES, ASSUMPTIONS, AND BIASES

Uncertainties and assumptions are identified and recorded to allow their clear recognition by the end user. This step initiates that process. All data should be examined for any characteristics that may represent a nonrandom selection process or a systematic error (bias) in sampling or analysis. It may be helpful to review the list of important parameters to assist in identifying uncertainties, assumptions, and biases. All important uncertainties, assumptions, and biases are identified, and for purposes of grouping like exposure, these should be as specific as possible. In preparing the risk assessment, more general information on uncertainties, assumptions, and biases may be acceptable. Uncertainties, assumptions, and biases will be evaluated in Step 18 to determine any influence on estimates of worker exposure in one or more groups. Steps 5 and 18 are extremely important but may be difficult to execute.

A. Uncertainties

Examples of problems that give rise to typical uncertainties in the input and output of an exposure analysis include:

- Data manipulation errors either by the persons collecting the monitoring data or during the analysis.
- The inherent uncertainty in a small data set (e.g., day-to-day and worker-to-worker variability are not accounted for).
- Uncertainties regarding differences in chemical concentration, throughput, or other process related variables.
- Use of an unknown monitoring or analysis method.
- Assumptions made from secondary sources that were applied to the primary data.
- Uncertainties of values below the detection limit.
- Possible interference of other chemicals with a specific test method.
- Uncertainty regarding missing or incomplete information needed to fully define the exposure.
- The use of generic or surrogate data when site-specific data are not available.
- Errors in professional judgment.

In evaluating and reporting uncertainty associated with measurements, the three most important categories of errors are sampling errors, laboratory analysis errors, and data manipulation errors (EPA, 92). There are two kinds of sampling errors: systematic errors (often referred to as biases) that result from the sampling process, and random errors that result from the variability of both the population and the sampling process. While random error cannot be eliminated, its effects can be minimized by using sampling strategies and by having sufficiently large data sets. Systematic errors can result from faulty calibration of critical components such as flow meters, thermometers, pressure sensors, sieves, or other sampling devices.

Other systematic errors can result from contamination, losses, interactions with containers, deteriorations, or displacement of phase or chemical equilibria (EPA, 92).

Generally, laboratory errors are smaller than sampling errors. Calibration is a major source of systematic error in analysis. Other sources of error include chemical operations such as sample dissolution, concentration, extraction, and reactions (EPA, 92).

Data manipulation errors include errors of calculation, errors of transposition, errors of transmission, use of wrong units, use of improper conversion factors, spatial or temporal averaging information loss, and misassociation errors that confuse samples and numerical results.

B. <u>Assumptions</u>

Throughout the analysis, assumptions must be made about the data. Many assumptions are made in response to uncertainties identified in the data. These assumptions must be clearly listed and their effect on the results quantified if possible. Examples of typical assumptions that are made during exposure analysis include:

- That plants and workers were randomly selected and that they represent the industry as a whole. (It should be noted that this is almost never true; if it is known not to be true, this assumption should not be made.)
- That the controls in place when the data were collected represent typically maintained controls.
- That the value selected for use for a nondetected measurement accurately represents the actual exposure at those facilities.
- That estimates of ancillary information gathered from other sources also represent the facilities in the monitoring data set.
- That job activities performed during the exposure period represent typical activities for that job category.

• That estimates of the duration of tasks used to convert data to 8-hour TWA values are accurate.

C. Biases

Bias is a systematic error inherent in a method or caused by some feature of the measurement system (EPA, 92). Systematic errors in sample selection, sampling errors, laboratory analysis or data manipulation can cause the results to be biased. If the facilities and workers were not randomly selected and the selection process documented, then the data may also contain biases. Common features that may introduce bias include:

- Systematic sampling, laboratory, or data manipulation errors that have been identified.
- Selection of only "well-controlled" plants such as a NIOSH industry-wide survey conducted to identify good control technology.
- Selection of only large facilities.
- Large disparity between the number of samples at different facilities (e.g., OSHA vs. NIOSH data) could lead to bias, depending on how the data are weighted and whether there are underlying sampling biases.
- Data that represent only OSHA complaint visits.
- When sampling for compliance with a ceiling limit, sampling workers with the highest potential for exposure.
- Selection of only plants that are members of a trade association.
- Selection of only companies that voluntarily supplied monitoring data.
- Averaging of a measurement representing many workers with a measurement representing few workers.
- Use of sampling or analytical methods at concentrations for which they are not validated.
- Sampling strategy bias towards compliance sampling.

D. ____ Development of Uncertainty/Assumptions List

In order to record and retain uncertainties, assumptions, and biases identified in the course of an occupational exposure assessment, a listing of the uncertainties and assumptions made at various steps will

be maintained. This list is initiated in this step and will initially contain uncertainties/assumptions associated with the data collection and classification. For example, in Step 4, some assumptions may have been required to relate job titles to specific activities. Moreover, there may have been uncertainties about the exposure profiles (number of workers, demographics of workers, source of chemical, etc.) for some of the groups defined by the important exposure parameters. These assumptions and uncertainties will be recorded in the uncertainty/assumption list.

In the course of following the guidelines defined in this document, other assumptions and uncertainties will be identified. All of them will be recorded on the uncertainty/assumption list for use in Step 18 (Treatment of Uncertainties, Assumptions, and Biases) and for presentation to the end-user with the quantitative results.

EXAMPLE

For the example chemical, a very detailed protocol and quality assurance plan were developed to select the facilities at which monitoring data would be collected. This protocol is more detailed than is typical but serves as an example of considerations that should be included to obtain a sample that is as representative as possible of the sample universe.

For manufacture of the example chemical monomer, the sample universe consisted of ten companies at 12 different plant locations. A walk-through survey was conducted at ten plants representing a 100 percent sample of the ten producers. The walk-through survey was used to gather information that was used to select a smaller sample set at which to conduct in-depth surveys. Monitoring data were collected at these in-depth surveys.

The purpose of the survey site selection strategy was to obtain a representative subset of monomer plants from which to characterize exposures by job title and work environment. To achieve this, the ten monomer production plants were divided into distinct subpopulations (strata) representing differences in the work place environment.

The strata were based on the presence or absence of three specific types of engineering controls, the mode of transportation (pipeline, rail car, tank truck, marine vessel) of the feed stock and product, and the existence of other production processes or final products at the plant. A single plant within each stratum was selected based on a scoring system that quantified the relative representativeness of each site. Four plants emerged as best representing the diversity of work environments seen in the example chemical monomer industry. In-depth surveys, including the collection of monitoring data, were conducted at these four facilities.

In the example data set, a serious potential bias in the analytical method for the chemical was identified. Potential interferences from C_4 chemicals made the measurements taken using previous methods suspect. Ways were investigated to mitigate the bias, but finally it was decided to exclude all data taken using the older analytical methods.

STEP 6: CREATE PRELIMINARY EXPOSURE DATA MATRIX

All data should be entered into a usable matrix using a personal computer for analysis. Software packages (spreadsheets, databases, etc.) are available with storage and retrieval capabilities that facilitate data analysis calculations. The matrix should be designed to be compatible with statistical programs that are likely to be used in the data analysis. Many statistical analysis packages have their own data matrix handling tools which provide a suitable, and in some cases preferable, alternative for data management. All parameters that were identified as having a potential impact on exposure, were requested by the end user, or were collected as ancillary information should be entered in the matrix. The use of a matrix will allow identification of missing information for some observations.

Inclusion of company name, plant location, and source of data in the data matrix is important because it provides a recordkeeping approach to allow easy referral of data back to the particular plant or study to obtain additional data. All potential variables should be entered into the data matrix and the field left blank when no data are found. Every effort should be made to fill in blanks in the matrix for all variables identified as important. An extra field or two should be included in the matrix for calculations such as converting to consistent units (Step 7). Also included would be any calculations made using assumptions such as the conversion of the TWA for the sampled time to an 8-hour TWA.

The exposure data matrix will be completed to the extent possible in Steps 7 through 9 by filling in missing information (where appropriate) and converting to consistent units. The revised exposure data matrix (Step 10) will serve to classify the data available and to assess the ability to meet the users' needs (Step 11). If possible, the data in the matrix will be used in the statistical analyses starting with Step 15.

EXAMPLE

Table 1 presents a partial example of the data matrix used in the example analysis. The full data set used in the analysis is presented in Appendix A. Only data on the important variables are presented in Table 1; however, data on all variables are included on the computer spreadsheet.

Plant ID	Industry	ID0 (a)	Process Type	Job Title	Control Type (b)	Sample Duration (min)	8-hr TWA (ppm)	Control Description
M1	Monomer	1	Process area	Process technician	2	460	0.57	Single mechanical seals & open-loop bomb sampling
M1	Monomer	1	Process area	Process technician	2	470	≤ 0.18	Single mechanical seals & open-loop bomb sampling
M1	Monomer	1	Process area	Process technician	2	506	1.71	Single mechanical seals & open-loop bomb sampling
M1	Monomer	1	Process area	Process technician	2	457	0.74	Single mechanical seals & open-loop bomb sampling
M1	Monomer	1	Process area	Process technician	2	449	0.37	Single mechanical seals & open-loop bomb sampling
M2	Monomer	2	Process area	Process technician	1	260	≤0.27	Dual mechanical seals on pumps & closed-loop sampling
M2	Monomer	2	Process area	Process technician	1	437	0.70	Dual mechanical seals on pumps & closed-loop sampling
M2	Monomer	2	Process area	Process technician	1	452	1.23	Dual mechanical seals on pumps & closed-loop sampling
M2	Monomer	2	Process area	Process technician	1	452	2.37	Dual mechanical seals on pumps & closed-loop sampling
M2	Monomer	2	Process area	Process technician	1	454	2.98	Dual mechanical seals on pumps & closed-loop sampling
M2	Monomer	2	Process area	Process technician	1	451	0.46	Dual mechanical seals on pumps & closed-loop sampling
M3	Monomer	3	Process area	Process technician	2	432	4.19	Single mechanical seals & open-loop bomb sampling
M3	Monomer	3	Process area	Process technician	2	435	≤ 0.19	Single mechanical seals & open-loop bomb sampling
M3	Monomer	3	Process area	Process technician	2	437	1.34	Single mechanical seals & open-loop bomb sampling
M3	Monomer	3	Process area	Process technician	2	436	0.09	Single mechanical seals & open-loop bomb sampling
M4	Monomer	4	Process area	Process technician	2	461	1.76	Single mechanical seals & open-loop bomb sampling
M4	Monomer	4	Process area	Process technician	2	441	0.49	Single mechanical seals & open-loop bomb sampling
M4	Monomer	4	Process area	Process technician	2	459	2.11	Single mechanical seals & open-loop bomb sampling
M4	Monomer	4	Process area	Process technician	2	424	≤ 0.07	Single mechanical seals & open-loop bomb sampling
M4	Monomer	4	Process area	Process technician	2	473	1.00	Single mechanical seals & open-loop bomb sampling
M4	Monomer	4	Process area	Process technician	2	496	0.92	Single mechanical seals & open-loop bomb sampling
M4	Monomer	4	Process area	Process technician	2	434	≤ 0.08	Single mechanical seals & open-loop bomb sampling
M4	Monomer	4	Process area	Process technician	2	430	2.55	Single mechanical seals & open-loop bomb sampling
M4	Monomer	4	Process area	Process technician	2	456	0.29	Single mechanical seals & open-loop bomb sampling
M4	Monomer	4	Process area	Process technician	2	471	0.55	Single mechanical seals & open-loop bomb sampling
M4	Monomer	4	Process area	Process technician	2	465	0.27	Single mechanical seals & open-loop bomb sampling
M4	Monomer	4	Process area	Process technician	2	420	≤ 0.14	Single mechanical seals & open-loop bomb sampling

Table 1. Example Preliminary Exposure Data Matrix - Full Shift Personal Samples

Plant ID	Industry	ID0 (a)	Process Type	Job Title	Control Type (b)	Sample Duration (min)	8-hr TWA (ppm)	Control Description
M1	Monomer	5	Control room	Process technician	1	466	≤0.02	General room ventilation
M1	Monomer	5	Control room	Process technician	1	447	≤ 0.02	General room ventilation
M1	Monomer	5	Control room	Process technician	1	485	≤ 0.02	General room ventilation
M2	Monomer	6	Control room	Process technician	1	455	0.25	General room ventilation
M2	Monomer	6	Control room	Process technician	1	451	≤ 0.08	General room ventilation
M2	Monomer	6	Control room	Process technician	1	452	0.52	General room ventilation
M3	Monomer	7	Control room	Process technician	1	442	≤ 0.04	General room ventilation
M3	Monomer	7	Control room	Process technician	1	425	≤ 0.11	General room ventilation
M4	Monomer	8	Control room	Process technician	1	453	1.87	General room ventilation
M4	Monomer	8	Control room	Process technician	1	449	1.70	General room ventilation
M2	Monomer	9	Loading area	Process technician	1	415	0.50	Slip-tube gauge
M2	Monomer	9	Loading area	Process technician	1	428	1.44	Slip-tube gauge
M2	Monomer	9	Loading area	Process technician	1	427	1.29	Slip-tube gauge
M3	Monomer	10	Loading area - railcar	Process technician	2	474	≤ 0.13	Magnetic gauge
M3	Monomer	10	Loading area - railcar	Process technician	2	260	≤ 0.12	Magnetic gauge
M3	Monomer	10	Loading area - railcar	Process technician	2	442	0.46	Magnetic gauge
M3	Monomer	10	Loading area/semi-tractor trailer	Process technician	2	484	2.40	Rotameter gauge
M3	Monomer	10	Loading area/semi-tractor trailer	Process technician	2	474	5.46	Rotameter gauge
M3	Monomer	10	Loading area/semi-tractor trailer	Process technician	2	446	0.08	Rotameter gauge
M4	Monomer	11	Loading area	Process technician	2	443	123.57	Slip-tube gauge
M4	Monomer	11	Loading area	Process technician	2	459	3.97	Slip-tube gauge

Table 1 (continued)

NOTE: Source of data: NIOSH/EPA. Laboratory analysis limit of detection ranged from 2 to 11 µg/sample, depending on the day of the analysis.

(a) IDO = Initial categories

(b) The following are the control types: 1) controlled, 2) uncontrolled, 3) laboratory with 12 air changes/hr, 4) 100% make-up air in laboratory, 5) 50% make-up air in laboratory, 6) 60% make-up air in laboratory.

STEP 7: CHECK FOR CONSISTENCY AND REASONABLENESS

Once the data have been loaded into the spreadsheet, the next step is to check them for consistency and reasonableness. It is recommended that, first, all the exposure measurements be converted to consistent units. This step describes some of the considerations related to conversion of units and the types of checks that can be made subsequently to verify that the results are reasonable.

For conversion of units, typically a standardized procedure consisting of grouping similar types of data, conversion to consistent concentration units, and conversion to consistent exposure periods can be used. For some data, however, all the information necessary to do the conversions is not known (e.g., actual exposure time period). In many of these cases, assumptions can be made that will allow use of the data in the analysis. All such assumptions should be recorded in the uncertainty/assumption list.

The general approach for conversion of data into consistent units is the following:

- Grouping of like types of data (e.g., 15 minute, long term, area, personal),
- Conversion to consistent concentration units (e.g., mg/m³ or ppm),
- Conversion to consistent exposure periods when defensible (e.g., 8-hour TWA), and
- Estimation of missing information.

A. Grouping of Like Types of Data

It is extremely important that different types of samples not be averaged. For example, area samples generally do not represent personal exposure, and 15-minute peak and ceiling sampling should not be adjusted to represent full shift exposure. Specific data groupings that usually form like data sets and, as a general rule, should <u>never</u> be pooled into a single data set include:

- Area samples
- Personal samples
- Short term exposure estimates
- Long term exposure estimates

EXAMPLE

In the example data set only personal TWA samples will be used.

B. <u>Conversion to Consistent Concentration Units</u>

The end user should be consulted for guidance on preferable reporting units early in the project. Occupational exposure monitoring data are typically reported in either ppm or mg/m³. NIOSH reports and journal articles report the occupational exposure values in either ppm or mg/m³, while OSHA Inspection Summary Reports almost always report occupational exposure values in ppm. Before conducting statistical analysis on different data sets, all measurements need to be converted into similar units. Values in ppm can be converted to mg/m³ by the following equation:

$$mg/m^3 = ppm \times \frac{MW}{24.45} \times \frac{P}{760} \times \frac{298}{(T+273)}$$

where:

Р	=	barometric pressure (mm Hg) of air sampled;
Т	=	workplace temperature (°C) of air sampled;
24.45	=	molar volume (liter/g-mole) at 25°C and 760 mm Hg;
MW	=	molecular weight (g/g-mole);
760	=	standard pressure (mm Hg); and
298	=	standard temperature (°K).

EXAMPLE

Consider a case in which a chemical concentration is reported to be 5 ppm at a pressure of 760 mm Hg and 25°C. The molecular weight of the example chemical is 54.1 g/g-mole. The occupational exposure can then be converted from ppm by the following equation:

$$mg/m^3 = 5 ppm \times \frac{54.1}{24.5} \times \frac{760}{760} \times \frac{298}{(25 + 273)}$$

 $mg/m^3 = 5 ppm \times 2.213$

Therefore, for the example chemical, a concentration of 5 ppm is equivalent to a concentration of 11.1 mg/m^3 .

C. <u>Conversion to Consistent Exposure Periods</u>

NIOSH and OSHA exposure limits for chemicals are often based on 8-hour TWAs; therefore, occupational exposure monitoring data are often converted into 8-hour TWAs in order to compare worker exposures to these regulatory or recommended limits. Monitoring data collected from OSHA are typically reported as 8-hour TWAs because they are sampled for compliance with an 8-hour TWA Permissible Exposure Limit (PEL). OSHA TWA measurements may utilize a zero exposure for the unsampled portion of the 8-hour day when calculating the TWA. It may be useful to determine whether the sample represents an actual 8-hour sample or an 8-hour TWA. Some NIOSH reports and journal articles present data collected for less than an 8-hour time period. The measurement samples are literally only representative of the exposure period actually sampled. However, professional judgment or reliable knowledge may sometimes be used to extrapolate data collected for shorter time periods to an 8-hour TWA (Patty, 81). Where the exposure during the shorter period is representative of the exposure during the shorter period is known, exposure values can be converted into 8-hour TWAs beased on the shorter exposure duration.

Based upon the job description in the NIOSH report or journal article, an estimate of the number of worker hours per day related to each job category may be estimated. This should be done with caution as many times the sampling time was dictated by the analytical method or other cause not related to exposure and is not representative of the entire day. If the measurement sample is judged to be representative of the exposure period and the exposure period is less than 8 hours, then an exposure value not already reported as an 8-hour TWA can be adjusted to an 8-hour TWA as follows:

8-hour TWA = exposed value $\times \frac{\text{exposed hours per day}}{8}$

This approach is only valid when you can assume that there was no exposure during the remainder of the workday. This is a key assumption that should not be made without good information indicating that this is indeed the case.

Peak and ceiling measurements should never be converted to 8-hour TWA exposures. These measurements are best taken in a nonrandom fashion. That is, all available knowledge relating to the area, individual, and process being sampled are utilized to obtain samples during periods of maximum expected exposure (Patty, 81). Therefore these measurements by design are not representative of the longer work period. They are representative only of the time period over which they are taken, which usually corresponds to an applicable standard for peak or ceiling exposure.

EXAMPLE

While most samples were taken to represent 8-hour TWA exposures, some were not. Information gathered during the plant visit was used to estimate the exposure period for those measurements that did not represent 8-hour TWAs.

D. Identification of Assumptions

Many times the conversion of data to consistent units involves the need to make assumptions about the process or the worker activities. For example, the conversion from mg/m^3 to ppm requires knowledge of the workplace temperature. If this is not given in the report, an engineering judgment must be made as to the typical temperatures in the work area. Other data may indicate that the sample time was 2 hours but not indicate if the job was performed for 2 hours or 8 hours per day. Again, engineering judgment of typical practices in that industry may have to be used to estimate the exposure period.

Since such assumptions can have large influences on the exposure value, all assumptions should be recorded in the uncertainty/assumption list and presented with the results of the analysis. Where assumptions have been made in such calculations, ranges of possible values can be estimated for later sensitivity analysis. For example, an assumption for one worker can be made based on data from other workers with the same potential for exposure. If the data for the other workers indicated a period of exposure ranging from 2 hours to 8 hours, then it is possible that the exposure period of this worker could range from 2 to 8 hours as well. Exposure values for these extreme times can be calculated and the results tested for sensitivity to the assumption (see Step 18). All data where assumptions need to be made for important parameters should be classified as Type 2 data.

Typical default values that can be assumed where there is no information to the contrary are:

- Where the monitoring method is unknown, the predominant method used for that agency/company during the appropriate time period may be assumed to have been used.
- Where there is no information to the contrary, ambient temperature and pressure (298°K, 760 mm Hg) may be assumed.

Where assumptions cannot be made because of lack of knowledge of the process or job activity, then these data should be classified as Type 3 or incomplete data. Classification as Type 3 results in values being excluded from the analysis.

EXAMPLE

Because EPA and NIOSH collected the data used in the analysis specifically for the analysis, no information needed to be estimated.

Data manipulation errors are caused by calculation errors, errors of transposition, errors of transmission, use of wrong units, use of improper conversion factors, spatial or temporal averaging information loss, and misassociation errors that confuse samples and numerical results (EPA, 92). Some of these errors can be identified by comparison with known standards. While most chemicals will not have all of the following parameters, comparison with those that do will help to flag possible data manipulation errors:

- Immediately Dangerous to Life or Health (IDLH)
- Analytical limit of detection
- Lower or Upper Explosive Limits (LEL, UEL)
- Applicable standards (OSHA PEL, ACGIH TLV, NIOSH REL, STEL, ceiling, etc.)

Data that appear to be outside of typical limits such as these may be outliers and should be rechecked for the accuracy of the value. The use of incorrect units for the data is one of the biggest causes for such errors, and verification of the value and units can usually substantiate the data.

Additional tests for outliers are discussed in Step 15.

EXAMPLE

For the example data set, the monitored levels were far below any regulatory limits (IDLH = 20,000 ppm; OSHA PEL = 1,000 ppm) and the limit of detection of the new analytical method was very low (0.0054 ppm). A verification of the units, experience with other situations, and confidence that the disparity between the PEL and the measured units reflects a real situation, not an error in units, suggested that the monitored levels were reasonable.

STEP 8: COLLECT ADDITIONAL MISSING INFORMATION

The purpose of this step is to fill data gaps in the matrix through the collection of additional information. Data points that lack specific information in the source document for parameters that are judged important may be difficult to classify during analysis. However, this missing information may be available by direct contact with the inspector identified in the report. Obtaining missing information may be as simple as properly classifying a process type or job description, or as difficult as identifying the controls in use when the measurements were taken.

For NIOSH and OSHA reports, the name or identification number of the inspector and the office location is usually present on the report. Where feasible, direct contact with this person by telephone is usually the best method to gather the data. Some inspectors will request that a letter be sent requesting release of the information under the Freedom of Information Act. For data from a trade association or from one agency office where extraction of the primary data or ancillary information may be time consuming, a written request or a trip to the location may be necessary. It is important to remember that collection of all missing important variables can change a Type 2 measurement to a Type 1 measurement.

EXAMPLE

For the example data set, the problem with the sensitivity and selectivity of the test method was so severe that all new data using a new test method were necessary. For most chemicals, this would not be the case and the collection of additional information on important variables for the existing data helps to increase the size of the Type 1 data sets.

STEP 9: ESTIMATE ADDITIONAL MISSING INFORMATION

Data gaps in the exposure matrix (i.e., missing ancillary information) can also be filled by estimating missing information when appropriate. If data gaps in the matrix are in areas critical to the accuracy of the assessment, the scope of the assessment may need to be narrowed, or further data collection may be necessary. If data gaps are not critical and if it is not feasible to contact the inspector or otherwise gather additional information, it may be appropriate to fill data gaps by making assumptions, using surrogate data, or using professional judgment, etc. Caution should be used when making assumptions or using other approaches to estimate missing data as this may increase the uncertainty associated with the assessment and/or cause outliers in the data set. If an assumption is made for an important variable, the data can only be used as Type 2 data. The use of assumptions, surrogate data, professional judgment, or combinations of these methods must be clearly documented and the rationale for each assumption or judgment given (via notations on the uncertainty/ assumption list).

In the absence of data, CEB uses these methods to develop screening level estimates of exposure. These screening level estimates generally err on the conservative side (i.e., overestimate exposure) and are used to determine whether potential exposures are of no concern and can be eliminated from further consideration. If the estimates are of concern, additional data and information are gathered and the estimates are refined if possible. Due to the uncertainty associated with these estimates, the assessment must be well characterized and used with caution.

If surrogate data are used, the differences between the surrogate and the substance of concern must be small, and the scenarios for which exposure is estimated must be very similar or the same. If conservative assumptions are used, the resulting exposures should be expressed appropriately using an appropriate exposure descriptor. It is important to be aware of and explain how many assumptions are used; their influence on the final conclusions of the assessment will be evaluated in later steps. The mathematical product of several conservative assumptions is more conservative than one assumption alone and can result in estimates that are unrealistically conservative bounding estimates (EPA, 92; IT, 91).

The following present typical kinds of assumptions, use of surrogate data or information, or professional judgments that may be made, as appropriate.

- Process type Other variables such as process temperature, drying time, etc., could be used with professional engineering judgment to make an estimate of the process type.
- Occupational control type Company practices and engineering controls in place could be used as surrogate information to estimate what was being used during the time the sample was taken. This assumes the current process and controls are the same or very similar to those used when the sample was taken.
- Production levels The average or range of production levels for the facility or industry could be used as a surrogate to estimate the production level when actual figures are not available. This assumes the production levels are the same or very similar.

• Concentration of the chemical in the process - The average or range of concentrations in other processes could be used as a surrogate for estimating the concentration in the process, assuming the processes and concentrations are very similar or the same.

EXAMPLE

The example data set was collected by NIOSH and EPA and all important parameters were identified and data collected. Therefore, a hypothetical example will be used to illustrate the process.

In the hypothetical example the age of the equipment was identified as an important variable for two reasons. First, newer process equipment tends to contain dual mechanical seals and has been shown to reduce fugitive release of the chemical, while older equipment does not. Second, in this industry newer facilities are often better maintained than older facilities.

Because the monitoring measurement in question was taken by OSHA, the OSHA inspector listed on the inspection summary was called. The inspector no longer worked for OSHA and the person contacted at the local office could find nothing in the file for that facility to indicate the age of the equipment. It was discovered that the facility was an older plant. An attempt to directly contact the facility where the monitoring data were collected indicated that the facility was closed about a year ago.

Because older facilities that are about to be closed generally have older equipment and tend to be poorly maintained it was assumed that this measurement represented data from a facility using older equipment. This assumption is based on professional engineering judgment and knowledge of the industry. The assumption and rationale would be documented within the assessment and presented with the results.

STEP 10: REVISE EXPOSURE MATRIX AND IDENTIFY DATA BY TYPE

The exposure data matrix should be updated to reflect any changes entailed by the checks of consistency and reasonableness, and to display the concentration measurements in consistent units. In addition, the exposure matrix can be modified to reflect the results of collecting additional information or estimating the values of ancillary data. At this point, the revised exposure matrix (in conjunction with the uncertainty/assumption list which details the treatment of uncertain values and lists all assumptions that have been made) should be indicative of the modifications that have occurred in the first round of updating the data. As indicated in the next step, additional rounds may be conducted.

Using the revised exposure matrix as the basis for classification, the data are categorized as Type 1, Type 2, or Type 3 data. Recall that the categorization of worker exposure data into the three distinct types is based on the following considerations:

- <u>Type 1 data consist of measurements for which all important parameters are available</u>. Typical sources of Type 1 data include statistically valid studies, and NIOSH and OSHA data for which all important parameters can be determined.
- Type 2 data consist of measurements where the important variables are not available but for which assumptions can be made to estimate them. For example, if the limit of detection is not known because the monitoring method is not stated, OSHA or NIOSH measurements may be assumed to have been taken using the recommended method for the time period. Typical sources of Type 2 data include NIOSH and OSHA reports which contain incomplete information and for which the inspector cannot be located or cannot provide the missing information. Other typical sources include journal articles, state agencies, and other federal agencies or departments.
- <u>Type 3 data consist of measurement summaries, anecdotal data, estimation techniques, or other</u> <u>data for which the important variables are not known and cannot be estimated.</u> A typical example is a data summary provided by a trade association. The association will not allow access to the primary data, and many questions remain unanswered on how the data were collected and tabulated.

The engineer will need to use professional judgement in classifying the data, but all data should be classified as either Type 1, Type 2 or Type 3. If it is questionable which type best describes the data, the data should be classified as a lower type. If new information is found that allow raising to a higher type, this should be done at that time.

When all data have been classified, it may be helpful to separate out the Type 3 data. A separate Type 3 exposure matrix may be created. The Type 3 data will not be subject to any statistical analyses, whereas Type 1 and, perhaps, Type 2 data will be analyzed. If the user needs can be met, the Type 3 data will be treated as described in Step 12.

EXAMPLE

In the example data set, all Type 3 data were excluded from the analysis due to potential bias in the monitoring methods used. For the sake of the example, some of the excluded data will be used in Step 12 to show how Type 3 data should be treated.

STEP 11: ASSESS ABILITY TO MEET USER NEEDS

The ability to meet the needs of the project manager is dependent on both the quantity and quality of the data collected. User needs were preliminarily defined in Step 1 and formally defined in Step 3. The purpose of this step is to formally determine if the assembled data are sufficient to meet the project manager needs defined in Step 3.

If there are insufficient data to meet the needs identified in Step 3, the project managers should be informed that their expectations should be modified to match the existing data or additional resources are needed to obtain the desired quality of data. If no decision can be reached, it may be appropriate to stop work until a decision is made so that resources are not wasted on work that will not meet the specified needs.

The most likely case is that most of the user needs can be met but that some requests will be difficult to fulfill. These potential difficulties should be identified in writing and sent to the project manager. The project manager can then reassess how important each need is and estimate how much additional effort, if any, should be expended to gather the necessary data.

If the CEB engineer is satisfied that the data are sufficient to meet the end user needs, proceed to Step 12. It may be determined that those needs can be met even if Type 3 data are all that are available. Typically, however, Type 1 or Type 2 data will be required. To obtain such data, additional rounds of data collection, or further estimates of ancillary information may be approved. If no additional information can be obtained, then the exposure assessment should proceed to Step 19, Presentation of Results, at which point a summary of the available data can be completed, detailing data deficiencies with respect to the end user needs.

EXAMPLE

For the example data set, the need to develop a new analytical method to account for a potential bias in the existing method as well as the need to collect new data caused a delay in the completion of the exposure assessment. The end users were notified of this delay; they approved the data collection and analyses based on the new data.

STEP 12: TREAT TYPE 3 DATA

If it is determined that user needs can be met, the next step is to use nonstatistical methods to present Type 3 data and to give alternate ways to generate additional Type 3 exposure estimates for comparison with existing estimates. When a comprehensive assessment is not needed and all of the individual monitoring data are Type 3 (i.e., many of the important variables are not known and cannot be estimated), no statistical analysis of the data should be done. Although descriptive statistics could be calculated for some Type 3 data sets, such analyses may mislead the end user into a false sense of confidence in these data. The preferred method is to describe the data qualitatively in the report, including its deficiencies, and any conclusions that can be drawn. A median and range may also be given for each data set. Each Type 3 data set should be presented separately. Preferred data sets should be identified and reasons given for the preference. In addition, any uncertainties, assumptions, and biases should be clearly identified, using the uncertainty/assumption list initiated in Step 5.

When only summary data, anecdotal data, or no monitoring data are found for a chemical, and a comprehensive exposure assessment is needed, the resolution depends to a large extent on the end use of the assessment. There are two primary options when there are insufficient data to perform the analysis:

- Collect monitoring data (i.e., conduct a survey for segments for which no data are currently available; conduct a monitoring study, etc.)
- Use other nonmonitoring methods

When there are insufficient data, the best method is to collect the required monitoring data. This alternative may not be viable as it can be extremely expensive and the time constraints on the analysis may not allow this option. As a result, it is often necessary to use other nonmonitoring methods. These include:

- Modeling of the exposure
- Use of a surrogate chemical or job type
- Comparison with a workplace standard
- Professional judgement

Modeling of the worker exposure can be used to estimate exposure where no monitoring data are available. Almost never will there be sufficient data available to validate a model as real time release, air movement and several receptor monitoring data are necessary. However, sometimes a previously validated model can then be used for other chemicals within the stated constraints of the model. For indoor exposures, such models typically require the estimation of a release rate, room size, ventilation rate, and exposure duration. When using models, the results should always be tested for reasonableness against any available monitoring data or calculations based on surrogate monitoring data. One advantage of the model

approach is that sensitivity analysis can be conducted to identify those factors that cause large uncertainties in predicted exposures. A sensitivity analysis simply involves running the model using a range of input variables and measuring how the results change as the input variables are changed.

The use of monitoring data for a similar chemical as a surrogate is another approach when no monitoring data are available for the chemical of interest. A rough exposure estimate can be made by adjusting the surrogate monitoring data for the differences in vapor pressure, molecular weight, and concentration of the chemical in the process. The degree of uncertainty in the approach depends on the similarities between the chemical and its uses and the surrogate and its uses, and how well the worker activities are understood in both situations. This approach is particularly useful in the analysis of new chemicals where little or no actual exposure to the chemical has occurred (IT, 91).

A final approach that can be used in the absence of monitoring data is to use professional judgment to develop a plausible exposure scenario based on knowledge of the operation, or assume compliance with the OSHA PEL for the substance. When professional judgment is used to develop an exposure scenario, no exposure descriptor is used, and the uncertainty associated with the assessment is high. This type of assessment is characterized as a "what-if" scenario and the uncertainty associated with the assessment must be carefully and fully communicated to the user. When assuming compliance with the OSHA PEL, a search of the OSHA Computerized Information System (OCIS) database should be conducted to check the assumption of compliance. The assessment should be characterized as a "what-if" scenario if the assumption of compliance cannot be supported based on monitoring data or other documentation. Engineers must be extremely careful to properly characterize the type of assessment presented if compliance with the OSHA PEL is assumed. There are currently different OSHA PELs for different industries, such as construction, agriculture, etc. Currently, OSHA does not inspect facilities with fewer than 11 employees. If this approach is used and if compliance data or other data have been evaluated, the workplace standard should be identified with an appropriate exposure descriptor. The uncertainty of these methods is high, but when properly used and presented, these estimates are acceptable for screening level assessments.

The outcome of this step is a nonstatistical report that qualitatively describes the data, including its deficiencies and any conclusions that can be drawn. If there are Type 1 or Type 2 data, then proceed to Step 13. If not, then the nonstatistical report will be the primary result of the exposure assessment and it can be presented as described in Step 19.

EXAMPLE

For the example chemical, some Type 3 data were available. The following gives examples of how such data should be described:

- Six companies completed studies to determine exposure to the chemical. Although attempts were made to obtain the original monitoring data, only summary results were made available.
- Although the data cannot be compared directly across several companies, the areas of higher exposure appear to be 1) the monomer transfer and storage area, 2) the reactor area, 3) the recovery area, and 4) the lab area.
- One source states that release and exposure to the chemical in the solution polymerization process are very similar to those in the emulsion process.
- If monitoring summaries examined in the analysis are representative of levels at polymer plants, they imply that additional controls would not be required at typical polymer plants to limit exposure to 10 ppm.

STEP 13: TREAT NONDETECTED VALUES

Measurements that are recorded as nondetected are assigned a numerical value so that they can be used to calculate descriptive statistics which characterize the data set. Care should be taken to ensure that the chemical reported as nondetected was actually being used at the time. Otherwise the descriptive statistic that is calculated will be biased by inclusion of a site where the chemical was never used. The first task in the treatment of nondetected values is to gather information on the analytical method. If a quality assurance plan was developed for the study, it may also contain useful information and should be reviewed. The NIOSH Manual of Analytical Methods provides information on NIOSH analytical methods (NIOSH, 84). That manual identifies the analytical method used for each chemical for which NIOSH has developed an analytical method. The OSHA Technical Manual (OSHA, 90) and OSHA Chemical Information File (OSHA, 85) provide information on current OSHA methods. Information to gather regarding the analytical method includes:

- Issue date,
- Applicability,
- Interferences,
- Other methods,
- Accuracy,
- Range and precision,
- Estimated limit of detection (mg/sample),
- Maximum sample volume (liter), and
- Evaluation of method.

If the issue date for the analytical method is after the date the sample was collected, the engineer should determine what other analytical methods are used for this chemical.

The second task in the treatment of nondetected values is the calculation of a representative value (Crump, 78; Hornung, 90). The limit of detection for these data must first be determined. There are two ways in which a limit of detection may be reported:

- The limit of detection of analytical equipment such as a gas chromatography (GC/MS, etc.), which is normally expressed in mg per sample, and
- The sampling limit of detection in measuring workplace air concentrations, which is normally expressed in mg/m³ or ppm.

The sampling limit of detection accounts for both the analytical limit of detection and the sample air volume and is the value needed for calculational purposes. In many cases, however, this value is not reported directly. The sampling limit of detection will often vary from sample to sample if different volumes of air are collected.

If the analytical method is not reported, the prevalent analytical method used at the time of the study should be assumed and this assumption recorded on the uncertainty/assumption list. If the sample volume is not reported, the maximum sample volume recommended in the analytical method could be used for calculational purposes, and this assumption recorded as well.

An analytical limit of detection is normally specified in a published sampling and analytical method, and a sampling limit of detection can be calculated if the sample volume is known or can be assumed. The following equation is used:

Sampling limit of detection $(mg/m^3) = \frac{\text{Analytical limit of detection } (mg) \times 1000 \text{ (liters/m}^3)}{\text{Air volume sampled (liters)}}$

EXAMPLE

For the example chemical, consider a case in which a 25.0-liter air sample has been analyzed for the example chemical using NIOSH Method 1024, which has a reported analytical limit of detection of 0.0003 mg per sample. The sampling limit of detection is therefore:

Sampling limit = $0.0003 \text{ mg x } 1000 \text{ liters/m}^3 = 0.012 \text{ mg/m}^3$ of detection 25.0 liters

A reported or calculated sampling limit of detection should not be directly substituted for those values reported as nondetectable because, by definition, such values are below the detection limit. A value lower than the sampling limit of detection must therefore be substituted for these values. As described by Hornung and Reed (Hornung, 90), the preferred method for calculating this value depends upon the degree to which the data are skewed and the proportion of the data that is below detection limits. The two methods are:

- 1) If the geometric standard deviation of the monitoring data set is less than 3.0, nondetectable values should be replaced by the limit of detection divided by the square root of two $(L/\sqrt{2})$.
- 2) If the data are highly skewed, with a geometric standard deviation of 3.0 or greater, nondetectable values should be replaced by half the detection limit (L/2).

If 50% or more of the monitoring data are nondetectable, substitution of any value for these data will result in biased estimates of the geometric mean and the geometric standard deviation (Hornung, 90). If it is necessary to calculate statistics using data sets with such a large proportion of nondetectable data, the potential biases introduced by these calculations should be described when presenting the results of the

analyses. It should be noted that there are other methods to address reporting limit of detection values (Aitchison, 57; Cohen, 61; EPA, 92; Waters, 90).

EXAMPLE

Preliminary examination of the data, categorized by the important exposure parameters (Step 4) indicated that geometric standard deviations tended to be at or above 3.0. Therefore, half the detection limit was used for all example calculations to represent nondetected values. That choice was recorded on the list of uncertainties and assumptions. The impact of choosing L/2 on the analyses will be examined in Step 18.

STEP 14: SEPARATE INTO TYPE 1 DATA AND TYPE 2 DATA

In Step 10, data in the exposure matrix were classified as either Type 1, Type 2 or Type 3 data. Type 1 data consist of measurements for which values of all important parameters are known. The data consist of studies that contain individual measurements, and include all backup and ancillary information. Type 2 data consist of measurements where values of important parameters are not known but for which assumptions can be made to estimate these variables. The data consist of individual monitoring measurements, but backup and ancillary information is highly variable. No Type 3 data (summaries, anecdotal, etc.) should be in the matrix. All such data should have been excluded in Step 10.

The data should now be sorted by the Type 1/Type 2 classification and separate matrices formed for each type of data. Type 2 data will only be used for statistical analysis when there are insufficient Type 1 data to perform the analysis. The products of this step are two separate matrices that will be used in the statistical analysis.

If only minimal Type 1 and Type 2 data exist, that together are still not sufficient for statistical analysis, all data are treated as Type 3 data and the analysis returns to Step 12. In this case a qualitative report that describes the data, including its deficiencies and any conclusions that can be drawn is prepared, as described in Step 12.

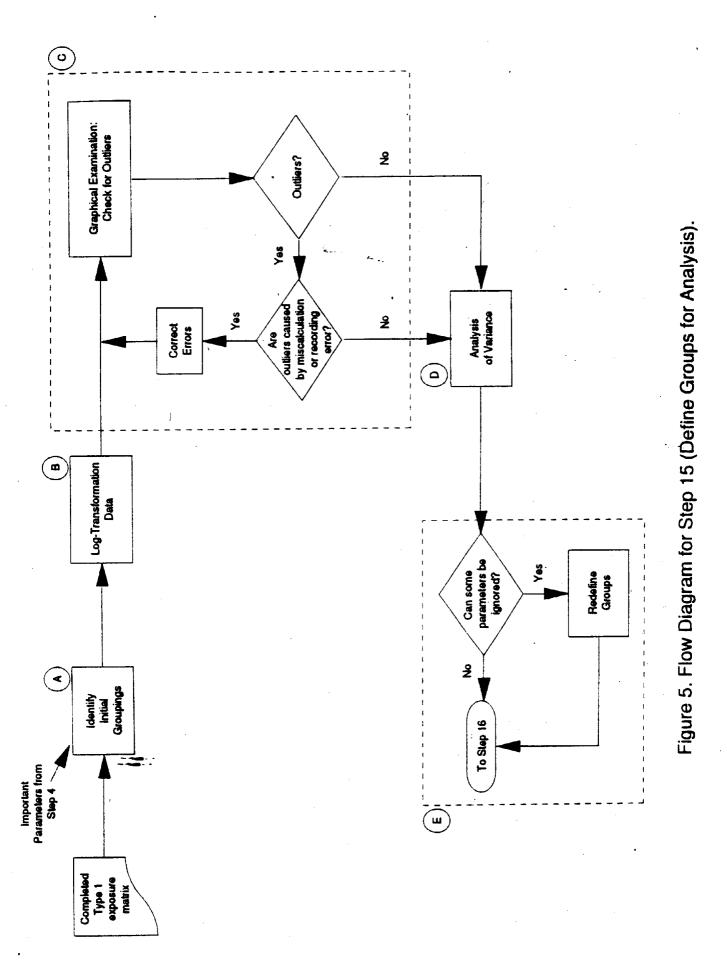
EXAMPLE

For the example data set, all newly collected data were of Type 1. Some previously collected data were Type 2 data and these will be considered as necessary (Step 16).

STEP 15: DEFINE GROUPS FOR ANALYSIS

The purpose of this step is to identify the groups that will be the basic units for the calculation of descriptive statistics. Each group is intended to include measurements representing samples from a single distribution of concentrations; the descriptive statistics computed for that group pertain to that one distribution. The principal output of the application of these guidelines will be the group-specific descriptive statistics.

The groups that result from this step are those that are determined to have as large a sample size as possible given the characteristics of and differences in exposures (e.g., those caused by effects of the parameters identified by the engineer or industrial hygienist in Step 4). Stated another way, the groups will be as large as possible while minimizing variation within the groups relative to variation between the groups. Statistical approaches are described to perform the necessary calculations. The initial grouping that is an input for the statistical calculations is based on the important exposure parameters identified by the engineer in Step 4. Combinations of the original categories may result in the definition of new groupings that will be subject to statistical description. Figure 5 presents a flow diagram defining the subtasks involved in the definition of the groups.



A. Identify Initial Grouping

For a given data set, the initial categories are determined by the important parameters identified by the CEB engineer or industrial hygienist in Step 4. The initial categories are defined by the combinations of all the important parameters. Note that if there are many important parameters, there could be very many initial categories which would tend to reduce the number of observations within any given category. The engineer is encouraged to try to reduce the number of important parameters considered. This may be accomplished, as discussed in Step 4, by eliminating from consideration as many variables regarded only as "blocking" factors as possible. It is to be hoped that truly explanatory variables can be found that account for much of the difference observed across blocks.

EXAMPLE

The data were collected for both the manufacture (monomer industry) and use (polymer industry) of the chemical. In the monomer industry, there were 209 measurements from four plants (M1, M2, M3, M4). In the polymer industry, there were 578 measurements from five plants (P1, P2, P3, P4, P5). The total data set consisted of 787 measurements: 516 full-shift personal samples, 37 short-term samples, and 232 area samples. For the example calculations, only the 516 full-shift personal samples were used. Values reported as nondetected were treated as described in Step 13, and the value of L/2 was used in all calculations. The value of L for each nondetected measurement was determined individually based on the sample volume and the reported analytical limit of detection. These data are presented in Appendix A. The variables deemed most important by the industrial hygienist/engineer were sample type, sample collection method, industry, company, process type, job title, and occupational control type. Consideration of sample type and sample collection method resulted in retention of only the full-shift personal samples collected by the newer method. Industry, typically considered a blocking variable, was retained because of the end user request to consider the monomer and polymer industries separately (see Step 3).

Examination of the 516 full-shift personal sample data points (Appendix A) showed that, after consideration of industry, company, process type, and occupational control, little or no additional information was provided by job title. That is, there tended to be only a single job title for any given process type. Thus, job title was not considered for the definition of the initial groups. On the basis of the remaining parameters, 58 initial groups were identified, with sample sizes as indicated (by industry, company, process type, and occupational control):

Monomer:

- M1, Control room, control 1: N=3
- M1, Lab, control 4: N=6
- M1, Process area, control 2: N=5M2, Control room, control 1: N=3M2, Lab, control 3: N=9M2, Loading area, control 1: N=3M2, Process area, control 1: N=6M3, Control room, control 1: N=2M3, Lab, control 6: N=7M3, Loading area, control 2: N=6M3, Process area, control 2: N=4M4, Control room, control 1: N=2M4, Lab, control 5: N=7M4, Lab, control 2: N=3M4, Loading area, control 2: N=2M4, Process area, control 2: N=2M4, Tank farm, control 1: N=5

Polymer:

- P1, Crumbing and drying, control 1: N=9
- P1, Lab, control 1: N=10
- P1, Maintenance, control 1: N=34
- P1, Packaging, control 1: N=30
- P1, Polymerization or reaction, control 1: N=6
- P1, Process area, control 1: N=5
- P1, Purification, control 1: N=6
- P1, Solutions and coagulation, control 1: N=9
- P1, Tank farm, control 1: N=5
- P1, Warehouse, control 1: N=2
- P2, Control room, control 1: N=6
- P2, Crumbing and drying, control 1: N=7
- P2, Lab, control 1: N=14
- P2, Maintenance, control 1: N=9
- P2, Packaging, control 1: N=6
- P2, Polymerization or reaction, control 1: N=29
- P2, Solutions and coagulation, control 1: N=5
- P2, Tank Farm, control 1: N=3
- P3, Lab, control 1: N=3
- P3, Maintenance, control 1: N=4
- P3, Polymerization or reaction, control 1: N=18
- P3, Solutions and coagulation, control 1: N=4
- P3, Tank farm, control 2: N=9
- P3, Unloading area, control 1: N=2
- P4, Crumbing and drying, control 1: N=13
- P4, Lab, control 1: N=17
- P4, Maintenance, control 1: N=7
- P4, Packaging, control 1: N=20
- P4, Polymerization or reaction, control 2: N=7
- P4, Solutions and coagulation, control 1: N=3
- P4, Tank farm, control 1: N=8
- P4, Warehouse, control 1: N=11
- P5, Crumbing and drying, control 1: N=6
- P5, Lab, control 1: N=8
- P5, Maintenance, control 1: N=16
- P5, Packaging, control 1: N=23
- P5, Polymerization or reaction, control 2: N=2
- P5, Purification, control 2: N=12
- P5, Solutions and coagulation, control 1: N=12
- P5, Tank farm, control 1: N=6
- P5, Warehouse, control 1: N=7

In the above list, the control types are as listed in Appendix A. The initial categories are

B. <u>Log-Transform the Data</u>

The tests of the grouping and the importance of the identified exposure parameters are conducted on the log-transformed concentration values. This is done because it is typically assumed that concentration data can be described by a log-normal distribution. If the concentrations are log-normally distributed, the effect of log-transforming the data is to create normally distributed values. One assumption underlying analysis of variance (ANOVA) methods (see subtask D below) is that the errors are normally distributed. Thus, under the general assumption of log-normally distributed concentrations and using a logtransformation of the concentrations, an assumption of the ANOVAs discussed below is satisfied.

We have not proposed here to test the assumption that the concentrations are log-normally distributed. This is considered appropriate in light of the theoretical rationale for suspecting that atmospheric concentration data follow a log-normal distribution and the extensive empirical evidence that a log-normal distribution can describe observed patterns of concentrations of various compounds (see Rappaport, 91, for a brief review). Moreover, ANOVA is robust with respect to departures from the assumption of normality. That is, ANOVA can still be reasonably expected to give the correct interpretation of the data even if the data deviate somewhat from a normal distribution. Nevertheless, testing the assumption of log-normally distributed concentrations can be considered an option, and Appendix B presents information related to the testing of data to see if it is normal or log-normal. If the engineer suspects that the concentration data should not be considered to be log-normal, he or she can apply the tests described in that appendix or consult a statistician for additional support. If departures from log-normally distributed concentrations should be added to the list of uncertainties and assumptions.

The data points are transformed into natural (base e) log values as described by Equation 1.

$$\mathbf{x}_{ti} = \ln (\mathbf{x}_i)$$
 Equation 1

where:

X _{ti}	=	a log transformed data point
Xi	=	a data point (as originally observed)
ln	=	the natural logarithmic function

C. Graphical Examination of the Data; Check for Outliers

Before the ANOVA(s) are performed to test the importance of the exposure parameters, the logtransformed data should be examined once more to determine if some errors have been introduced. This examination will focus on the pattern of observed values, rather than individual observations as in Step 7, to determine if there are any values that appear "unusual." The unusual observations can be considered to be the outliers, those observations that do not appear to fit in with the rest of the data. "Box-andwhisker" plots can be used to identify outliers. Box-and-whisker plots can be created for each of the initial categories. If there are relatively few observations per category, less than 6 to 10 typically, such plots may not be very informative. One can also combine some of the initial categories and examine box-and-whisker plots for such combinations. Caution should be exercised when such combinations are considered, because it is not clear at this stage of the analysis which categories ought to be combined. Combination of categories with quite different mean values, for example, may lead to a bi-modal distribution that will be relatively uninformative with respect to identification of outliers.

Outliers can be identified from a box-and-whisker plot as the individual observations that are displayed beyond the limits of the whiskers. More information about the box and the whiskers of such a plot is presented in Appendix B. Any outliers so identified should not be dropped from analysis. Rather, those data points should be examined to determine if they have been entered or calculated incorrectly. Sources of error include, but are not necessarily limited to, misclassification (an observation was recorded as belonging to one group when in actuality it belongs in another group), transcription (an incorrect value was transcribed from the lab sheets entered into the computer data base), or calculation errors (e.g., when units were converted).

If errors are detected, then they should be corrected and the graphical examination of the data reevaluated. If no errors are detected, then the data points should be retained and considered in the ANOVA.

EXAMPLE

Figure 6 shows the box-and-whisker plots for the initial categories from the monomer industry. The numbers of observations within each category are small, so not much can be determined with respect to outliers. However, in the category consisting of process area concentrations at company M1, there is one relatively low value; and in the tank farm at company M4, there is a high value. The former is an observation below the detection limit (below 0.18 ppm, set equal to 0.09 ppm for these analyses) which appears low relative to the 4 detected concentrations of 0.37 ppm or above at the M1 process area. The latter is a concentration of 1.53 ppm, which, compared to the other 4 concentrations from the M4 tank farm (all of which were less than 0.31 ppm and included 3 non-detects), looks suspicious.

Figure 7 shows the SAS output for all of the monomer industry initial categories combined. The box-and-whisker plot from that output shows two outliers, both on the high side. Investigation of those observations revealed that they were from the lab at M4 (with control type 2) and from the loading area at M4. These points were not detected in Figure 6 because the initial categories in which they were classified had few observations (3 and 2, respectively).

When these outliers were investigated, it was determined that they did not result from data manipulation errors. Furthermore, they did not appear to be the result of atypical situations (e.g., a spill) at the plants involved. Because there was no evidence that they were unusual or erroneous, these concentrations were retained for the subsequent analyses.

The concentrations in the polymer industry initial categories were similarly examined. Again, no evidence of erroneous or atypical data were discovered and all data points were retained for analysis.

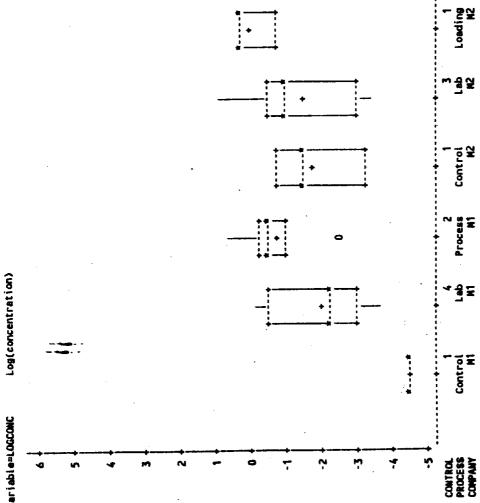
D. <u>Analysis of Variance</u>

ANOVA techniques are the recommended basis for revising the initial grouping. Such techniques are applied to determine if the observed concentrations within some of the initial groups are similar enough to warrant combination of those groups. This approach is based on determinations of whether or not the exposure parameters suggested by the engineer as potentially important actually discriminate between exposure levels, i.e., whether or not those parameters are statistically significant with respect to concentration differences.

The application of ANOVA may not be straight-forward in many real cases. Difficulties can arise if there are several factors being considered, if confounding or aliasing of the effects of those factors is possible, or if there are correlations among the observations (e.g., if there is nesting of the effects of one factor within another factor). The ANOVA approach described here is relatively easy; suggested interpretations of standard statistical output are provided. However, it is recommended that the engineer







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Figure 6: Box-and-Whisker Plot for Monomer Industry Categories

Process M2

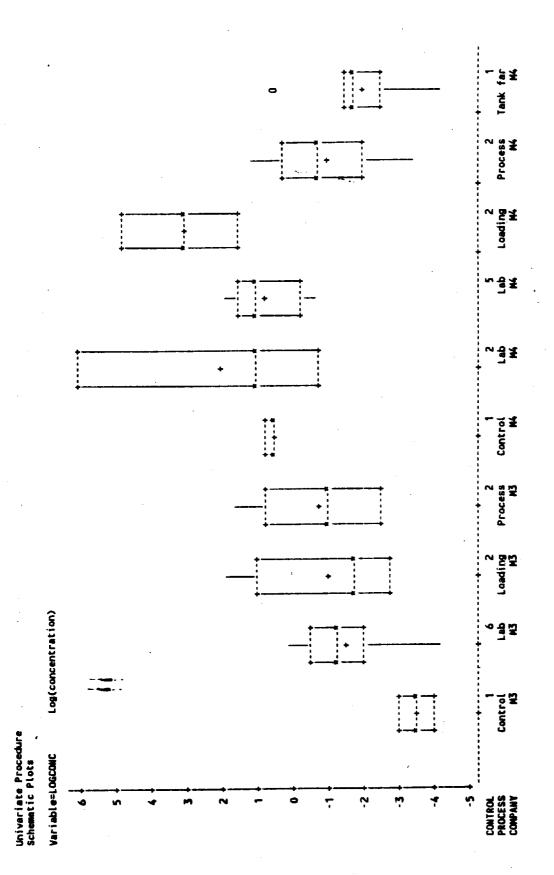


Figure 6: Box-and-Whisker Plot for Monomer Industry Categories

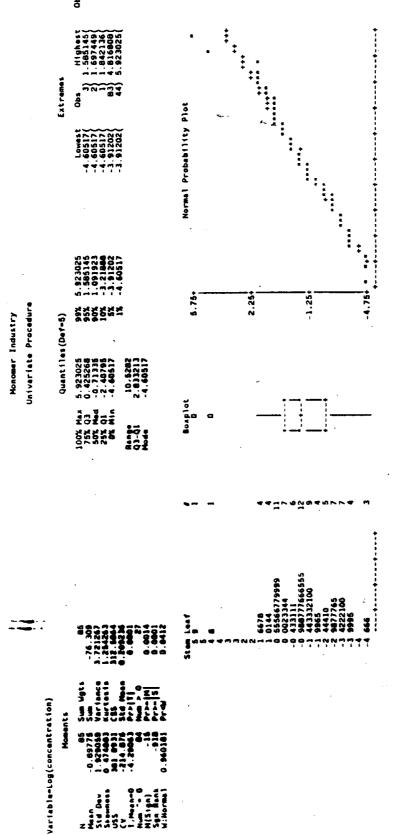


Figure 7. SAS Output for All Monomer Industry Categories Combined

065 61 57 57

An ANOVA of only the main effects (the important exposure parameters identified in Step 4) is recommended. That is, for the purpose of identifying which factors to retain for the definition of the final categories, examination of the contributions of the factors themselves and not their interactions should be sufficient. The presence of an interaction means that the effect of one factor is not the same across all the values of some other factor or factors. While such interactions may exist, it may be difficult to evaluate them if there are relatively few distinct combinations of factors for which we have observations. A statistician should be consulted to determine the effect of ignoring interaction terms in any particular case that appears to be problematic.

Although, in Step 4, the engineer was encouraged to identify explanatory exposure variables (e.g., control type, job title, etc.) as opposed to blocking variables (e.g., company or industry), inclusion of some blocking variables in the ANOVA can help to avoid potential difficulties. The inclusion of blocking variables in ANOVAs is typically recommended so as to account for sources of variability that are not otherwise accounted for by the explanatory variables, especially when there are known or suspected differences across the units that are being observed that can not be controlled. Blocking by company, for example, can make the test of control type more sensitive, if there are company-to-company differences that can not otherwise be factored out. Moreover, problems of correlation (e.g., observations obtained at one date being more closely related to one another than they are to observations from another date, even if the observations came from the same plant and process type) might be minimized by blocking, especially blocking by calendar time if the concentration measurements have been collected over a relatively long period of time. Blocking may not be the ideal solution (nested ANOVAs might be considered-see Appendix B), but a simple main effects ANOVA with suitable blocking factors may be sufficient for the purposes of determining which factors to retain for group definition. Again, consultation with a statistician is recommended. Moreover, if large block-to-block differences are observed, the engineer may find it useful to determine if there are some explanatory variables that might account for those differences.

For each of the factors in the ANOVA, whether it is an explanatory or a blocking variable, the result of interest will be the F-test that compares the variability in concentrations accounted for by that factor to the "error" variability. The error variability (assessed by the mean squared error) measures the inherent randomness of observations within groups. When differences in means across the groups defined by the factor under consideration are large relative to the within-group variability, then the F-test of that factor returns a significant result. This suggests that that factor is indeed important and should be retained for defining exposure groups. A significant result can be defined as an F-test with an associated p-value less than 0.05. The determination of significance is dependent on sample size, so it may be appropriate to adjust the 0.05 cut-point as a function of sample size. For small sample size, a larger p-value might be warranted; for larger sample sizes, a smaller p-value could be used. A statistician should be consulted if such adjustments are considered.

It is recommended that the partial sums of squares be used for the F-tests of significance. These sums of squares (called Type III sums of squares in the SAS output) are considered by many statisticians to be the most desirable. Such sums of squares are not sensitive to the order of the factors in the model. The sums of squares for one factor account for the effects of all other factors. Moreover, they are not functions of the numbers of observations per group. All these features make the partial sums of squares

appropriate for the purposes of determining how to refine the initial grouping by ignoring some of the exposure parameters.

EXAMPLE

The SAS output for the ANOVA of the monomer industry groups is displayed in Figure 8. The last column of the output shows the p-values associated with the 3 factors being considered: company, process type, and control type. All three of the p-values exceed 0.05 for the partial sum of squares, suggesting that none of them significantly account for observed differences in concentrations. Rather than removing all of the factors from consideration, however, it was decided to first remove only the blocking variable, company, to see what effect this would have on the other two factors.

Figure 9 shows the ANOVA results when only process type and control type are considered. In this case, both of those factors contribute strongly to observed differences in exposure. The lack of significance for those factors when company was included illustrates a difficulty that can be encountered when there are relatively few observations and factors with many values: there is confounding (overlap) of the effects and the significance of one or more of them may be masked. Because we were not interested in company per se and were willing to remove it from consideration, the importance of process type and control type could be revealed. Both factors are retained for redefining groups in the monomer industry.

For the polymer industry groups (Figure 10), the company blocking variable and the process type parameter were highly significant but the control type was not. This suggests that control type can be ignored in the polymer industry. Apparently, the differences between the controlled and uncontrolled work areas did not result in significant differences in exposure, when the other factors of company and process type were considered. The fact that company was a significant factor suggests that other differences between companies, in addition to control technologies, are contributing to different exposure levels. At this point in time, the relevant differences among companies have not been identified, so company is retained as a factor used to define exposure categories.

General Linear Models Procedure Class Level Information

Class Levels Values COMPANY 4 M1 M2 N3 M4

PROCESS 5 Control room Lab Loading Process area Tank farm

Number of observations in data set = 85

	Pr > F	0.0003	्र. च		LOGCONC Mean	-0.89775311	Pr > F	0.0796 0.0922 0.2357	
	f Value	3.60					f Value	2.35 2.08 1.40	
	Mean Square	9.77543998	2.71223840		Root MSE	1.64688749	Mean Square	6.37224818 5.64401676 3.788833364	
Log(concentration)	Sum of Squares	117.30527971	195.28116513	312.58644484	C.V.	- 183.4455	Type III SS	19.11674454 22.57606702 18.94416819	
Dependent Variable: LOGCONC	DF	12	22	l Total 84	R - Square	0.375273	DF	M 4 10	
Dependent	Source	Model	Error	Corrected Total			Source	COMPANY PROCESS CONTROL	

Figure 8: SAS Output for Test of Company, Process Type, and Control Type in Monomer Industry

General Linear Models Procedure Class Level Information

Values 1 Class Levels Contral **room tab Loading** Process area Tank farm ŝ PROCESS

123456 • CONTROL Number of observations in data set = 85

Dependent Variable: LOGCONC Log(concentration)

Mean Square sum of Squares ğ Source Ĕ Ē 3

Pr > F

f Value

	0.0005			LOGCONC Mean	-0.89775311	Pr > F	0.0033	
	3.82					F Value	4.33	
	10.90983724	2.85863880		Root MSE	1.69075096	Mean Square	12.37078810 11.51091551	
•	98.18853517	214.39790968	312.58644484	c.v.	- 188.3314	Type III SS	49.48315238 57.55457757	
1	0	ъ	78	R - Square	0.314116	DF	-4 10	
	Model	Error	Corrected Total			Source	PROCESS CONTROL	

Figure 9: SAS Output for Test of Process Type, and Control Type in Monomer Industry

.

General Linear Models Procedure Class Level Information

Class Levels Values

COMPANY 5 P1 P2 P3 84 P5

Control Flow Crumbing and dry Laboratory Maintenance Packaging Polymerization o Process area Purification Solutions and co Tank farm Unloading area Warehouse 12 PROCESS

Number of observations in data set = 431

Dependent V	Variable: L	.OGCONC	Dependent Variable: LOGCONC Log(concentration)			
Source		Df	sum of Squares	Mean Square	f Value	Pr > F
Model		91	1279.36507409	79.96031713	47.59	0.0001
Error		414	695.61144185	1.68022087		
Corrected Total	Iotal	430	1974.97651593			
	æ	R - Square	C.V.	Root MSE		LOGCONC Mean
	0.0	0.647787	- 47 .86522	1.29623334		-2,70809000
Source		DF	Type III SS	Mean Square	f Value	Pr > F
COMPANY PROCESS CONTROL		*=-	487.37213944 686.59871410 0.96805416	121.84303486 62.41806492 0.96805416	72.52 37.15 0.58	0.0001 0.0001 0.483

Figure 10 SAS Output for Test of Company, Process Type, and Control Type in Polymer Industry

E. <u>Redefining Groups</u>

Based on the results of the ANOVA(s), it may be possible to ignore one or more of the factors that were originally considered for importance. The regrouping is accomplished by simply dropping the non-significant factors (essentially pooling some groups).

EXAMPLE

For the monomer industry groups, ignoring the company parameter and reclassifying results in a drop to 11 groups, from the initial 17. Unfortunately, for the polymer industry group, elimination of control type from the definition of the groups does not reduce the number of groups for which descriptive statistics are required. Each of the initial groups could have been completely defined by company and process type alone (i.e., no process type within a company had more than one control type in place). Thus, the 41 initial polymer industry groups are retained for calculation of descriptive statistics in Step 17.

The groups that are carried through to Step 16 are listed here:

- Monomer process area, control 1, N=6Monomer process area, control 2, N=21Monomer control room, control 1, N=10Monomer loading area, control 1, N=3Monomer loading area, control 2, N=8 Monomer lab, control 2, N=3Monomer lab, control 3, N=9Monomer lab. control 4. N=6Monomer lab, control 5, N=7Monomer lab, control 6, N=7Monomer tank farm, control 1, N=5P1, Crumbing and drying, N=9P1, Lab, N = 10P1, Maintenance, N=34P1, Packaging, N=30P1, Polymerization or reaction, N=6P1, Process area, N=5P1, Purification, N=6P1, Solutions and coagulation, N=9P1, Tank farm, N=5P1, Warehouse, N=2P2, Control room, N=6P2, Crumbing and drying, N=7P2, Lab, N = 14P2, Maintenance, N=9P2, Packaging, N=6
- P2, Polymerization or reaction, N=29P2, Solutions and coagulation, N=5P2, Tank Farm, N=3P3, Lab, N=3P3. Maintenance, N=4P3, Polymerization or reaction, N = 18P3, Solutions and coagulation, N=4P3, Tank farm, N=9P3. Unloading area. N=2P4, Crumbing and drying, N=13P4, Lab, N=17 P4, Maintenance, N=7P4, Packaging, N=20P4, Polymerization or reaction, N=7P4, Solutions and coagulation, N=3P4, Tank farm, N=8P4, Warehouse, N=11P5, Crumbing and drying, N=6P5. Lab. N=8P5, Maintenance, N=16 P5, Packaging, N=23P5, Polymerization or reaction, N=20P5, Purification, N=12P5, Solutions and coagulation, N=12P5, Tank farm, N=6
 - P5, Warehouse, N=7

STEP 16: TREATMENT OF TYPE 2 DATA

Categories with insufficient Type 1 data are identified and may be supplemented with Type 2 data (Figure 11). Type 2 data should only be added for those categories that require it, and Type 3 data should never be added.

A sample size of 6 is a common minimum cited in the literature (Patty, 81; Hawkins, 91) for calculation of simple descriptive statistics. The addition of Type 2 data is considered only for groups having fewer than six samples.

A summary of the Type 2 data not used in the statistical analysis will be prepared, similar to the summary of Type 3 data completed in Step 12.

A. Considering Addition of Type 2 Data

There will be a "trade off" that must be carefully considered when faced with a group with small sample size. The addition of additional data points will tend to improve the estimation of the descriptive statistics desired, all else being equal. However, when Type 2 data are all that are available for boosting sample sizes, all things are not equal. The Type 2 data are not as good as the Type 1 data considered heretofore, typically because the Type 2 data lack information about some important parameter or because some substantial uncertainty is associated with the measurements. In some instances or for some categories, the addition of such Type 2 data may not be desirable, even when sample sizes are low, because the additional uncertainty is considered to outweigh the benefits of increased sample size. It may be the case that a sample size of 5, for example, is preferable to adding one or more Type 2 data points because the information that was missing from the Type 2 data, and the assumptions made in order to use the Type 2 data, may have a substantial impact on the applications intended by the end user. The decision, therefore, must consider the end user needs and how sample size and assumptions relate to those needs.

B. Adding Type 2 Data

When Type 2 data are added to the data set, a record of that addition and the associated assumptions must be added to the ongoing list of uncertainties and assumptions. The impact of the assumptions and uncertainties will be assessed in Step 18.

C. Summary of Remaining Type 2 Data

Whatever Type 2 data have not been included for statistical analysis should be summarized. The summary may be similar in nature to the summary of the Type 3 data (Step 12), but a slightly more quantitative report may be possible for some Type 2 data. This report on the Type 2 data can be used or

referred to in the presentation of results, as a supplement to the statistical information based on the Type 1 data (supplemented as needed by Type 2 data).

EXAMPLE

In the example data set, 12 groups resulting from processing in Step 15 had Type 1 data sample sizes less than 6. For one of those groups, monomer loading area with control 1 (N=3), additional Type 2 data were located (Table 2). These data were considered to be Type 2 data because of known biases in the measurement procedure and assumptions that were made about the correction factor to apply to adjust for that bias. Nevertheless, it was possible to estimate values for the samples, as shown in Table 2. The eleven Type 2 values were added to the Type 1 data of this group, because the two sets of values appeared to be generally consistent and the effect of uncertainty about the Type 2 values was considered to be offset by the advantage of increasing sample size for this group. The inclusion of these data is noted on the list of uncertainties and assumptions.

No other Type 2 data were available to boost sample sizes for the other eleven groups with small sample size. These groups will be treated appropriately in subsequent steps.

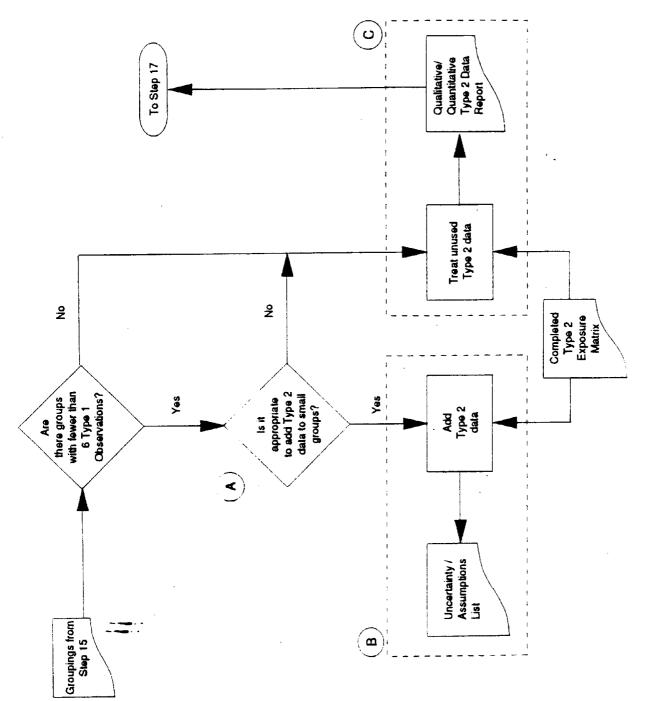


Figure 11. Flow Diagam for Step 16 (Treatment of Type 2 Data).

Plant ID	Industry	Process type	Job title	Control type (a)	Sample duration (min)	8-hr TWA (ppm)	Control description
A1	Monomer	Loading area	Process technician	1	415	0.50	Magnetic gauge
A1	Monomer	Loading area	Process technician	1	428	0.30	Magnetic gauge
A1	Monomer	Loading area	Process technician	1	427	0.10	Magnetic gauge
A1	Monomer	Loading area	Process technician	1	474	0.90	Magnetic gauge
A2	Monomer	Loading area	Process technician	1	260	2.80	Magnetic gauge
A2	Monomer	Loading area	Process technician	1	442	3.10	Magnetic gauge
A2	Monomer	Loading area	Process technician	1	443	0.80	Magnetic gauge
A3	Monomer	Loading area	Process technician	1	459	7.50	Magnetic gauge
A3	Monomer	Loading area	Process technician	1	484	0.60	Magnetic gauge
A3	Monomer	Loading area	Process technician	1	474	2.40	Magnetic gauge
A3	Monomer	Loading area	Process technician	1	446	1.70	Magnetic gauge

Table 2. Type 2 Data Used in Statistical Analysis

(a) Control Type 1 is "controlled," as in Table 1.

STEP 17. CALCULATE DESCRIPTIVE STATISTICS FOR EACH GROUP

For each group defined in the previous steps, means and standard deviations, as well as geometric means and geometric standard deviations will be estimated. Because no tests have been conducted to determine the nature of the distributions of concentrations within the groups, relatively simple and consistent estimators of those parameters are recommended. This step describes the calculations necessary for estimating the descriptive statistics.

The sample mean and sample standard deviation are consistent estimators of the mean and standard deviation, respectively. In the case of normality, they are also unbiased estimators. The sample mean is given by Equation 2.

$$\mathbf{MEAN} = \frac{\sum_{i=1}^{n} \mathbf{X}_{i}}{n}$$
 Equation 2

where:

MEAN	=	sample mean
\mathbf{X}_{i}	=	a data point
n	=	number of data points

The sample standard deviation is the square root of VAR, $SD = (VAR)^{0.5}$, where VAR is given by Equation 3.

$$VAR = \frac{\sum_{i=1}^{n} (X_i - MEAN)^2}{n-1}$$
 Equation 3

where:

VAR	=	sample variance
MEAN	=	sample mean
X _i	=	a data point
n	=	number of data points

.

The geometric mean and geometric standard deviation can be estimated from the log-transformed data. Equations 4 and 5 present those estimates:

$$GM = \exp \{LMEAN\}$$
 Equation 4

$$GSD = \exp \{LVAR^{0.5}\}$$
 Equation 5

where

$$LMEAN = \frac{\sum_{i=1}^{n} x_{ii}}{n}$$
 Equation 6

$$LVAR = \frac{\sum_{i=1}^{n} (X_{ii} - LMEAN)^{2}}{n-1}$$
 Equation 7

and

n

It may also be useful to calculate standard errors for the estimators of the means. The standard error is related to the variability of the estimator of the mean. That estimator is estimating the true mean of the distribution of observations, but because it is only an estimator, there is some uncertainty concerning the value of the true mean. That uncertainty is characterized by the standard error.

The derivation of a standard error for the sample mean, SE, is given by Equation 8.

$$SE = SD/(n)^{0.5}$$
 Equation 8

where

SD = standard deviation estimate n = number of observations.

EXAMPLE

Table 3 displays the descriptive statistics calculated for the groups retained from Step 15. That table provides the statistics for any group with sample size of at least 6. For the groups with samples sizes less than six, median values are all that are provided.

Table 3: Descriptive Statistics for Groups in Example Data Set

		Descriptiv	ve Statisti	CS	
	No. of	Mean		Geom. Mean	Geom. Std.
Group	Samples	(ppm)	(ppm)	(ppm)	Dev.
Monomer Control Room, Control 1	10	0.448	0.724	0.236	3.106
Monomer Lab, Control 2	3	2.610 *			
Monomer Lab, Control 3	9	0.524	0.629	0.335	2.572
Monomer Lab, Control 4	6	0.298	0.357	0.191	2.569
Monomer Lab, Control 5	7 7	3.087	2.256	2.492 0.264	1.924
Monomer Lab, Control 6		0.350 1.709	0.304 1.913	1.139	2.116 2.463
Monomer Loading, Control 1	14 8	17.010	43.110	6.243	4.120
Monomer Loading, Control 2 Monomer Process Area, Control 1	0 6	1.312	1.131	0.994	
Monomer Process Area, Control 2	21	0.918	1.054	0.603	2.502
Monomer Tank Farm, Control 1	5	0.160 *		0.005	2.502
P1, Crumbing and drying	9	0.043	0.019	0.040	1.515
P1, Lab	10	2.909	3.348	1.908	2.505
P1, Maintenance	34	0.857	2.310	0.298	4.277
P1, Packaging	30	0.039	0.031	0.031	2.003
P1, Polymerization or reaction	6	0.696	1.100	0.372	3.062
P1, Process area	6	0.118	0.122	0.082	2.346
P1, Purification	6	4.357	2.312	3.849	1.646
P1, Solutions and coagulation	9	0.027	0.008	0.026	1.343
P1, Tank farm	5	0.440 *		0.020	
P1, Warehouse	2	0.020 *			
P2, Control room	6	0.028	0.030	0.019	2.382
P2, Crumbing and drying	7	0.032	0.013	0.030	1.485
P2, Lab	14	0.636	1.267	0.285	3.547
P2, Maintenance	9	0.030	0.009	0.029	1.341
P2, Packaging	6	0.033	0.006	0.032	1.201
P2, Polymerization or reaction	29	0.077	0.144	0.036	3.417
P2, Solutions and coagulation	5	0.030 *			
P2, Tank farm	3	0.360 *			
P3, Lab	3	0.020 *			
P3, Maintenance	4	0.020 *			
P3, Polymerization or reaction	18	0.057	0.068	0.036	2.583
P3, Solutions and coagulation	4	0.020 *			
P3, Tank farm	8	0.112	0.231	0.049	3.626
P3, Unloading area	2	14.600 *	·		
P4, Crumbing and drying	13	0.016	0.020	0.010	2.682
P4, Lab	17	0.184	0.275	0.102	2.955
P4, Maintenance	7	0.004	0.004	0.003	2.140
P4, Packaging	20	0.006	0.006	0.004	2.374
P4, Polymerization or reaction	7	0.003	0.001	0.003	1.180
P4, Solutions and coagulation	3	0.003 *	<		
P4, Tank farm	8	2.366	4.203	1.161	3.299
P4, Warehouse	11	0.004	0.002	0.004	1.627
P5, Crumbing and drying	6	0.055	0.031	0.048	1.697
P5, Lab	8	3.972	3.035	3.156	1.970
P5, Maintenance	16	1.200	1.253	0.830	2.360
P5, Packaging	23	0.058	0.034	0.050	1.730
P5, Polymerization or reaction	20	0.740	0.886	0.474	2.568
P5, Purification	12	9.523	6.727	7.778	1.889
P5, Solutions and coagulation	12	0.082	0.047	0.071	1.709
P5, Tank farm	6	3.020	1.750	2.613	1.713
P5, Warehouse	7	0.045	0.015	0.043	1.382

* Values marked by asterisks are medians for groups with less than 6 observations.

STEP 18: TREAT UNCERTAINTIES, ASSUMPTIONS, AND BIASES

In the course of completing some previous steps, uncertainties, assumptions and biases will have been compiled in an ongoing list. The listing of uncertainties, assumptions, and biases will be treated in this step to provide important information to the end user. Evaluating uncertainty, assumptions, and biases provides a sense of the integrity of the results, whether significant gaps exist in the available data or information upon which the assessment is based and whether decisions made on the basis of the data will be tenuous. In addition, an uncertainty analysis provides information to better focus resources needed to refine the assessment and improve (reduce) the uncertainty (EPA, 92).

This step describes procedures for the treatment of data limitations imposed by uncertainties, assumptions, and biases. To the extent possible, those procedures will be quantitative; sensitivity analyses and confidence limit calculations are examples of quantitative approaches. The EPA Exposure Assessment Guidelines (EPA, 92) and Hornung (Hornung, 91) contain additional methods for quantifying uncertainty. In many cases, however, treatment may be qualitative, where quantification is not possible. Because this step is vital to a risk assessment and the management decisions associated with it, and because it may be difficult to execute, even a qualitative discussion of uncertainty will be extremely important.

A. <u>Sensitivity Analysis</u>

Sensitivity analysis can be used to test the effect of uncertainty or assumptions on the results, over the expected range of the uncertain or assumed values. The sensitivity analysis involves fixing the value for one variable at a credible lower bound while the other variables remain at their "best-estimate" values, and then computing the results. Then a credible upper bound value for the one variable is used while the other variables remain at their "best-estimate" values, and again the results are computed. Both sets of results are evaluated, over all uncertainties and assumptions (i.e., those relating to values of the observations used in the calculations), to determine which variables have the greatest impact on the assessment of exposure. Such analyses may also help focus resources for further refinement of the assessment. Since a sensitivity analysis does not provide any information on the likelihood of the variables assuming any particular values in their ranges of values, the analysis is most useful in screening-level assessments.

An approach known as Monte Carlo simulation can be used to quantitatively combine the contributions of various uncertainties. If ranges and/or distributions for the uncertain parameters can be specified, then values from those distributions can be sampled repeatedly, with exposure descriptive statistics recalculated with each repetition, to develop a "picture" of the distribution of descriptive statistic values. Monte Carlo simulation is a computer-intensive approach that can handle complex systems and combinations of many parameters. The user should consult a statistician if Monte Carlo approaches are to be considered.

Where limited data exist, such as for a new chemical, comparison with similar chemicals (surrogates) or the use of modeling may be used to estimate concentrations for the chemical of interest

(Step 12 describes methods for treatment of Type 3 data). A sensitivity analysis can address uncertainty in the following manner: the model is run using a range of expected values for model parameters as in Monte Carlo simulation discussed above; changes in the estimated concentrations for different input parameter values are a function of the sensitivity to the model parameters and of the degree of uncertainty associated with the parameter values. A more complete evaluation of uncertainty due to modeling would be to consider alternative models and ranges for their input parameter values.

B. <u>Confidence Intervals</u>

Confidence intervals can be calculated to quantify the uncertainty associated with estimates of summary statistics. In particular, one is often interested in the uncertainty concerning the mean exposure. As discussed in Step 17, the standard error of the mean characterizes the variability of the estimate of the mean and is the basis for confidence limit calculations for the mean. Confidence limits address uncertainty associated with sampling error, not other sources of uncertainty.

For a normal distribution, a 90% confidence interval for the mean extends from 1.645 standard errors below the estimator of the mean to 1.645 standard errors above the mean estimator. A 95% confidence interval is \pm 1.96 standard errors, and a 99% confidence interval is \pm 2.58 standard errors around the estimator of the mean. The values 1.645, 1.96, and 2.58 are the multipliers of the standard errors that are used to derive confidence intervals corresponding to three levels of confidence (90%, 95%, and 99%, respectively). In practice, one does not know what the true standard error is any more than one knows what the true mean is. To account for this added level of uncertainty, the values for the multipliers of the standard error are increased, the degree of the increase depending on the sample size.

A particularly common situation for confidence limit calculation is for a normal distribution mean. In that case, multipliers for the standard error can be found in a table of T distribution percentiles. Those percentiles depend on the sample size as desired. For example, for a normal distribution with an estimated mean of 5 ppm, a standard deviation of 1.5, and a sample size of 25, the resulting 95% confidence interval for the mean ranges from (5 - 2.064*(1.5/5)) to (5 + 2.064*(1.5/5)), i.e., from 4.4 to 5.6 ppm. In that calculation, (1.5/5) is the standard error estimate from Equation 6 (see Step 17) and 2.064 is the 97.5th percentile of the T distribution with 24 degrees of freedom (the estimates of standard deviation and standard error have degrees of freedom equal to the sample size minus one). The use of the 97.5th percentile results in 2.5% probability above and 2.5% probability below the confidence interval, i.e., a 95% confidence interval.

Even though we have not tested the groups defined in Step 15 to see if they are normal or not, the calculations outlined above should hold approximately, since the sample mean is approximately normal no matter what the distribution of the underlying observations may be. The adequacy of the approximation depends on the sample size and on the extent to which the standard deviation estimate divided by the square root of the sample size approximates the standard error of the mean. Appendix B presents additional material on confidence limits, especially as related to means of lognormal distributions.

C. Quantification of Bias

If the data were not statistically sampled, the results may be biased. This bias is separate from and should not be confused with bias in the data measurement which can be defined as a systematic error inherent in a method or caused by some feature of the measurement system (EPA, 92). Statistical bias is caused by the sample population not being representative of the population under study. It should be noted that data collected from other agencies and published sources are almost never randomly selected, although a particular bias may be difficult to identify. Despite the difficulty, it is extremely important to identify potential biases and clearly present them in the results presentation. Furthermore, if random sampling was carried out only in a subpopulation, the summary statistics may apply only to that subpopulation and may not be representative of a larger group. There are no quantitative methods to extend the sample results beyond the bounds of the subpopulation.

Bias can also occur because of inappropriate selection of sample location, sample time, or workers to be sampled. For example, measurements of peak exposures are intended to measure the period of highest exposure for that job category. Therefore, if a time period that does not represent maximum exposure or an individual in a job category that would not represent peak exposure are measured, then this selection would cause the measurements not to be representative of peak exposure.

Quantification of biases is always difficult and may be beyond the scope of the exposure assessment. If quantification is not possible, biases should be qualitatively described in the results presentation. One method of quantification is to segregate the potentially biased data and compare the exposures with the remaining data sets. Where a large quantity of data is available, this may allow quantification of the bias. Where only limited data are available, such comparisons may not yield dependable results.

Another method is to try to quantify the bias through use of other information. For example, if the data are biased because the plants are "well controlled," then information gathered from other sources or estimated from the monitoring data may be used to estimate the control efficiency and the distribution of controls in the industry. This, in turn, can be used to quantify the bias. Likewise, if only large facilities were surveyed and other data indicate differences in control between large and small facilities, the effect on exposure estimates may be estimable.

D. Weighting Factors to Mitigate Bias

The most common way to mitigate known quantifiable biases is through the use of a weighting factor. Weighting factors are used to adjust the influence of different pieces of data to equal their weight in the population being judged as a whole. For example, when determining an annual exposure, values may be weighted by the number of days annually that a worker is exposed. Weighting can also be used to calculate averages within a job category or other subpopulation. Weighting should always be clearly explained so that the user is aware that the descriptive statistics are based on weighted data. Weighting factors used to mitigate bias should be clearly presented.

EXAMPLE

Sensitivity Analysis

For the monomer process area/control 2 group and for the P4/polymerization and reaction group, sensitivity analyses were performed to quantify the effect of the assumption that nondetected measurements were equal to half the detection limit, L, on the calculation of the descriptive statistics. A lower bound for the value to be used for nondetects was set at L/4. The upper bound was set at L/2, another common choice for the value of a nondetect. For the monomer process area/control 2 group, the resulting descriptive statistic estimates were as follows:

		Nondected value:	
Statistic	L/4	L/2	L/√2
MEAN	0.91	0.92	0.92
SD	1.06	1.05	1.05
GM	0.59	0.61	0.61
GSD	2.5	2.5	2.5

The estimate of the means and standard deviations for this group were very insensitive to the choice of values for the nondetects. Only five of the 21 observations were below detection limits.

		Nondected value:	
Statistic	L/4	L/2	L/√2
MEAN	0.0016	0.0033	0.0046
SD	0.00027	0.00054	0.0007
GM	0.0016	0.0032	0.0046
GSD	1.2	1.2	1.2

For the P4/polymerization group, the results were as follows:

The change of the mean for the P4/polymerization group was considerably greater than that observed in the monomer process area/control 2 group, ranging from 52% below to 39% above the initial estimate of the mean. All seven of the P4/polymerization group observations were below detection limits. Clearly, the sensitivity of the results, in this case to the assumed values of nondetects, can vary from group to group.

Quantification and presentation of the results of sensitivity analyses and their variations across groups will be useful for subsequent risk assessment/risk management decisions. The results of such sensitivity analysis can be used by the risk assessor/risk manager to determine if his or her actions and decisions could be subject to change as a result of uncertainty concerning relatively low concentrations (those below the limit of detection). If they are subject to change, the implications of those changes can be determined or the decisions re-evaluated.

Other Means of Mitigating Bias

The collection of the data used in this example analysis provides an example of the identification of a bias in the collection method and how the bias was mitigated by using a different method. The potential for bias exists if the collection or analytical method has not been validated over the entire range of exposures. NIOSH Method S-91 for the example chemical illustrates this (NIOSH, 84). This method was developed to meet compliance monitoring needs associated with the OSHA standard at the time of 1,000 ppm (2,000 mg/m³). The method was validated over a range of concentrations from 481 to 2,237 ppm (1,065 to 4,950 mg/m³). Because of new animal test data indicating toxicity at much lower concentrations, and the fact that industry was controlling exposures to much lower levels, the existing method had to be reviewed. It was found that the S-91 method poorly separated the example chemical from other C_4 hydrocarbons. This and other possible interferences probably systematically overestimated the example chemical content of the samples at lower concentrations.

In the case of the example chemical, a new extraction method was developed that improved the sensitivity and selectivity of the method and new measurements were taken. Where sufficient time or resources are not available, correction factors may be developed and the overestimate at lower concentrations adjusted by these factors. Any such adjustments should be clearly identified in the data and the results. The correction factor values are themselves subject to uncertainty and should be included in the list of uncertainties/assumptions for presentation to the end user.

STEP 19: PRESENT RESULTS

Because the results of the analysis may need to be used by engineers, economists, and other decision-makers who are not statisticians, presentation techniques will to a large extent determine their usefulness. To properly use the results of the analysis, the end user must know the purpose, scope, level of detail and approach used in the assessment. In addition, key assumptions used, the overall quality of the assessment (including uncertainties in the results), and the interpretation of data and results are as important as estimates of exposure. The results must also be presented in a form that corresponds to the modeling or other needs of the end user. Finally, it is important that the original data values and all important variables be presented in an appendix to the report. This step describes four aspects of results presentation:

- A) Characterization of exposure (narrative explanation)
- B) Presentation of descriptive statistics
- C) Presentation of assumptions and uncertainties
- D) Presentation of original data

A. Characterization of Exposure

The characterization of exposure is the overall narrative which consists of discussion, analysis and conclusions that summarize and explain the exposure assessment. It provides a statement of the purpose of the assessment, the scope, level of detail, and approach used in the assessment. It presents the estimates of exposure by route of exposure (e.g., inhalation, dermal) for the population, subpopulation, or individuals, in accordance with the needs identified by the user. It should also include an overall evaluation of the quality of the assessment, and a discussion of the degree of confidence the engineer has in the estimates of exposure and the conclusions drawn. The data and results should be presented in keeping with the terms defined in the EPA Exposure Assessment Guidelines (EPA, 92) for bounding estimates, reasonable worst case estimates, worst case estimate, maximally exposed individual, maximum exposure range, etc.

The engineer should include a discussion of whether the scope and level of detail were sufficient to meet the needs of the user. If user needs were not met it is preferable to identify the tasks or mechanisms (monitoring, collecting additional information, etc.) that will be needed in order to fully meet the needs of the user, and how this lack of data or information impacts the assessment. A general discussion of research or additional data to improve the assessment is also quite useful; data gaps should be identified in order to focus further efforts to reduce uncertainty. An appendix may be a suitable place for this discussion.

The methods used to quantify exposure (e.g., models, use of surrogate data, use of monitoring data) should be clearly identified in the exposure characterization. A discussion of the strengths and weaknesses of the methods and of the data used should be included.

When Type 2 and Type 3 data were available but not used for the quantitative characterization of exposure, summaries of the information available from the Type 2 and Type 3 data bases should be included. Recall that the summaries of the Type 2 data may be more quantitative in nature and may provide some numerical estimates. The numerical estimates and qualitative appraisals of the Type 2 and Type 3 data can be compared with the summary statistics from Type 1 data (if available) to suggest discrepancies or potential differences. If the Type 2 and/or Type 3 results suggest exposures that appear to be different from the results of analyzing the Type 1 data, potential explanations for the differences should be provided.

The end user will sometimes request a characterization of exposure for the entire population (e.g., all workers in a given industry). The identification of subpopulations defined by the important exposure parameters entails that descriptive statistics *per se* probably should not be derived for the entire population, say by combining the descriptive statistics for each category (although, see Appendix B for some issues related to such combinations). The best overall summary may be the presentation of the descriptive statistics for each category, perhaps in graphical format. Such a presentation preserves much more information then a formal, quantitative combination of means, for example, over all the categories. In conjunction with a prose description of the numerical variety of circumstances (e.g., of the many combinations of factors that affect exposure level), such tabular and graphical representations should convey the information necessary for risk assessment and risk management decisions. Semi-quantitative summaries (e.g., presentation of the range of mean exposure levels) may also be useful.

B. <u>Presentation of Descriptive Statistics</u>

The results should be presented in accordance with the needs of the end user as defined in Step 3. The end user should have identified the required descriptive statistics and presentation methods.

Where sufficient data are present, the plotting of the data on an appropriate scale in addition to the accompanying descriptive statistics is usually the best presentation method. Where box-and-whisker plots were used to identify outliers, these plots can be presented in an appendix. It is also useful to present a characterization of the data by the percentage of nondetected values and percentage of values above the detection limit, etc.

There may be some Type 1 data groups that had few observations and for which descriptive statistics were not calculated. These groups must be verbally summarized and the indications of the degree of exposure suggested by these groups compared and contrasted to the quantitative estimates for the other Type 1 data groups. This comparison and contrast is similar to that provided for the Type 2 and Type 3 data sets. Qualitative and semi-quantitative results from the data not used to derive quantitative estimates must be compared, to the degree possible, with the quantitative results. Possible explanations for apparent discrepancies should be provided.

EXAMPLE

Table 4 presents summary information for all of the groups considered in the example.

Although most users wish to receive the data in tabular form, some may wish to have graphic presentations also provided. Figure 12 provides a box-and-whisker plot of the data for the monomer industry groups. Figure 13 provides an example of a bar graph for several of the groups, comparing mean and maximum concentrations with several target levels.

C. Presentation of Assumptions and Uncertainties

A figure summarizing and clearly presenting all assumptions and uncertainties (treated in Step 18) should be accompanied by a more complete explanation in the text. Wherever possible, the effect of those assumptions and uncertainties on the results of the analysis will be quantified (see Step 18). Figure 14 presents an example of how this information may be presented; it may be considered to be the product of the cumulative listing of assumptions and uncertainties produced from the various steps of the exposure assessment.

The first column of Figure 14 presents a description of the uncertainty. The uncertainties can range from the length of the work day to the actual concentration when non-detected values are recorded. The second column presents the associated assumption if one was made. The third column presents an estimate of the range of possible values for the assumed value. Finally, column 4 presents an estimate of the effect of the assumption on the results. Some of the effects presented in the last column may have to be group-specific.

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P2, Control room196 ≤ 0.006 0.0700.0160.0280.0120.0300.0192.382233P2, Crumbing and drying4070.0180.0520.0270.0320.0050.0130.0301.4850P2, Lab63140.0294.1200.0440.6360.3391.2670.2853.54700P2, Maintenance9490.0210.0480.0260.0300.0030.0090.0291.34100P2, Packaging2560.0220.0380.0340.0330.0020.0060.0321.26777 </td <td>-</td> <td></td> <td>-</td> <td></td>	-											-	
P2, Crumbing and drying4070.0180.0520.0270.0320.0050.0130.0301.48500P2, Lab63140.0294.1200.0440.6360.3391.2670.2853.54700P2, Maintenance9490.0210.0480.0260.0300.0030.0090.0291.34100P2, Packaging2560.0220.0380.0340.0330.0070.0270.1440.0363.41727P2, Polymerization or reaction10529< 0.0080.7800.0330.02800P2, Tak farm5930.1230.4360.36200P3, Lab453 \leq 0.0090.4290.01600P3, Vaintenance7440.0110.0260.02000P3, Solutions and coagulation4604 \leq 0.0060.1640.019133P3, Maintenance7440.0110.0260.020													
P2, Lab6314 0.029 4.120 0.044 0.636 0.339 1.267 0.285 3.547 0 0 P2, Maintenance949 0.021 0.048 0.026 0.030 0.000 0.029 1.341 0 0 P2, Packaging256 0.022 0.038 0.033 0.002 0.006 0.032 1.201 0 P2, Polymerization or reaction10529 < 0.008 0.780 0.033 0.077 0.027 0.144 0.036 3.417 2 7 P2, Solutions and coagulation6505 0.015 0.038 0.028 $$ $$ $$ $$ $$ $$ 0 0 P3, Lab453<<< 0.009 0.429 0.016 $$	-		-										
P2, Maintenance9490.0210.0480.0260.0300.0030.0090.0291.34100P2, Packaging2560.0220.0380.0340.0330.0020.0060.0321.20100P2, Polymerization or reaction10529 \leq 0.0080.7800.0330.0070.0270.1440.0363.41727P2, Solutions and coagulation65050.0150.0380.02600P2, Tank farm5930.1230.4360.36200P3, Lab453<													
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P2, Tank farm5930.1230.4360.36200P3, Lab453 ≤ 0.009 0.4290.016133P3, Maintenance7440.0110.0260.02000P3, Folymerization or reaction10018 ≤ 0.006 0.2500.0320.0570.0160.0680.0362.583211P3, Solutions and coagulation4604 ≤ 0.006 0.1640.019125P3, Tank farm4180.0090.6820.0340.1120.0820.2310.0493.62600P3, Unloading area4520.77028.51014.64000P4, Crumbing and drying2413 ≤ 0.005 0.0810.0130.0160.0060.0200.0102.682431P4, Maintenance617 ≤ 0.006 0.0130.0030.0040.0032.140686P4, Packaging40020 ≤ 0.006 0.0260.0030.0010.0040.0032.140686P4, Polymerization or reaction2047 ≤ 0.006 ≤ 0.008 0.0030.0030.0000.0010.0031.1807100													
P3, Lab453 ≤ 0.009 0.4290.016133P3, Maintenance7440.0110.0260.02000P3, Polymerization or reaction10018 ≤ 0.006 0.2500.0320.0570.0160.0680.0362.583211P3, Solutions and coagulation4604 ≤ 0.006 0.1640.019125P3, Tank farm4180.0090.6820.0340.1120.0820.2310.0493.62600P3, Unloading area4520.77028.51014.64000P4, Crumbing and drying2413 ≤ 0.005 0.0810.0130.0160.0060.0200.0102.682431P4, Lab6017 ≤ 0.006 0.9430.0690.1840.0670.2750.1022.955318P4, Maintenance617 ≤ 0.006 0.0260.0030.0040.0010.0042.3741680P4, Polymerization or reaction2047 ≤ 0.006 ≤ 0.008 0.0030.0030.0010.0031.1807100													
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P3, Solutions and coagulation4604 \leq 0.0060.1640.019125P3, Tank farm4180.0090.6820.0340.1120.0820.2310.0493.62600P3, Unloading area4520.77028.51014.64000P4, Crumbing and drying2413 \leq 0.0050.0810.0130.0160.0060.0200.0102.682431P4, Lab6017 \leq 0.0060.9430.0690.1840.0670.2750.1022.955318P4, Maintenance617 \leq 0.0060.0260.0030.0040.0010.0042.140686P4, Packaging40020 \leq 0.0060.0260.0030.0060.0010.0042.3741680P4, Polymerization or reaction2047 \leq 0.006 \leq 0.0080.0030.0030.0010.0031.1807100	•											-	
P3, Tank farm 41 8 0.009 0.682 0.034 0.112 0.082 0.231 0.049 3.626 0 0 P3, Unloading area 45 2 0.770 28.510 14.640 0 0 P4, Crumbing and drying 24 13 < 0.005													
P4, Crumbing and drying 24 13 < 0.005 0.081 0.013 0.016 0.006 0.020 0.010 2.682 4 31 P4, Lab 60 17 < 0.006							0.112	0.082	0.231	0.049	3.626	0	
P4, Lab 60 17 < 0.006 0.943 0.069 0.184 0.067 0.275 0.102 2.955 3 18 P4, Maintenance 61 7 < 0.006	-	45	2	0.770	28.510	14.640						0	0
P4, Maintenance 61 7 < 0.006 0.013 0.003 0.001 0.003 2.140 6 86 P4, Packaging 400 20 < 0.006 0.026 0.003 0.001 0.003 2.140 6 86 P4, Packaging 400 20 < 0.006 0.026 0.003 0.001 0.004 0.003 2.140 6 86 P4, Polymerization or reaction 204 7 < 0.008 0.003 0.003 0.001 0.003 2.140 6 86 P4, Polymerization or reaction 204 7 < 0.008 0.003 0.003 0.001 0.003 1.180 7 100		24	13	≤ 0.005	0.081	0.013	0.016	0.006	0.020	0.010	2.682	4	31
P4, Packaging 400 20 < 0.006 0.026 0.003 0.006 0.001 0.004 2.374 16 80 P4, Polymerization or reaction 204 7 < 0.006	P4, Lab	60	17	≤ 0.006	0.943	0.069	0.184	0.067	0.275	0.102	2.955	3	18
P4, Polymerization or reaction 204 7 < 0.006 < 0.008 0.003 0.003 0.000 0.001 0.003 1.180 7 100	P4, Maintenance	61	7	≤ 0.006	0.013	0.003	0.004	0.001	0.004	0.003	2.140	6	86
	P4, Packaging	400	20	≤ 0.006	0.026	0.003	0.006	0.001	0.006	0.004	2.374	16	80
P4, Solutions and coagulation 315 3 ≤ 0.005 ≤ 0.008 0.003 3 100	P4, Polymerization or reaction	204	7	≤ 0.006	≤ 0.008	0.003	0.003	0.000	0.001	0.003	1.180	7	100
	P4, Solutions and coagulation	315		≤ 0.005	≤ 0.008	0.003							100
P4, Tank farm 45 8 < 0.006 12.030 0.392 2.366 1.486 4.203 1.161 3.299 1 12	-												
P4, Warehouse 56 11 < 0.005 < 0.018 0.003 0.004 0.001 0.002 0.004 1.627 10 91	P4, Warehouse												
P5, Crumbing and drying 39 6 0.033 0.116 0.043 0.055 0.013 0.031 0.048 1.697 0 0												-	
P5, Lab 36 8 0.100 8.870 4.580 3.972 1.073 3.035 3.156 1.970 0 0													
P5, Maintenance 80 16 0.072 3.890 0.655 1.200 0.313 1.253 0.830 2.360 0 0	•												
P5, Packaging 44 23 ≤ 0.014 0.144 0.042 0.058 0.007 0.034 0.050 1.730 1 4	P5, Packaging	44	23	≤ 0.014	0.144	0.042	0.058	0.007	0.034	0.050	1.730	1	4

Table 4: Descriptive Statistics Presentation, Example Data Set

					Ι	Descript:	ive Statis	stics			Non-	-Detects
	No. of Exposed	No. of	Minimum	Maximum	Median	Mean	SE (ppm)	Std. Dev.	Geom. Mean	Geom. Std.		
Group	Workers	Samples	(ppm) (a)	(ppm) (a)	(ppm) (a)	(ppm)	(b)	(ppm)	(ppm)	Dev.	No.	Percent
P5, Polymerization or reaction	52	20	0.035	2.800	0.400	0.740	0.198	0.886	0.474	2.568	0	0
P5, Purification	90	12	2.770	24.140	7.580	9.523	1.942	6.727	7.778	1.889	0	0
P5, Solutions and coagulation	555	12	≤ 0.006	0.169	0.090	0.082	0.014	0.047	0.071	1.709	1	8
P5, Tank farm	41	6	1.070	6.010	2.760	3.020	0.714	1.750	2.613	1.713	0	0
P5, Warehouse	30	7	0.033	0.068	0.039	0.045	0.006	0.015	0.043	1.382	0	0

Table 4: Descriptive Statistics Presentation, Example Data Set

(a) The minimum, maximum, and median are provided as additional descriptive statistics.(b) Standard error measures precision of the mean.

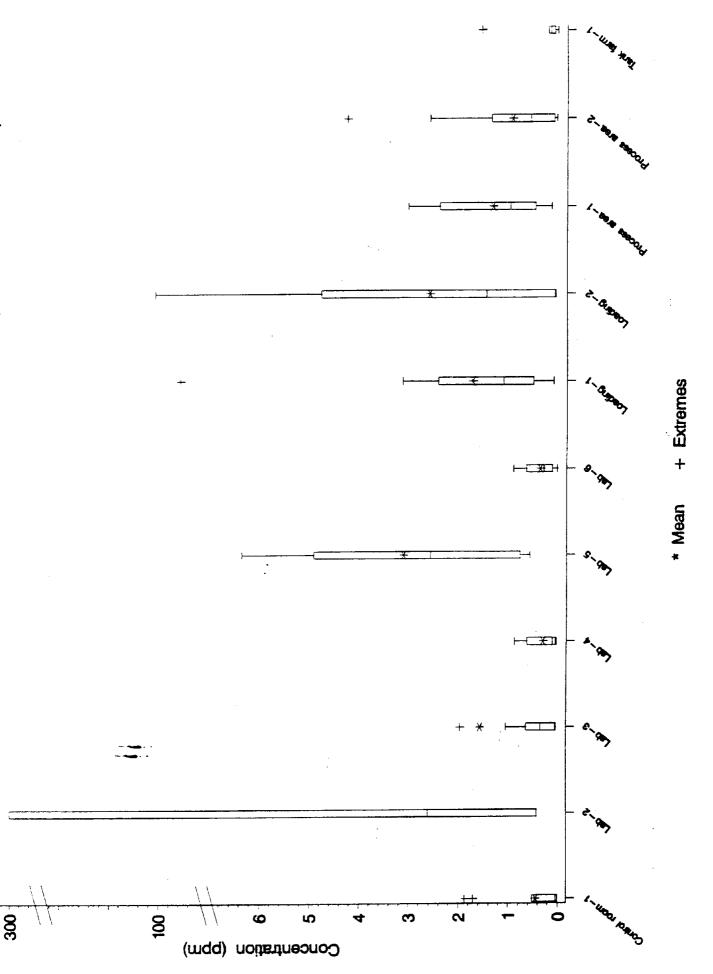
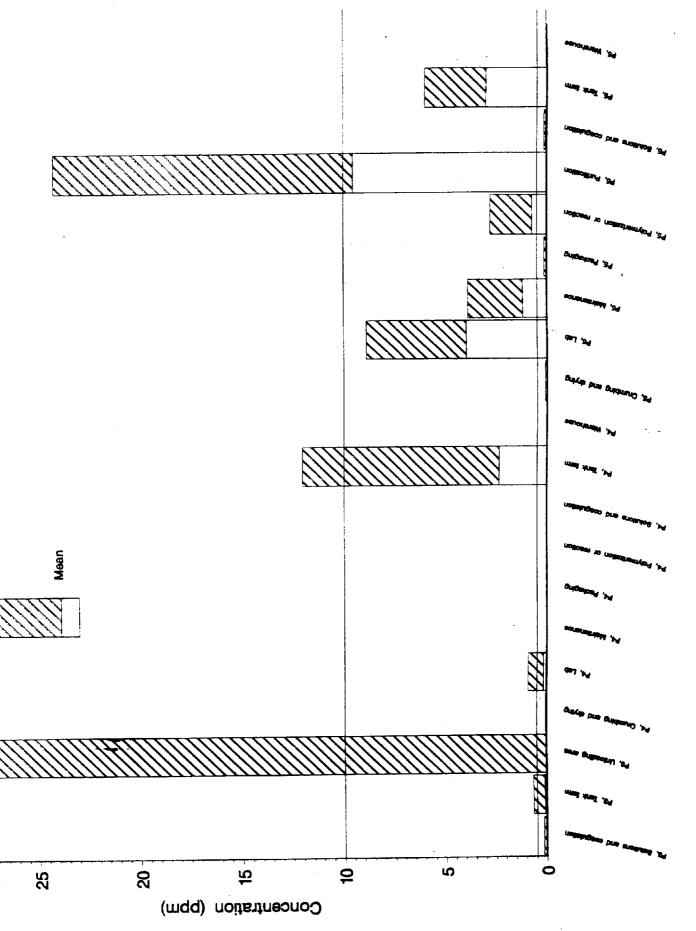
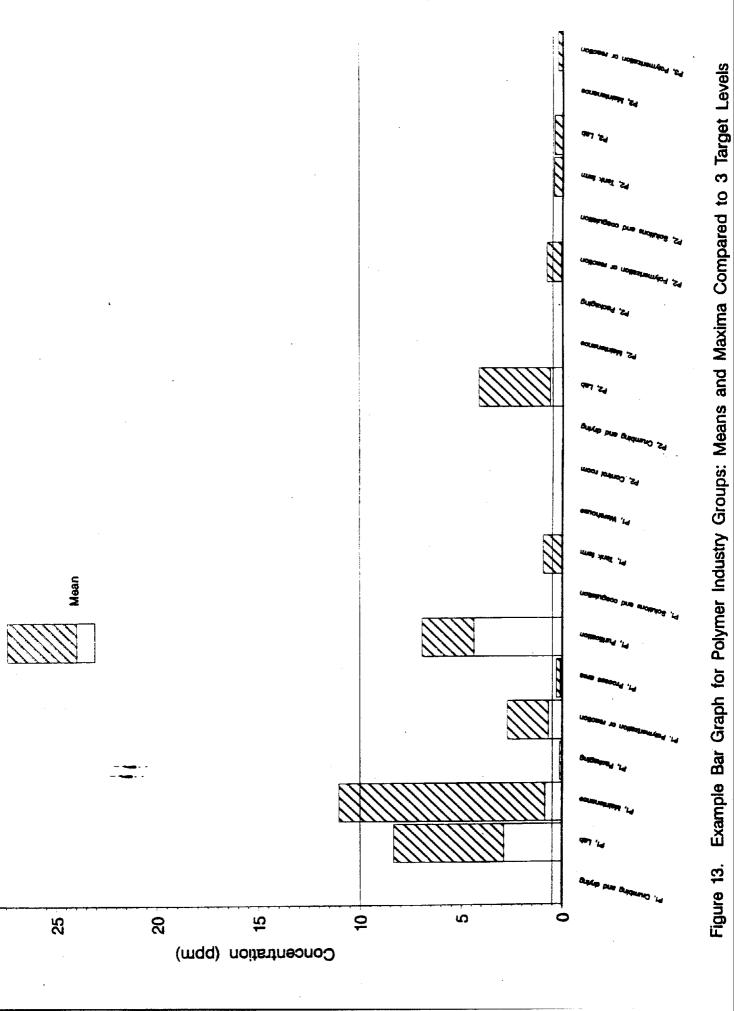


Figure 12. Box-and-Whisker Plot for Monomer Industry Groups



Example Bar Graph for Polymer Industry Groups: Means and Maxima Compared to 3 Target Levels Figure 13.



Uncertainty	Associated assumption	Reasonable possible variance of assumption.	Effect on results
For job category A the length of work day is not known for 30% of the monitoring data.	Length of work day assumed to be 6 hours.	Reasonable range is 5 to 7 hours.	Maximum 6% change in descriptive statistic for job category A (sensitivity analysis).
Actual exposure not known for values recorded as nondetected (5% of values).	A value of $L/\sqrt{2}$ was assumed. L = 1 ppm. ND = 0.71 ppm.	A value of L/2 could better represent actual exposure.	Maximum 2% change in overall descriptive statistic (sensitivity analysis).
NIOSH indicates that data for industry B represents "well controlled" facilities.	None made.	NIOSH personnel roughly estimated that exposures at well controlled facilities can be 20% lower than the industry average.	Descriptive statistics for industry B may underestimate exposure by up to 20% (NIOSH estimate).
Plants in the industry C data set were not randomly selected but rather all available data was used.	The data set for industry C represents the industry as a whole.	Not quantifiable.	Unknown
For job category D only OSHA compliance data were used.	None made.	Not quantifiable.	Facilities where OSHA complaints are made may have higher exposure than the industry as a whole (engineering judgment).
etc.	etc.	etc.	etc.

Figure 14. Example Format for Presentation of Assumptions and Uncertainties.

EXAMPLE

No biases were identified for the Type 1 data. The only assumptions used for the Type 1 data sets were:

- The use of L/2 for the value of nondetected in the calculation of descriptive statistics
- Estimated duration of tasks provided by the companies where the monitoring was done were used to convert some values to 8-hour TWAs.

For the Type 2 data, the following bias was identified:

• Some Type 2 data was taken using the old analytical method which may overestimate concentrations due to interference by other C₄ chemicals.

The bias associated with the Type 2 data may explain discrepancies between the Type 1 and Type 2 analysis results.

D. Present Original Data

Even though every attempt should be made to satisfy user needs, poor communication or changing requirements may dictate changes even after the exposure assessment is finalized. Therefore, presentation of all original data used in the calculations and all important variables associated with the data will allow additional statistics to be calculated by the end user when required.

EXAMPLE

Appendix A presents the 516 full shift personal samples that were used in the example calculations in this report.

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GLOSSARY OF TERMS

- <u>Accuracy</u> the measure of the correctness of the data, as given by the difference between the measured value and the true value.
- <u>Sample Mean</u> the sum of all the measurements in the data set divided by the number of measurements in the data set.
- Bias a systematic error inherent in a method or caused by some feature of the measurement system.
- <u>Bimodal Distribution</u> a probability density function with two relative maxima values.
- <u>Bounding Estimate</u> an estimate of exposure that is higher than the exposure of the individual in the population with the highest exposure. Bounding estimates are useful in constructing statements such as ".. exposure is not greater than" the estimated value.
- <u>Confidence Interval</u> a range of values that contains the true value of a parameter in a distribution a predetermined proportion of time if the process of determining the value is repeated a number of times.
- <u>Descriptive Statistics</u> statistics that describe conditions and events in terms of the observed data; use is made of tables, graphs, ratios, and typical parameters such as location statistics (e.g., arithmetic mean) and dispersion statistics (e.g., variance).
- <u>Frequency Histogram</u> a graphical representation of a frequency distribution, typically using bars to exhibit the frequency or relative frequency of occurrence of each value or group of values in a data set.
- Geometric Mean the nth root of the product of n values.
- <u>High End Estimate</u> a plausible estimate of individual exposure for those persons at the upper end of an exposure distribution, conceptually above the 90th percentile, but not higher than the individual in the population with the highest exposure.
- <u>Homogeneous Categories</u> groups or categories with the same or similar modifying attributes.
- <u>Limit of Detection</u> the minimum concentration of an analyte that, in a given matrix and with a specific method, has a 99% probability of being identified, qualitatively or quantitatively measured, and reported to be greater than zero.
- <u>Log-normal Distribution</u> a probability distribution restricted to positive real values. If the random variable Y has a log-normal distribution, then $X = \log_e Y$, then X has a normal distribution.
- <u>Maximally Exposed Individual (MEI)</u> a semiquantitative term referring to the extreme uppermost portion of the distribution of exposures. For consistency, this term should refer to the portion of the individual exposure distribution that conceptually falls above the 98th percentile of the distribution, but is not higher than the individual with the highest exposure.
- <u>Maximum-Likelihood Estimate</u> an estimate based on finding the values of parameters that give the maximum value of the likelihood function. The likelihood function is the probability of observing the data, as a function of the parameters defining a distribution. The maximum likelihood approach is applicable whenever the underlying distribution of the data is known or assumed. It is a common statistical estimation procedure.

- <u>Median</u> the value in a measurement data set such that half the measured values are greater and half are less.
- <u>Nonparametric Statistical Methods</u> methods that do not assume a functional form with identifiable parameters for the statistical distribution of interest (distribution-free methods).
- <u>Normal Distribution</u> a symmetric probability distribution whose maximum height is at the mean, applicable to positive and negative real numbers. The normal distribution is the common "bellshaped" curve. Also called a Gaussian distribution.
- Precision a measure of the reproducibility of a measured value under a given set of conditions.
- <u>Probability Sampling</u> sampling method in which each population element has a known and nonzero probability of being selected. Basic probability sampling methods include simple random sampling, stratified sampling, and cluster sampling.
- <u>Quantification Limit</u> the concentration of analyte in a specific matrix for which the probability of producing analytical values above the method detection limit is 99%.
- <u>Random Sampling</u> the selection of a sample of size n in such a way that each possible sample of size n has the same chance of being selected.
- <u>Reasonable Worst Case</u> a semiquantitative term referring to the lower portion of the high end of the exposure distribution. For consistency, it should refer to a range that can conceptually be described as above the 90th percentile in the distribution, but below about the 98th percentile.
- <u>Representativeness</u> the degree to which a sample is, or samples are, characteristic of the whole medium, exposure, or dose for which the samples are being used to make inferences.
- <u>Sample</u> a small part of something designed to show the nature or quality of the whole. Exposurerelated measurements may be samples of exposures of a small subset of a population for a short time, for the purpose of inferring the nature and quality of the parameters important to evaluating exposure.
- <u>Sample Cumulative Distribution Function</u> a function that estimates the theoretical cumulative distribution function of a population. If a sample of n independent values is available, the value of the sample cumulative distribution at x is the proportion of the sample values that are less than or equal to x.
- <u>Standard Deviation</u> a measure of the variability of the values in a sample or a population. The positive square root of the variance of the distribution.
- <u>Statistical Inference</u> the process of using knowledge about samples to make statements about the population.
- <u>Statistical Significance</u> an inference that the probability of an observed pattern (with respect to the data being measured or the comparison being made) is so low that it is highly unlikely to have occurred by chance alone (within the constraints of the hypothesis being tested). The inference is that the hypothesis being tested is probably not true; that hypothesis is rejected in favor of a stated alternative hypothesis.

Statistically Selected Sample - a sample chosen based on a statistically valid sampling plan.

<u>Stratified Random Sample</u> - a sample obtained by separating the population elements into nonoverlapping groups called strata, and then selecting a simple random sample for each stratum.

- <u>Theoretical Cumulative Distribution Function</u> a function that uniquely defines the probability distribution of a random variable, x. The function specifies the probability that the random variable assumes a value less than or equal to x.
- <u>Worst Case</u> a semiquantitative term referring to the maximum possible exposure that can conceivably occur, whether or not this exposure actually occurs or is observed in a specific population.

APPENDIX A

SPREADSHEET MATRIX FOR TYPE 1 EXAMPLE DATA SET FULL SHIFT PERSONAL SAMPLES

APPENDIX A

The data set presented in Appendix A represent 516 full-shift personal samples grouped into 58 initial categories. In addition to these data, 37 short-term samples and 232 area samples were collected. Since these data were not used in the example analysis they were set aside and are not presented in this appendix.

Table A-1. Spreadsheet Matrix for Type 1 Example Data Set - Full Shift Personal Samples

	Control description	Single mechanical seals & open-loop bomb sampling	Dual mechanical seals on pumps & closed-loop sampling	Dual mechanical seals on pumps & closed-loop sampling	Dual mechanical seals on pumps & closed-loop sampling	Dual mechanical seals on pumps & closed-loop sampling	Dual mechanical seals on pumps & closed-loop sampling	Dual mechanical seals on pumps & closed-loop sampling	Single mechanical seals & open-loop bomb sampling	General room ventilation	General room ventilation	General room ventilation			General room ventilation	Slip-tube gauge	Slip-tube gauge	Slip-tube gauge	Magnetic gauge	Magnetic gauge	Magnetic gauge	Rotameter gauge	Rotameter gauge	Rotameter gauge																							
8-hr TWA.	(wdd)	0.57	<=0.18	1.71	0.74	0.37	<=0.27	0.70	1.23	2.37	2.98	0.46	4.19	<=0.19	1.34	0.09	1.76	0.49	2.11	<=0.07	1.00	0.92	<=0.08	2.55	0.29	0.55	0.27	<=0.14	<=0.02	<=0.02	<=0.02	0.25	<=0.08	0.52	<=0.04	<=0.11	1.87	1.70	0.50	1.44	1.29	<=0.13	<=0.12	0.46	2.40	5.46	0.08
Sample	(min)	460	470	506	457	449	260	437	452	452	454	451	432	435	437	436	461	441	459	424	473	496	434	430	456	471	465	420	466	447	485	455	451	452	442	425	453	449	415	428	427	474	260	442	484	474	446
Control	type (b)	2	2	2	2	2	-	-	-	-		-	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	-	-		-	-	-	-	-	-	-	-	-	-	5	2	2	2	2	2
	Job title	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician					
	Process type	Process area	Process area	Process area	Process area	Process area	Process area	Process area	Process area	Process area	Process area	Process area	Process area	Process area	Process area	Process area	Process area	Process area	Process area	Process area	Process area	Process area	Process area	Control room	Control room	Control room	Control room	Control room	Control room	Control room	Control room	Control room	Control room	Loading area	Loading area	Loading area	Loading area - railcar	Loading area - railcar	Loading area - railcar	Loading area/semi-tractor trailer		Loading area/semi-tractor trailer					
1D0	(a)	-	-	-	-	-	3	7	3	5	5	3	e	m	m	m	4	4	4	4	4	4	4	4	4	4	4	4	S	S	s	9	9	9	-	~	00	~	6	6	6	10	10	10	10	10	10
	Industry	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer
Plant	Q	Ш	IW	IW	IW	IW	M2	M2	M2	M2	M2	M2	M3	M3	M3	M3	M4	IW	IW	IW	M2	M2	M2	M3	M3	M4	M4	M2	M2	M2	M3	M3	M3	M3	M3	M3											

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Control description	Slip-tube gauge	Slip-tube gauge	Make-up air 100% for lab ventilation; MFV of hoods: 82 lipm	Make-up air 100% for lab ventilation; MFV of hoods; 82 lipm	Make-up air 100% for lab ventilation; MFV of hoods: 82 lipm	Make-up air 100% for lab ventilation; MFV of hoods: 82 lfpm	Make-up air 100% for lab ventilation; MFV of hoods: 82 lfpm	Make-up air 100% for lab ventilation; MFV of hoods: 82 Ifpm	Lab ventilation (12 air changes/hour); MFV of hoods: 178 & 163 Ifpm	Lab ventilation (12 air changes/hour); MFV of hoods: 178 & 163 lfpm	Lab ventilation (12 air changes/hour); MFV of hoods: 178 & 163 lfpm	Lab ventilation (12 air changes/hour); MFV of hoods: 178 & 163 lfpm	Lab ventilation (12 air changes/hour); MFV of hoods: 178 & 163 lfpm	Lab ventilation (12 air changes/hour); MFV of hoods: 178 & 163 lfpm	Lab ventilation (12 air changes/hour); MFV of hoods: 178 & 163 lfbm	Lab ventilation (12 air changes/hour); MFV of hoods: 178 & 163 lfpm	Lab ventilation (12 air changes/hour); MFV of hoods: 178 & 163 lfbm	Make-up air 50% for GV; MFV of hoods:70 lfpm; exhaust enclosure for hom	Make-up air 50% for general ventilation; MFV of hoods: 110 lfbm	Make-up air 50% for general ventilation; MFV of hoods: 110 lfpm	Make-up air 50% for GV; MFV of hoods:70 lfpm: exhaust enclosure for lpm	Make-up air 50% for general ventilation; MFV of hoods: 110 lfpm	Make-up air 50% for general ventilation; MFV of hoods: 110 ffpm	Make-up air 50% for general ventilation; MFV of hoods: 110 lfpm	Make-up air 60% for lab ventilation; MFV of hoods: 61 lfpm	Make-up air 60% for lab ventilation; MFV of hoods: 138 Ifpm	Make-up air 60% for lab ventilation; MFV of hoods: 138 Ifpm	Make-up air 60% for lab ventilation; MFV of hoods: 61 lfpm	Make-up air 60% for lab ventilation; MFV of hoods: 61 Ifpm	Make-up air 60% for lab ventilation; MFV of hoods: 138 Ifpm	Make-up air 60% for lab ventilation; MFV of hoods: 61 lipm	Steam manifold with enclosed exhaust system	Steam manifold with enclosed exhaust system	Steam manifold with enclosed exhaust system												
hr TWA, (ppm)	123.57	3.97	0.05	0.62	0.87	0.15	0.07	0.03	1.96	<=0.10	<=0.08	0.36	0.34	<=0.09	0.63	0.25	1.04	<=0.04	0.63	0.89	0.23	0.28	0.28	0.12	0.56	0.76	1.73	4.82	4.88	2.55	6.31	373.54	2.61	0.42	0.20	<=0.04	<=0.31	<=0.15	1.53	0.770	28.510	0.362	0.436	0.687	0.113	0.962
Sample duration 8-hr TWA (min) (ppm)	443	459	484	483	478	492	486	487	410	392	463	467	418	395	490	463	498	464	441	159	470	449	449	451	454	410	449	472	515	474	467	452	482	400	485	502	210	491	476	245	229	510	510	473	485	485
Control (type (b)	2	2	4	4	4	4	4	4	ŝ	ŝ	ŝ	ŝ	3	ß	3	S	3	9	9	9	9	9	9	9	5	5	5	5	5	5	5	2	2	2	1	1	1	1	1	2	2	1	1	-	1	
Job title	Process technician	Process technician	Lab technician - Wet	Lab technician - Dry	Lab technician - Dry	Lab technician - Wet	Lab technician - Wet	Lab technician - Dry	Lab technician - Wet	Lab technician - Supervisor	Lab technician - Supervisor	Lab technician - Dry	Lab technician - Dry	Lab technician - Supervisor	Lab technician - Wet	Lab technician - Wet	Lab technician - Dry	Lab technician - Dry	Lab technician - Dry	Lab technician - Wet	Lab technician - Dry	Lab technician - Wet	Lab technician - Wet	Lab technician - Wet	Lab technician - Dry	Lab technician - Wet	Lab technician - Wet	Lab technician - Dry	Lab technician - Dry	Lab technician - Wet	Lab technician - Dry	Lab technician - Bomb voiding	Lab technician - Bomb voiding	Lab technician - Bomb voiding	Process technician											
Process type	Loading area	Loading area	Laboratory	Laboratory	Laboratory	Laboratory	Laboratory	Laboratory	Laboratory	Laboratory	Laboratory	Laboratory	Laboratory		Laboratory	Laboratory	Laboratory																	area	Unloading area	Tank farm	Tank farm			Tank farm						
1D0 (a)	Ξ	Ξ	12	12	12	12	12	12	13	E	13	13	13	13	E	I3	13	4	14	4	14	14	14	4	15	15		_	_	-	_	-		16	11	17	17	17	17	18 1		19 T	19 I	-		19 I
Industry	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Monomer	Polymer	Polymer	Polymer	Polymer	Polymer		Polymer
Plant ID	M4	M4	¥.	W	W	W	W	W	M2	M3	M3	W3	M3	M3	M3	M3	M4	M4	M4	M4	M4	M4	M4	M4	M4	M4	M4	M4	M4	M4	M4	P3	P3	Id	Ы	Ы	Z	H								

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Sample duration 8-hr TWA, (min) (ppm)	0.362	0.436	0.125	0.030	110.0	0.013	0.682	0.033	0.063	0.048	0.009	1.372	12.029	4.632	<=0.006	0.584	0.072	0.201	0.035	2.671	1.698	6.012	2.853	3.822	1.066	1.798	6.018	1.331	5.585	4.457	6.954	6.776	21.877	3.690	24.138	5.882	10.822	6.916	5.081	8.386	8.246	9.686	2.774	2.714	0.068	1.259
Sample duration (min)	438	444	436	496	467	466	469	455	487	406	396	491	501	383	485	472	464	477	447	479	470	472	471	470	290	494	477	499	472	481	472	469	227	432	446	449	441	458	480	437	448	449	462	509	489	469
Control type (b)	1		- 0	7	2	2	2	2	2	2	2	2	7	2	2	2	2	2	2	2	2	2	2	2	2	-	-	-	-	-	-	2	2	5	2	2	2	2	2	5	2	5	2	-	-	-
Job title	Process technician	Process technician	Process technician																																											
Process type	Tank farm	Purification	Polymerization or reaction	Polymerization or reaction	Polymerization or reaction																																									
1D0 (a)	20	20	20	21	21	21	21	21	21	21	21	22	22	22	22	22	22	22	22	23	33	33	23	23	23	24	24	24	24	24	24	25	25	25	25	25	25	25	25	25	25				_	
Industry	Polymer	Polvmer	Polymer	Polvmer	Polvmer	Polymer	Polvmer	Polymer	Polymer																																					
Plant	P2	P2	P2	P3	P4	. b4	. X	e K	2 12	i X	: X	a a	Ы	Id	Ε	Id	ΡI	Ы	P5	P5	P5	P5	P5	BS	P5	PS	P5	5d	P5	P5	Id	bi	Id													

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Sample duration 8-hr TWA,	(mdd)	0.035	0.047	0.052	161.0	150.0	6/0.0	0.194	0.073	0.016	0.033	0.012	0.779	0.022	<=0.008	0.027	0.068	0.028	0.041	0.031	0.041	0.015	0.055	0.022	0.047	0.112	<=0.008	0.012	0.050	0.138	0.016	0.031	0.052	0.250	0.200	0.012	0.036	0.009	0.033	<=0.006	0.032	<=0.006	0.105	0.033	0.079	0.021	160.0
Sample duration	(min)	510	491	470	441	450	443	450	462	455	451	455	447	451	345	462	438	460	449	453	453	437	455	458	457	449	346	457	384	451	458	458	457	498	401	471	426	480	489	473	508	497	495	424	472	465	408
Control	type (b)	-	-					-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	_	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Job title	Process technician																																													
	Process type	Polymerization or reaction																																													
Do	(a)	26	26	26	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	28	28	28	28	28	28	28	28	28	28	28	28	28	28
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Sample duration 8-hr TWA, (min) (ppm)	0.043	0.014	0.026	0.028	<=0.006	<=0.006	<=0.008	<=0.006	<=0.006	<=0.006	<=0.008	0.348	0.467	0.524	0.066	0.544	0.125	0.614	0.156	1.471	0.343	1.524	0.451	2.303	0.082	2.553	0.196	2.800	0.064	0.035	0.135	0.027	0.020	0.019	0.024	0.032	0.023	0.025	0.028	0.046	0.038	0.032	0.018	0.015	0.028	0.164
Sample duration (min)	493	462	399	475	487	432	349	470	472	473	335	435	433	463	460	446	453	445	470	476	469	471	432	474	449	362	431	468	440	434	469	457	475	468	453	509	490	482	465	325	461	463	410	422	474	483
Control type (b)		1	-	-	5	2	5	2	2	2	2	2	2	2	2	2	2	2	2	7	2	2	2	2	2	2	2	2	2	7	7	5	2	5	2	2	2	2	2	2	2	2	2	2	2	2
Job title	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician																														
Process type	Polymerization or reaction	Solutions and coagulation																																												
(a)	28	28		28	29	29	29	29	29	1000	29	30		-	30		30	30	30	30		30	30	30		30	30	-		30	30	31	31	31	31	31	31	31	31	31	32	32	32	32	32	33
Industry	Polvmer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer																													
Plant ID	E	P3	P3	£	P4	P5	ß	P2	PS	PS	P3	P5	PS	P5	PS	PS	PS	£	PS	PS	P5	P5	P5	R	S	Ы	ΡI	Ы	ΡI	ΡI	Ы	Id	Id	PI	P2	P2	P2	P2	P2	P3						

8-hr TWA.	(mdd)	0.018	<=0.006	0.021	<=0.008	<=0.005	<=0.006	0.092	0.134	0.109	0.087	0.042	0.080	0.169	<=0.006	0.037	0.095	0.107	0.028	0.014	0.043	0.071	0.031	0.028	0.053	0.069	0.039	0.040	0.019	0.027	0.042	0.052	0.018	0.025	0.041	<=0.005	0.013	0.014	<=0.006	<=0.006	0.015	0.081	0.019	<=0.006	600.0	0.017	0.010
Sample	(min)	462	469	399	367	522	450	436	406	463	433	443	443	419	456	453	416	412	448	480	467	501	458	475	462	491	487	475	412	337	435	298	407	407	185	496	513	467	449	483	478	501	523	498	501	478	483
Control	type (b)	2	2	5	5	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	5	2	2	2	2	2	2	2	2	2	2	2	2	7	2	2	2	2	2	2	2	2	2	2	7	2	2
	Job title	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician																	
	Process type	Solutions and coagulation	Crumbing and drying																																												
0(11	(a)	33	33	33	34	34	34	35	35	35	35	35	35	35	35	35	35	35	35	36	36	36	36	36	36	36	36	36	37	37	37	37	37	37	37	38	38	38	38	38	38	38	38	38	38	38	38
	Industry	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer																	
Plant	Ð	P3	P3	B	P4	P4	P4	P5	PS	PS	P5	P5	P5	PS	P5	PS	PS	P5	P5	ΡI	ΡI	Ы	Ы	Ы	Ы	ΡI	Ы	Η	P2	P4																	

Control description																																												
Sample duration 8-hr TWA, (min) (ppm)	0.017	0.048	0.033	0.038	0.116	0.036	0.059	0.037	0.031	0.020	0.029	0.154	0.014	0.102	0.056	0.012	0.022	0.050	0.020	0.014	0.067	190.0	0.031	5000	020.0	0.074	0.069	0.026	0.012	0.025	0.024	0.018	0.036	0.040	0.014	0.014	100.0	0.00	860.0	0.034 CCA 0	0.022	150.0	<=0.008	. 0.00
	509	454	470	454	439	430	438	478	461	462	475	490	460	476	481	490	469	492	459	490	481	463	486	462	407	493	481	492	492	469	431	422	448	464	404	114	004	4/0	C+++	144	421	449	403	
Control type (b)	6	10	2	2	2	2	2	2	2	2	2	2	2	5	2	5	2	2	2	2	20	2	2	C1 C	7 0	10	10	2	2	2	2	0 0	2	2 0	4 0	4 0	4 0	7 0	4 (4 0	2 0	7 0	7	•
Job title	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process technician	Process lechnician	Process technician	r locess technician Decrease technician	E locess technician Decess technician	Process technician	Decress technician	Process technician	Process technician	Process technician	Process technician	
Process type	Crumbing and drying	0 0		Crumbing and drying	Crumbing and drying	Crumbing and drying	Crumbing and drying		Packaging	Portraging	r achaging Packaoine	Packaging	Packaging		Packaging	Packaging	Packaging	Packaging	Packaging	Fackaging Darbaaina	Fachaging Decleration		rackaging	rackaging	Prockaging	Packaging	Packaging	Packaging																
(a)	38		-		39	39	39	40	40	40	40	40	40	40											99				40					99										
Industry	Palvmer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	rolymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	
Plant ID	Fd	: 2	2	2	S	S	PS	Id	Ы	Ы	Ы	E	E	Ы	Ы	Ы	Ы	Ы	Z	Ы	Ξ	E	Ξ	2 3	E	E	: =	E	Η	Id	Ы	E	Ξ	E a	Zā	2 8	7.1	7.1	74	27	52	P2	P4	

	Sample 8 to TWA	(mqq)	<=0.006	<=0.006	0.013	<=0.006	<=0.007	<=0.007	0.026	<=0.006	<=0.006	<=0.006	<=0.006	<00.0=>	0.013	<=0.00/	0.012	<=0.006	<=0.006	0.032	0.033	0.037	0.100	0.100	0.036	<=0.014	0.036	0.144	0.044	0.100	0.042	0.051	0.076	0.088	0.037	0.076	0.039	0.028	0.033	0.112	0.029	0.058	0.020	0.014	0.007	<=0.008	<=0.008	<=0.006
•2	Sample	(mim)	441	496	488	468	449	406	278	465	463	458	444	211	494	765	461	46/	473	471	413	433	458	451	438	161	436	417	452	449	459	442	432	439	435	460	463	420	473	444	475	463	461	464	448	476	394	479
	later.	type (b)	2	2	2	7	7	2	7	2	7	7	6	2	0 0	7	7 1	7	7	2	2	2	7	6	2	2	7	7	7	7	7	2	7	7	2	7	7	2	2	2	2	7	2	2	2	5	5	2
		Job title	Process technician																																													
		Process type	Packaging	Warehouse	Warehouse	Warehouse	Warehouse	Warehouse	Warehouse																																							
	W.II	(a)	42	42	42	42	42	42	42	42	42	42	42	42	42	42	42	42	42	43	43	43	43	43	43	43	43	43	43	43	43	43	43	43	43	43	43	43	43	43	43	43	44	44	45	45	45	45
		Industry	Polymer																																													
		E A	P4	P5	ĿS	P5	Ρl	Ρl	P4	P4	P4	P4																																				

Sample duration 8-hr TWA, (min) (ppm)	<=0.006	<=0.006	<=0.006	<=0.007	<=0.005	<=0.006	<=0.018	0.039	0.043	0.034	0.034	0.064	0.033	0.068	0.081	4.360	0.057	5.860	0.253	7.714	1.561	0.858	0.015	8.329	0.058	0.052	0.029	0.029	1.954	0.032	2.398	0.038	4.116	0.050	0.050	0.034	0.029	0.029	<=0.009	0.016	0.429	0.057	0.336	0.782	<=0.010	0.943
	488	473	469	430	518	483	150	419	423	429	458	415	468	419	503	458	483	457	452	437	469	443	442	462	439	438	445	437	394	440	437	432	441	435	447	392	442	437	310	355	354	500	488	473	272	385
Control type (b)	2	2	5	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	7	2	2	2	2	2	2
Job title	Process technician	Laboratory tech - analysis																																												
Process type	Warehouse	Laboratory																																												
11D0 (a)	45	45	45	45	_		45	46	46	46	46	46	46	46	47	47	47	47	47	47	47	47	47	47	48	48	48	48	48	48	48	48	48	48	48	48	48	48	49	49	49					
Industry	Polvmer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polvmer	Polvmer	Polvmer	Polvmer	Polymer	Polymer	Polymer	Polymer													
Plant	P4	P5	P5	P5	53	S	15	PS	Ы	Ы	ΓI	Ы	ΡI	Ιd	Ы	Ы	Ы	Ы	P2	P3	Ed	e ca	P4	P4	P4	P4	$\mathbf{P4}$																			

Sample duration 8-hr TWA.	(udd)	0.023	0.176	<=0.006	0.286	0.069	<=0.006	0.103	600.0	0.062	0.142	0.098	0.023	0.100	6.130	0.272	8.865	4.239	5.360	4.915	1.895	0.045	0.045	0.018	2.616	0.089	8.035	0.021	080.0	090.0	0.084	0.015	0.149	0.093	0.967	0.252	0.169	0.168	0.185	0.038	0.077	0.036	0.027	0.198	0.089	0.138	11.020
Sample duration	(min)	481	295	484	469	483	483	481	486	483	480	478	474	411	430	415	475	441	420	439	476	470	464	471	456	439	442	461	388	470	385	467	439	450	470	467	464	463	462	459	438	522	438	432	481	475	469
Control	type (b)	2	2	5	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	7	2	2	2	7	2	2	2	2	2	2	2	2	2	2	2	2
	Job title	Laboratory tech - analysis	Maintenance																																												
	Process type	Laboratory																									•																				
ID0	(a)	50	50	50	50	20	20	50	50	50	50	50	50	51	51	51	51	51	51	51	51	52	52	52	52	52	52	52	52	52	52	52	52	52	52	52	52	52	52	52	52	52	52	52	52	52	52
	Industry	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer		Polymer																			
Plant	Ð	P4	R	53	R	P5	R	P5	PS	P5	Ы	Ы	Ы	Ы	Ы	Η	μ	Ы	ΡI	Ы	Ы	ΡΙ	Ы	ΡΙ	Ы	ΡI	Id	Ρl	Η	Ρl	Ρl	ΡI	Ы	Γl	ΡI	Id											

Table A-1. Spreadsheet Matrix for Type 1 Example Data Set - Full Shift Personal Samples

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Sample duration 8-hr TWA.	(mdd)	0.423	0.680	0.108	0.034	0.081	0.476	0.213	0 450	1000	0.033	0.075	0.076	0.037	0.038	0.022	0.048	0.030	0.021	0.026	0.019	0.011	0.013	<=0.006	<=0.006	<=0.006	<=0.006	<=0.006	<=0.006	2.709	1.754	0.072	1.742	0.795	1.290	0.927	0.130	0.333	0.275	3.891	0.516	0.406	0.421	3.743	0.204	0.062	0.070
Sample duration 8	(mim)	320	441	460	490	464	182	461	452	101	426	180	379	375	372	374	368	464	401	403	401	402	428	492	489	483	489	474	483	444	437	448	442	449	454	284	379	445	490	453	468	334	478	461	476	445	445
Control	type (b)	2	¢	10	10	. (0	10		10	10	10	40	2	5	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	5	2	2	2	2	2	2	2	2	5	2	2	. 61	2	2
	Job title	Maintenance	Process technician	Process technician																																											
	Process type																																													Control room	Control room
001	(a)	5		2 5	5	3.5	5	3 5			3 5	3 5		_		53	53	53	54	_	54		55	55	55	35	55	55	55	56	56	56	56	56	56	56	56	56	56	56	56	56	56	56	56	57	57
	Industry	Polymer	Delement	Polymer	Palvmer	Polymer	Palvmer	Palvmar	Dolymor	Dolymor	Dalumar	Dolumor	Polymer	Polymer	Polymer	Polvmer	Polvmer	Polvmer	Polymer	Polvmer	Polymer	Polymer	Polymer	Polymer																							
Plant	QI	Id	G	Ξ	ā	: a	ā	1	1	- 6	71	71	5.J	2.4	P2	P2	P2	P2	P3	P3	P3	P3	P4	P5	P5	P5	S	P5	P5	P5	P5	S	PS	P5	P5	P5	PS	5d	P5	P2	P2						

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Table A-1.

Control description							
ControlSample duration8-hrTWAtype (b)(min)(ppm)	<=0.008	<=0.006	0.304	0.056	<=0.006 0.230	0.023	0.094
Sample duration (min)	366	452	434	449	487	456	486
Control type (b)	2 0	101	7 7	2 0	7 7	2	2
Job title	Process technician Process technician	Process technician	Utilities operator	Utilities operator	Utilities operator	Utlities operator	Utlities operator
Process type	Polymer 57 Control room Polymer 57 Control room	Polymer 57 Control room			Polymer 58 Process area	Polymer 58 Process area	Polymer 58 Process area
(a)	57 57	57	58	58	28 0	58	58
Industry (a)	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer	Polymer
Plant ID	P2 P2	P2 P2	P1	Id	L L	Ы	Id

(a) IID0 = Initial categories (b) The following are the control types: 1) controlled, 2) uncontrolled, 3) laboratory with 12 air changes/hr, 4) 100 percent make-up air in laboratory, 5) 50 percent make-up air in laboratory, 6) 60 percent make-up air in the laboratory.

Note: Source of data - NIOSH/EPA field study. Laboratory analysis limit of detection ranged from 2 to 11 µg/sample, depending on the day of the analysis. Samples from the same plant and process type were collected on different days. **APPENDIX B**

BACKGROUND INFORMATION ON STATISTICAL METHODOLOGY

APPENDIX B

BACKGROUND INFORMATION ON STATISTICAL METHODOLOGY

This appendix presents background information for statistical methods used in these guidelines, as well as others that may be useful in the context of occupational exposure monitoring. Some of the topics include log-normal distributions, analysis of variance, data transformations, tests of distributions, cluster analysis, outliers, and confidence intervals. The engineer may wish to become familiar with these methods and the statistical assumptions associated with each method. References such as Massey, 51, for the K-S test; Cochran, 63; Daniel, 78; Conover, 80; etc. should be obtained and consulted, as needed. EPA statisticians should also be consulted, as required.

Box-and-Whisker Plot

Box-and-whisker plots are useful for the graphical identification of possible outliers. The box plot presents a clear depiction of outliers, compared to the majority of the whole data set. The box portion of a box plot extends from the 25th percentile to the 75th percentile of the observed data (i.e., 25% of the observations are at or below the bottom of the box and 25% are above the top of the box). That range is called the interquartile range. The whiskers extending from the box cover only 1.5 times the interquartile range. Any points outside 1.5 times the range are presented individually. This allows clear identification of outliers.

Analysis of Variance

Analysis of variance is the basis for many statistical techniques. It is applicable to normally distributed data (observations for which the errors are assumed to be normally distributed), especially in the context of testing for significance of possible explanatory variables.

Nested analysis of variance is a particular form of analysis of variance that addresses the issues associated with hierarchical (nested) data structures. In such structures, the variations induced by one variable are nested within (vary around) means that are dependent on the value of another variable, and which may also vary. Box (78) presents a nice discussion of nested designs and their analysis. Samuels (85) discusses the nested structure for occupational exposure data.

Tests of Distributions

The guidelines assume a log-normal distribution but there are three common approaches to quantitatively testing groups of data to determine if they can be described by certain distributions: the Shapiro-Wilk statistic, the Kolmogorov-Smirnov approach, and the ratio statistic.

The Shapiro Wilk statistic involves covariances between the order statistics of a standard normal distribution. It is similar to a test that examines the correlation (squared) between the observed order statistics and hypothetical order statistics. Order statistics are simply the observations (or hypothetical values) arranged in ascending order: the first order statistic is the smallest value, the second order statistic is the next smallest, etc. Simulation studies have suggested that the Shapiro-Wilk statistic is more powerful than the Kolmogorov-Smirnov test. Note that it can be applied only for testing for normality. Bickel (77) gives a short discussion and references to material on the Shapiro-Wilk statistic.

The ratio test was proposed in Waters (91) as a procedure for testing for log-normality. It makes use of two estimates of the mean of a log-normal distribution. In fact the ratio that gives this test its name is the ratio of those two estimates and is very easy to calculate. Its application requires the estimation of the coefficient of variation (related to the geometric standard deviation) and use of tables derived in Waters (91). Those tables are not complete for large values of the coefficient of variation. Waters (91) compared the ratio test favorably to the Shapiro-Wilk and Kolmogorov-Smirnov approach.

The Kolmogorov-Smirnov (K-S) approach is a widely used technique. The particular application presented here is for testing for normality, and has been called the Lilliefors test. K-S approaches are applicable more generally for testing for a variety of distributions.

The calculations needed to apply the Lilliefors test are discussed in some detail here. The procedure consists of the following: 1) deriving the sample cumulative distribution function for the observed data; 2) calculating the sample mean of the data (which may be concentrations if testing for normality or log-transformed concentrations if testing for log-normality); 3) calculating the sample standard deviation of the data; 4) standardizing the data; 5) determining the theoretical cumulative distribution; 6) identifying the value for passing the K-S test (the critical value); 7) calculating the maximum difference between the theoretical cumulative distribution and the sample cumulative distribution (the test statistic); and 8) determining if the data pass the test.

1. Derive the Sample Cumulative Distribution Function

The monitoring results for a group are arranged in ascending order: lowest value first and the highest value last. Next, the values for the sample cumulative distribution function are calculated on the sorted data. The cumulative distribution function for each data point is equal to the proportion of values less than or equal to the given point, as presented in Equation B1.

$$SCD_i = i / n$$
 Equation B1

where:

 $SCD_i =$ the sample cumulative distribution function value for observation i number of data points.

2. Calculate the Sample Mean of the Data

The sample mean of the data is calculated using Equation 9 (for the concentrations) or Equation 2 (for transformed data) from Step 19.

3. Calculate the Sample Standard Deviation of the Data

The sample standard deviation of the transformed data is calculated using Equation 10 (for the concentrations) or Equation 3 (for transformed data) from Step 19.

4. Standardize the Data

The purpose of this step is to standardize the data to the standard normal distribution curve. The equation for standardizing the transformed data is presented in Equation B2.

$$z_i = (y_i - SM)/SSD$$
 Equation B2

where:

 $z_i = a$ standardized data point

SSD	=	the sample standard deviation of the data from 3 above
SM	=	the sample mean of the data from 2 above
\mathbf{y}_{i}	=	a data point (either a concentration or transformed concentration)

Subtracting SM shifts the mean to zero, and then dividing by SSD scales the variable so that the standard deviation is 1 rather than SSD.

5. Determine the Theoretical Cumulative Distribution

This step consists of calculating a values corresponding to a theoretical (normal) cumulative distribution function for the standardized transformed data. The distribution may be calculated manually using a standard normal table or determined by one of several statistical software packages (see Appendix C). A standard normal table may be found in many statistical texts, including Bickel (77).

6. Identify the Value for Passing the K-S Test

Table B1 presents critical values for the Lilliefors test (Conover, 80).

The critical values depend on the sample size and the level of statistical significance required. For sample sizes between the values on Table B1, the value for the next highest sample size can be used.

7. <u>Calculate the Differences Between the Values of the Theoretical Cumulative Distribution</u> and the Sample Cumulative Distribution

This step consists of subtracting the values of the theoretical cumulative distribution function from the values of the sample cumulative distribution function and taking the absolute value, for each of the data points. The goal is to identify the maximum vertical difference between the sample and theoretical cumulative distribution functions. Since the sample cumulative distribution function is constant for values between the data points, the differences examined should include those between the value of the sample cumulative distribution function at a particular data point value and (1) the value of the theoretical cumulative distribution function at that data point value and (2) the value of the theoretical cumulative distribution function at the next data point value.

8. Determine If the Data Pass the Lilliefors Test

If none of the absolute values of the differences between the theoretical cumulative distribution and the sample cumulative distribution exceed the critical value identified in 6 above, then it may be concluded that the data can be described by a normal distribution. If one or more of the absolute differences exceed the critical value, the normal distribution is not appropriate.

	Level of significance											
Sample size	0.20	0.15	0.10	0.05	0.01							
4	0.300	0.319	0.352	0.381	0.417							
5	0.285	0.299	0.315	0.337	0.405							
6	0.265	0.277	0.294	0.319	0.364							
7	0.247	0.258	0.276	0.300	0.348							
8	0.233	0.244	0.261	0.285	0.331							
9	0.223	0.233	0.249	0.271	0.311							
10	0.215	0.224	0.239	0.258	0.294							

TABLE B1. CRITICAL VALUES FOR LILLIEFORS TEST (Conover, 80)

11	0.206	0.217	0.230	0.249	0.284
12	0.199	0.212	0.223	0.242	0.275
13	0.190	0.202	0.214	0.234	0.268
14	0.183	0.194	0.207	0.227	0.261
15	0.177	0.187	0.201	0.220	0.257
16	$\begin{array}{c} 0.173 \\ 0.169 \\ 0.166 \\ 0.163 \\ 0.160 \end{array}$	0.182	0.195	0.213	0.250
17		0.177	0.189	0.206	0.245
18		0.173	0.184	0.200	0.239
19		0.169	0.179	0.195	0.235
20		0.166	0.174	0.190	0.231
25	0.142	0.147	0.158	0.173	0.200
30	0.131	0.136	0.144	0.161	0.187
Over 30	<u>0.736</u> √N	<u>0.768</u> √N	<u>0.805</u> √N	<u>0.886</u> √N	$\frac{1.031}{\sqrt{N}}$

Data Transformations

The guidelines consider a simple data transformation, the log transformation. That transformation is just one of a family called the Box and Cox transformations. Such transformations are often considered prior to analysis of data in order to make the data more normal and to make the variances in different groups more similar, both of which are desirable for most analysis of variance approaches, for example. The reader is referred to Stoline (91) for a discussion of the Box and Cox family of transformations applied to environmental data. Samuels (85) also considers transformations other than the log transformation for occupational exposure data. The guidelines do not recommend transformations other than the log transformation because of the computations involved, because the properties (e.g., mean and standard deviation) of the log-normal distribution are well known whereas the interpretation and calculation of descriptive statistics based on other transformations is not straightforward, and because the log-normal distribution for concentration data.

Log-normal Distribution

The log-normal distribution has been studied and applied to concentration data for many years (Aitchison, 57; Johnson, 70). The estimation of the mean of the log-normal distribution is discussed in detail in Attfield (92). Note that the formula for MLE_A in Attfield (92) is incorrect as stated: multiply the formula given by exp(x) to get the corrected value for MLE_A . Confidence limits for the mean of a log-normal distribution are presented in Armstrong (92). Samuels (85) shows how confidence intervals for the concentration data means can be derived from standard deviations and standard errors associated with transformed data.

Confidence Intervals

The calculation of confidence interval is an important means of presenting the degree of certainty about the estimates of any particular parameter. It is important to note that a confidence interval for a mean, for example, must be based on the variance associated with that estimate, not with the variance associated with the individual observations in the population. Thus, the standard error of the mean (which is the square root of the variance of the mean estimator) should be used to define a confidence interval for the mean.

Confidence intervals for means also depend on the data structure and the distribution of the data. Although asymptotically (as the sample size gets very large) a mean will be normally distributed, no matter what the underlying distribution of the observations may be, for relatively small sample sizes the normal approximation may be poor. Thus, confidence intervals for a log-normal mean, for example, have been specifically defined (Armstrong, 92). Standard errors and therefore confidence intervals can be defined for transformed concentrations and converted back to the original scale (Samuels, 85). Standard errors that take into account nested data structures can also be computed (Samuels, 85) and used to define confidence intervals.

Techniques to Combine Groups

One of the final quantitative steps in the guidelines is to obtain statistics for combinations of groups. As is discussed in the text, this should only be attempted when appropriate. The only techniques identified as appropriate are from stratified sampling theory. These techniques can be considered because they allow for estimation of means and standard deviations across groups with widely different population sizes. The properties of these estimates are not known for nonrandom sampled data. This fact should be stated if such estimates are used.

Cluster Analysis

Another approach to defining groups for statistical analysis is based on a procedure known as cluster analysis. That approach examines characteristics of the measurements within groups (clusters) and determines when two groups are similar enough to be combined. The cluster analysis approach is described here is some detail.

Cluster analysis is an iterative procedure by which clusters are combined. Combination proceeds in order of similarity: the most similar groups are combined first, then the next most similar, etc. Each group of measurements (e.g., a set of observations sharing the same values for all the important exposure parameters identified by the engineer or industrial hygienist) starts out as a single cluster; when two groups are combined, the combined group replaces the two groups that were combined, for the purposes of comparison with other groups and additional combination.

In order to conduct a cluster analysis, some measure of similarity is required. The simplest measure, and one that can easily be used for routine application to occupational exposure data, is based on the mean values of the measurements within groups: two groups are considered similar when the difference between their mean values is small. This clustering method is referred to as the unweighted pair-group method using arithmetic averages (UPGMA).

The advantage of this method of clustering is that it does not require the specification or assumption of an underlying distribution for the measurements within the groups. A disadvantage is that this method only compares the mean values within groups and does not consider other descriptors of the within-group measurements, such as variation. Some other methods for defining the similarity of groups are discussed and compared with the UPGMA method in the SAS manual. In some applications those other methods may be more appropriate than the simple UPGMA procedure. Consultation with a statistician is recommended in those cases, and may even be required when the UPGMA method is all that is desired.

A cluster analysis can proceed until all the groups are combined into one cluster. Output from a computer package will specify which clusters are combined at each step and the similarity (difference in means for the UPGMA method) of the clusters combined at each step. The engineer can examine the output and determine at what point the clustering is sufficient, where "sufficient" clustering is based on consideration of sample sizes attained, on the similarity of the clusters that are combined, or on a combination of those two factors.

The goal of this procedure is to increase sample sizes and define uniform groups. It is inappropriate to combine groups that are quite dissimilar, just to get big sample sizes. Thus, some decision by the engineer, in consultation with the statistician, must be made about the weight to be given to the conflicting pressures of those two considerations (sample size vs uniformity). It is recommended that the engineer and statistician decide on a "stopping rule" prior to the running of the cluster analysis. The stopping rule will specify the largest measure of similarity (largest difference in means for the UPGMA method) that will be considered acceptable for combination to occur. The knowledge of the engineer and the statistician is required to select a stopping rule, as there is currently no statistical test or probabilistic measure that can tell the user when the clustering of groups is inappropriate. An examination of the initial groups, their means, and the overall mean for all groups may provide some indication of a stopping rule to consider.

One drawback to the cluster technique is that it can combine groups which do not belong together from an engineering perspective. *A priori* selection of appropriate and inappropriate groupings of data based on engineering judgement can be used to prevent inappropriate clustering of the data. The ANOVA technique discussed in Step 15 does not have this problem. However, the ANOVA technique is most appropriate for data from designed, controlled experiments.

APPENDIX C

LISTING OF COMPUTER SOFTWARE FOR VARIOUS STATISTICAL ANALYSES

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Box-and-Whisker Plot

There are many software packages available on the PC for this technique. These include CSS, NWA Statpak, Solo, SPSS/PC Plus, Statgraphics, Statpac Gold, Systat/Sygraph, SAS, and BMDP.

Analysis of Variance

Analysis of variance is a standard statistical tool available in the software packages CSS, NWA Statpak, Solo, SPSS/PC Plus, Statgraphics, Statpac Gold, Systat/Sygraph, SAS, and BMDP. Not all of these packages can provide the results needed to obtain variance components for a nested analysis of variance. SAS has a special procedure, PROC NESTED, which does just that.

Distribution Tests

The Shapiro-Wilk test is provided as an option in the SAS procedure PROC UNIVARIATE.

Many software statistical packages have the K-S type test procedures for the PC: CSS, NWA Statpak, SPSS/PC Plus, Statgraphics, Statpac Gold, and Systat/Sysgraph. For these packages, the user compares a normal distribution to a set of data.

Theoretical Cumulative Distribution

The many software packages available for computing the standard normal theoretical cumulative distribution function include CSS, NWA Statpak, Solo, SPSS/PC Plus, Statgraphics, Statpac Gold, Systat/Sysgraph, SAS, and BMDP.