An Exposure Assessment Strategy for Laboratories

A Practical Guide

Joe C. Spurgeon, Ph.D., MBA, CIH
Bayshore Environmental, Inc.

December, 2005

FORWARD

The purpose of this document is to describe an efficient and cost-effective methodology for assessing exposures in chemical laboratories. One of the primary benefits of applying this methodology is that daily exposures can be estimated for each employee based on their anticipated work schedule for that day, and simple administrative controls can be applied to prevent excessive exposures before they occur.

Laboratories are unique work environments, and require a specialized approach. First, laboratories are task-based work environments. Exposures are generally associated with specific procedures (ie, distillation) and procedural tasks (ie, loading and unloading). These similar exposure tasks (SET) differ in contact time, agents employed, and the frequency they are performed. In addition, a particular laboratory worker may perform a different combination of procedures on different days.

Second, because laboratory exposures are typically task-based, the standard approach of relying on 8-hour time-weighted average (TWA) exposures is not applicable. This is really the core message of this document. The exposure assessment methodology has been developed specifically for task-based environments.

Third, this is a practical guide to that methodology. It can be implemented by laboratory Chemical Hygiene Officers (CHO's) and health & safety committees, even when these functions are performed as collateral duties. Minimizing the amount of information necessary to perform the assessment is a key element of the strategy.

Fourth, many laboratory procedures are performed on a periodic, seasonal or campaign basis. This increases the difficulty of obtaining a sufficient amount of exposure data on many procedures and tasks. Therefore, the database of 2,000 samples is a valuable resource for the health and safety professional; and one that would be expensive and time-consuming to duplicate.

However, this document describes an empirical approach. Although the sample results that are discussed directly relate to the specific procedures that were included in the study, it is believed that the exposure assessment methodology that was developed for task-based work environments will have general applicability to many laboratories.

TABLE OF CONTENTS

	PAGE
CHAPTER 1: INTRODUCTION	01
Purpose of the Document	01
Definition of an Exposure Assessment	02
The Basis for EASL	02
Benefits of EASL	04
Application to Simulation Models	05
CHAPTER 2: THE LABORATORY ENVIRONMENT	08
Laboratories as Work Environments	08
Similar Exposure Tasks	09
Chemical Hygiene Plan	11
Medical Surveillance Program	12
CHAPTER 3: MEASURES OF EXPOSURES	15
Occupational Exposure Limits	15
Time-Weighted Average Exposure	16
Maximum Percent of the OEL	17
Short-Term Exposures	19
Contact Time	22
Long-Term Average Exposure	25
Long-Term Average OEL	26
Risk Assessment	27
Hazards Lacking Exposure Guidelines	28
CHAPTER 4: SITE INSPECTIONS AND SAMPLING	31
Workplace Characterization	32
Purpose	32
Field Data	33
Work Practices	34
Pressure Differentials	35
Exposure Potentials and Differential Pressures	36
Ventilation Guidelines	38

PAGE

Quantitative Exposure Assessment 39
Observing Work Practices 40
Censored Data 43
The Sampling Strategy 45
Sample Documentation 45
Random Sampling 46
Sampling Schedules 48
Sample Types 49
Sampling Methods 51
Sample Collection Times 52
Sample Size 53
Variability of Exposures 55
Task Duration and Concentration 55
Variability of Data within SET 56
Geometric Standard Deviations 57
Sample analysis 59
Laboratory Data 59
Analytical Methods 59

CHAPTER 5: ASSESSING EXPOSURES 60

Objectives 60
Exposure Potentials 60
Exposure Assessment Criteria 63
Qualitative Assessment Rating 64
Compliance Rating 65
Exposure Control Rating 66
Activity Rating 67
Hazard Rating 68
Task Scale 68
Application of the QAR 69
Estimating Sampling Priorities for SET 72

CHAPTER 6: MANAGING EXPOSURES 73

Response Actions 73
Work Schedules 73
Comparing Facilities 74
Facility Exposure Index 75
Cost Analysis 77

PAGE

CHAPTER 7: QUALITY ASSURANCE PLAN 78

Purpose 78
Applicability 79
Limitations 79
Organizational Needs and Requirements 80
Measures of Success 82
Quality Control Requirements 83
Exposure Assessment Program 84
Measures of Exposure 87
The Database 88
Estimating TWA Exposures 89
Data Usage 89

REFERENCES 90

LIST OF TABLES

	PAGE
Table 1. Summary Exposure Parameters for Example SET.	06
Table 2. Comparison of exposure parameters by calculation and simulation.	07
Table 3. Table 3. Parameter distributions specified for Monte Carlo simulation.	07
Table 4. Definition of a Similar Exposure Task (SET)	10
Table 5. Regulated Chemical Agents with an OSHA Medical Surveillance Requirement.	14
Table 6. Distribution of MAX%OEL Values	17
Table 7a. Evaluating MAX %OEL Values as Exposure Criteria for n = 5.	18
Table 7b. Evaluating MAX %OEL Values as Exposure Criteria for n = 4.	18
Table 7c. Evaluating MAX %OEL Values as Exposure Criteria for n = 3.	19
Table 8. Hours per Year Spent Performing Various Laboratory Tasks.	23
Table 9. Example comparison of TWA and LTA exposure potentials for a suspected human carcinogen	26
Table 10. SET with Maximum Y%OEL Values Exceeding 20 %.	27
Table 11. OSHA Estimates of the Lifetime Cancer Risk for Exposures to DCM.	28
Table 12. Elements of an Exposure Assessment Strategy.	31
Table 13. Minimum Information to be Collected during The WC.	33

PAGE

Table 14: Maximum Differential Pressures by Laboratory Usage 36

Table 15. Procedures Including Censored Data and Having MAX %OEL Values of 25 % or Greater. 45

Table 16. Minimum Information to be Collected during the QNA 45

Table 17. Sample Types and Typical Sampling Locations. 49

Table 18. Example guidelines for the collection of personal samples. 50

Table 19. Example guidelines for the collection of area samples 50

Table 20. Example guidelines for the collection of environmental samples 50

Table 21. Example guidelines for the collection of wipe samples 50

Table 22. Number of SET for each Facility with an Initial Quantitative Assessment 54

Table 23. Frequency Distribution of Sample Sizes for Personal Samples 54

Table 24. Relative Standard Deviations for Task Times and Concentrations for Selected SET. 56

Table 25. Solvent extraction procedure using DCM and performed by the same chemist on eight different days. 56

Table 26a. Assessing Exposure Probabilities based on Frequency and Level of Exposure. 61

Table 26b. Assessing Exposure Probabilities based on Potential for Exposure. 61

Table 26c. Assessing Exposure Probabilities based on Existing Exposure Data. 61

Table 27a. Assessing Consequences of Exposure based on Descriptive Phrases. 62

PAGE

Table 27b. Assessing Consequences of Exposure based on Descriptive Phrases. 62

Table 27c. Assessing Consequences of Exposure based on Descriptive Phrases. 62

Table 28. Criteria for Classifying the Exposure Potentials of SET. 63

Table 29. Suggested Exposure Control Ratings for Typical Work Locations 66

Table 30. Minimum OEL Values Resulting in a Positive QAR for a SET 66

Table 31. Suggested Activity Ratings for Common Laboratory Procedures 67

Table 32. Suggested Chemical Class Ratings for Airborne Agents 68

Table 33. Types of SET in the LEAP Database with Qualitative Assessments. 69

Table 34. Summary of Sampling Decisions for SET Performed on the Bench Top. 70

Table 35. Summary of Sampling Decisions for SET Performed in Fume Hoods. 71

Table 36. Sampling Priority for SET with a Negative QAR. 72

Table 37. Example statistical parameters calculated for a SET. 72

Table 38. Suggested Response Actions based on the Maximum Yearly Percent OEL 73

Table 39. Average Exposure Parameters for Two Example Laboratory Procedures. 74

Table 40. Example Exposure Indices Calculated for Facility E 76

Table 41. Calculated FEI Values for Example Facilities. 76

LIST OF FIGURES

PAGE

Figure 1. Short-term exposures measured for various sample collection times. 21

Figure 2. Short-term Exposure Limit Values for Filling Sample Vials. 21

Figure 3. Distribution of Contact Times for Laboratory Procedures 24

Figure 4. Actual Task Times versus Reported Task Times. 24

Figure 5. Lead Wipe Samples Collected from Work Surfaces 28

Figure 6. Airborne *Penicillium* from Aerated Aquatic Tanks. 29

Figure 7. Airborne Fungi from Aerated Neutralization Tanks. 30

Figure 8. Solvent vapor concentrations during the breakdown of an extraction apparatus 34

Figure 9. Relationship between Exposures and Differential Pressures 36

Figure 10a. Differential pressures measured in administrative offices 37
Figure 10b. Differential pressures measured in laboratory offices 37

Figure 11. Two Extraction Cycles using Separatory Funnels in a Fume Hood: PID and Charcoal Adsorption Tube 41

Figure 12 Effect of variable sample volumes on censored data. 44

Figure 13. Rank Order of Fungal and Bacterial Concentrations 58

Figure 14. Concentrations of Airborne Lead in Containment. 69

Figure 15. Maximum %OEL Values as a Function of the QAR for Bench Top Procedures. 70

CHAPTER 1: INTRODUCTION

Purpose of the Document

The document provides persons responsible for the health & safety (H&S) function in laboratories with a practical and cost-effective exposure assessment strategy for assessing worker exposures. This strategy is referred to as the Exposure Assessment Strategy for Laboratories (EASL). EASL was developed to provide an EAS tailored to the requirements of laboratories, which are unique work environments and require a specialized exposure assessment strategy.

EASL is a practical approach to laboratory health & safety, and is intended to be a "how to" manual, with every step in the implementation of a laboratory EAS fully described . In addition, numerous examples of actual laboratory data are presented to illustrate the concepts that are discussed. Finally, a detailed knowledge of industrial hygiene (IH) concepts is not required to either under stand the material or to implement the program that is described.

It recognizes that scarce resources are an issue, and focuses on performing the assessment in the most cost-effective manner possible. This is accomplished by allowing an effective exposure assessment to be completed without the collection of a large number of samples; promoting the organization's health & safety goals while at the same time conserving scarce resources.

EASL is cost effective because the focus is on observing the workplace, not on collecting samples. In fact, every effort has been made to minimize the need for sampling (although some is still required).

The exposure potentials of possibly 50 % or more of commonly performed laboratory procedures can be assessed by a qualitative assessment alone, without the need to collect any samples. The majority of the remaining procedures can probably be assessed with fewer than three samples.

EASL was structured to minimize the administrative burden placed on the Chemical Hygiene Officer (CHO) and/or Health & Safety Committee (HSC), since many times these positions are staffed by collateral-duty personnel, with limited training in industrial hygiene.[(1)] The methodology limits the necessity to track exposures for the majority of laboratory workers by identifying the limited number of procedures associated with excessive exposures; then focusing resources on those procedures.

EASL acknowledges that contributions are often made by both "organizational" (staff) and "line" (facility) personnel. For example, a dual-phase quantitative assessment is proposed that is intended to utilize staff, facility and consultant personnel.

Finally, EASL allows exposure data from multiple sites to be combined. For example, 10 universities could form a consortium, and list the 50 most common laboratory procedures performed in their laboratories. Each member could then be assigned the task of assessing

exposures to five of those procedures, minimizing both the cost and the time required to collect the shared data..

This document describes a methodology for performing exposure assessments in laboratories, hospitals, and research facilities. It provides guidance to the CHO in gradually evolving their organization from compliance monitoring towards assessing exposures using a systematic methodology, and finally towards risk assessment and risk management. In order to be successful, the CHO has to gain, and then maintain, the trust of their organization's management, the facility's management, and the laboratory staff. When implemented properly, this should be an evolutionary process that is adopted by management as part of an organization's strategic (long-term) health and safety plan.

Definition of an Exposure Assessment

An exposure assessment is *the systematic identification, evaluation and documentation of exposure potentials in the workplace*.[2-5]

There are several key words in this definition. First, *systematic* implies there is a written protocol that can be applied consistently within the workplace, both between the various facilities in an organization and over time. Second, simply measuring exposures and putting the data in a drawer is not sufficient; a method for *evaluating* exposures should be developed as part of the assessment protocol. Finally, a consistent method for collecting and *documenting* the exposure data implies that an electronic database will probably have to be developed and maintained.

An exposure assessment strategy (EAS) describes how these tasks will be accomplished.[2, 3] It includes:

- The systematic characterization of the workplace for potential hazards;
- The definition and identification of "similar exposure groups" (SEG);
- The characterization of the exposure potentials within each SEG;
- A method for documenting the information in an accessible format;
- The implementation of response actions;
- A method for communicating the results; and
- A plan for maintaining the program and conducting periodic reevaluations of the workplace to assess exposure trends.

The Basis for EASL

The database of samples discussed in this document was assembled as part of the U.S. Environmental Protection Agency's (EPA) Laboratory Exposure Assessment Project (LEAP), which was active from 1993 through 1999. The EPA operated ten regional Environmental Support Laboratories during that period. Government employees in those laboratories, as well as

contractor personnel, analyzed samples collected from the ambient environment, hazardous waste sites, or as part of enforcement actions.

The standard EPA analytical methods that were monitored as part of the study are mandated by regulation. These, or similar methods, are often adopted by other countries, and may be used in many government, academic, and corporate laboratories throughout the world. However, the focus of this document is not on characterizing exposures for those specific methods, but on the methodology that was developed to characterize those exposures, which should be applicable to many common laboratory procedures.

The purpose of LEAP was to assess potential exposures to chemical, physical, and biological hazards in those laboratories. The analytes included organic solvents, mineral acids, heavy metals, herbicides/pesticides/PCB's, fungi and bacteria, noise measurements, and differential pressure measurements. Approximately 2,000 samples, including about 1,500 area and personal samples, were collected over a six year period; and reflect a variety of conditions and work practices.

Although samples were only collected in six of the ten regional EPA facilities, a qualitative assessment was performed in nine of the facilities. The field data and sample results were entered into an electronic spreadsheet, and then analyzed for exposure patterns and other usable results.

EASL is a compilation of practical guidelines that were derived from those results. This is both an advantage and a limitation that should be recognized by the reader. The advantage is that real data are presented as a learning tool. Assembling a similar database of 1,500 samples would probably be cost prohibitive for many organizations. In addition, it required six years of planning and field work to collect those data.

The disadvantage is that the data describe the exposure potentials of the procedures included in the database, but they do not predict the exposure potentials of other procedures. Therefore, EASL should not be implemented without first validating the applicability of the methodology to a particular facility.

The distinction between LEAP and EASL may also require clarification. As used in this document, LEAP refers to the EPA project that was active from 1993 through 1999, which was responsible for the collection of the exposure data. The collection of the exposure samples and the resulting exposure database were funded and approved by EPA. However, the various concepts, parameters, and products that compose the assessment strategy described in this document were developed independently following the completion of LEAP, and have not been approved by EPA. EASL is the exposure assessment strategy that was developed following the completion of LEAP.

Benefits of EASL

Performing an exposure assessment provides several benefits to an organization. First, it is a record that exposure potentials in the workplace were assessed, and assists in complying with 29 CFR 1910.1450. The second benefit of EASL is that an exposure assessment results in the periodic and systematic observation of the work place by trained H&S personnel. Experience with LEAP suggests this factor can be more important in controlling exposures than sampling - and doesn't cost nearly as much. Exposure assessments can be even most effective in reducing exposures when they are integrated into the CHP and facility audits, and encourage worker participation. For example, the periodic safety inspections performed by the CHO/HSC offer an excellent opportunity to also perform a qualitative exposure assessment.

Third, an electronic database is generally required to archive the field data. This continues to grow over the years, and provides institutional memory. These data may be important for compliance purposes, workmen's compensation issues, retrospective epidemiological studies, and facility audits. In addition, the data can serve as inputs into the Chemical Hygiene Plan (CHP), Personal Protective Equipment Plan, and the Medical Surveillance Program.

Fourth, EASL was developed as a practical method for minimizing the administrative burden imposed on the CHO and/or HSC. Experience with LEAP suggests that fewer than 20 % of workers in some laboratories may be assigned to procedures with significant exposure potentials. EASL directs time and resources to those few instances that require attention, thereby reducing the existing administrative burden. In addition, the administrative burden is reduced even further as proactive steps are implemented to control exposures, providing a positive incentive to promote worker health & safety.

Fifth, and possibly the most important benefit of EASL, is that excessive worker exposures can be avoided before they occur. Once the exposure potentials of laboratory procedures have been characterized, it's a simple matter for a supervisor to assess a worker's potential exposure by reviewing their daily work schedule, and summing the exposures from each of the assigned tasks. Therefore, inexpensive administrative controls, such as modified work schedules, can be used to prevent excessive exposures.

Finally, EASL incorporates the concept of the long-term average exposure by calculating the "yearly percent of the Occupational Exposure Limit" (Y%OEL). This concept allows the exposure risk to chronic toxicants, such as carcinogens, to be assessed based on dose rather than concentration. A task-based exposure assessment strategy, when properly implemented, can:

- Preclude the need for extensive compliance monitoring;
- Actually reduce the administrative burden on the CHO;
- Allow supervisors to factor expected exposures into the development of daily work assignments; and
- Assess exposures based on both concentration and dose.

Application to Simulation Models

When estimating average or GM concentrations, even small data sets are probably adequate to calculate the parameter directly.

When estimating extreme values in a distribution, Monte Carlo simulation may provide a better estimate of the parameter, and with greater certainty.

Once exposure assessment data have been collected, they can be used as inputs into computer simulation models to provide better estimates of exposure parameters.

The modeling of exposures has increased in importance in industrial hygiene, primarily because it is cost effective.[6] One of the significant aspects of the LEAP database is that the data, whenever possible, were collected in sufficient detail to support the development of exposure models for SET.

The EASL database contains the average values for the CT, agent concentration, and ER for each SET that was sampled. In addition, estimates of the minimums and maximums of these parameters are recorded, so the ranges of these parameters can also be estimated. Not only can the TWA exposure be calculated, but the range can also be calculated. In addition, the CT and the ER are not only static parameters, but they are distributions. Therefore, the EASL database can be used to estimate exposure distributions using computer simulation models.

The measure of central tendency for a lognormal distribution is the GM, or the 50^{th} percentile concentration. This is the concentration, the measure of exposure, that is known with the greatest degree of certainty. The uncertainty associated with an exposure average may be estimated using confidence limits (CL). For example, the 95 % upper (UCL) and lower (LCL) confidence limits on the GM reflect the uncertainty associated with that parameter.

Concentrations other than the GM are known with less certainty. For example, the 95^{th} percentile concentration (C_{95}) would be more representative of peak exposures rather than the average exposure. However, the uncertainty associated with this concentration is significantly greater than with the GM concentration, and the confidence interval can be very broad.

A second method of evaluating uncertainty is to input the exposure data into a Monte Carlo computer simulation model. However, this requires that the data be in a format that can be used as input into these programs. Fortunately, the EASL database was developed with computer simulation models in mind. For example, the data in Table 1 was taken directly from the LEAP database.

The SET in Table 1 illustrate the type of exposure information that is contained in the LEAP database, and accessible by the end-user. Although a number of statistical parameters were calculated for the LEAP data, the data in Table 1 are limited to the average and range for the CT

and ER for each SET. The parameters in Table 1 are in a form that readily supports simulation models.

Table 1. Summary Exposure Parameters for Example SET.

SET	S-1	S-2	S-3	S-4
Apparatus	Separatory Funnel	Soxhlet	Soxhlet	Separatory Funnel
Task	Shake	Unload	Unload	Disposal
Hazard	DCM	DCM	n-Hexane	DCM
Controls	Fume Hood	Fume Hood	Fume Hood	Fume Hood
Sample Size	20	5	5	2
Time_[hr] (Min)	0.88	0.25	0.25	0.33
Time_ [hr] (Avg)	2.34	0.46	0.46	0.38
Time_[hr] (Max)	5.00	0.67	0.67	0.42
CONC_[ppm] (Min)	0.56	0.54	0.81	16.13
CONC_[ppm] (Avg)	7.17	7.69	4.71	24.44
CONC_[ppm] (Max)	49.41	38.36	23.70	34.15
ER_[ppm/hr] (Min)	0.63	2.16	3.24	48.42
ER_[ppm/hr] (Avg)	3.06	16.77	10.28	65.17
ER_[ppm/hr] (Max)	9.88	57.52	35.54	81.91

SET S-1 in Table 1 has a sample size of 20, and both the GM and C_{95} might be estimated with a reasonable certainty by calculating these parameters directly from the data. A good estimate of the GM for S-2 and S-3, each with a sample size of five, could still be calculated but the estimate for C_{95} would be very broad.

However, even the average values for these parameters could not be estimated with much certainty in SET S-4, since only two samples were collected. Unfortunately, SET S-4 is representative of the majority of the data in the LEAP database; with 70 % of the SET characterized by three or fewer samples.

However, by using the average and range for the contact time and the measured concentration of agent as variables in a simple Monte Carlo simulation program, a sample size of 10,000 can be simulated by specifying 10,000 reiterations. The simulated data in Table 2, for example, were calculated using Crystal Ball software, a relatively simple Monte Carlo simulation template for Excel.[7]

Table 2 compares the GM and C_{95} for a SET involving a bench top extraction using DCM. These parameters were calculated directly from the data (n = 5) using a simulated sample size of 10,000 (number of reiterations). The comparisons are reported as a percentage of the OSHA PEL.

Table 2. Comparison of exposure parameters by calculation and simulation.

PARAMETER	SET UP	LOAD	UNLOAD
GM: Calculation	5.5 %	45 %	4.1 %
GM: Simulation	5.4 %	45 %	4.0 %
C_{95}: Calculation	27 %	71 %	40 %
C_{95}: Simulation	21 %	98 %	28 %

The values obtained for the GM were essentially the same by both calculation and simulation. Even for small sample sizes, such as n = 5, the calculated value for the GM might be expected to provide a good estimate for the true value of the parameter.

However, a wider variation occurred between the calculated and simulated values for C_{95}, which is consistent with the greater uncertainty associated with extreme values in a distribution. In addition, the simulated C_{95} values were not consistently higher or lower than the calculated values. So, which value of C_{95} is a more reliable estimate of peak exposures, one calculated using n = 5 or one estimated using n = 10,000?

The assumptions (program inputs) required to perform the calculations, which are very simple, are illustrated in Table 3. If the field data are collected as recommended, these parameters will be included in the database. The user is presented with a number of options for selecting the type of distribution that best describes a particular parameter. As an example, the options in Table 3 were used to calculate the data in Table 2.

Table 3. Parameter distributions specified for Monte Carlo simulation.

PARAMETER	DISTRIBUTION
GM, GSD	Lognormal
Minimum, Average, Maximum	Triangular
Concentration Range	Uniform

CHAPTER 2: THE LABORATORY ENVIRONMENT

Laboratories as Work Environments

A worker in most work environments performs the same or similar tasks for a full work shift. These same tasks, or at least a set of similar tasks, are typically repeated every day. In addition, their fellow workers are typically exposed to a similar environment. Measuring the full-shift personal exposure of a worker in this type of environment provides useful information. Not only about that worker but also their fellow workers; and not only on that day but on subsequent days, as well.

Therefore, personal exposures, as well as regulatory compliance, can be assessed by utilizing occupational exposure limits (OELs) based on 8-hour time-weighted average (TWA) exposure measurements. The most familiar of these OELs are the OSHA Permissible Exposure Limits (PEL) and the American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values (TLV).[8, 9]

However, laboratory workers may participate in a variety of laboratory tasks (procedures) during a work day, and the combination of tasks included in the daily work assignment may change frequently, even daily. In addition, measuring full-shift exposures on any given day, the typical approach for compliance monitoring, will probably not be representative of exposures on other days. In addition, such measurements can not be associated with an identifiable exposure group.

Therefore, collecting full-shift exposure data, although a standard practice in many work environments, may provide little usable information in laboratories and other task-based environments; and may represent a poor use of resources.

Research facilities, academic institutions, government laboratories, the specialty chemicals and pharmaceutical industries, hospitals, and clinics are examples of work places where exposures are associated with discrete procedures that operate intermittently, at irregular intervals, seasonally, or on a campaign basis.[4] These are task-based work environments, and exposure patterns have been described as “non-continuous, with marked systematic variation”.[4]

The operations typically performed in laboratories have also been described in the following terms:[10]

- Dynamic operations that are small in scale, with frequent variations in scale;
- Subject to frequent changes in scope;
- Involving a wide spectrum of hazards;
- Lacking consistency in hazards and exposures across operations; and
- Job titles are generic and not associated with exposure groups.

An industrial hygienist might characterize laboratories as “multi-task work environments with predominantly partial-period exposures”. The work environments in many laboratories fit this definition. For example, the work environment may be characterized as follows:

- Exposures are typically associated with standard laboratory procedures, some of which may be performed infrequently;
- The hazardous properties of many of the agents utilized in laboratories may not be well characterized, since either the sample matrix has not been fully characterized or the agent is the subject of research;
- Individuals may participate in a variety of procedures during a work day, and the combination of tasks included in the daily work assignment may change frequently;
- Exposures are typically partial-period, may be of short duration, and the scale may vary from microliters to liters for the same agent;
- Concentrations of airborne agents are influenced by high ventilation rates, the design of the laboratory; and work practices; and
- The professional work force is generally well educated.

Similar Exposure Tasks

The American Industrial Hygiene Association (AIHA) exposure assessment strategy stratifies personnel into groups that are expected to have similar exposures, generically referred to as similar exposure groups.[2, 3] For example, assume that a group of workers perform very similar work tasks involving the same contaminants. One might assume that the exposures of the group members to those contaminants might be similar. If this similarity in exposures is verified, exposures would only have to be characterized for a limited number of workers in order to estimate typical exposures for the entire group.

Laboratories are typically task-based work environment.[11] Therefore, these exposure groups are referred to as Similar Exposure Tasks (SET) in EASL. The SET are defined as standard laboratory procedures and/or their sub-tasks. The basic assumption is that if the exposure potential for a particular SET has been characterized, then the exposures for everyone performing that SET have been characterized.

The definition of SET is a critical step in the EASL protocol, since the data obtained for a few members of a SET will be applied to everyone in the SET, now and possibly for several years into the future.

Recommendations for defining SET are included in EASL. The example criteria should be helpful in assessing the exposure potential of SET, but they are only suggested as initial guidelines. The assessment of exposure potentials is ultimately based on the requirements of the workplace; and on the professional judgment of the persons responsible for implementing the assessment strategy.

For example, the initial assumption might be that personnel exposed to n-hexane in Lab 100 during liquid-liquid extraction form a single exposure group. Someone washing glassware in Lab 100 during the sample preparation step may or may not be in the same SET.

Once SET have been defined and described during the workplace characterization, they are evaluated and prioritized for monitoring as part of the qualitative exposure assessment. The laboratory procedures that are evaluated during the initial qualitative exposure assessment are then separated into at least two groups: (1) those that may be capable of producing significant exposures, and (2) those that are not expected to result in significant exposures. Those SET initially assessed as having the potential for producing significant exposures are assigned a higher priority for sampling.

The Standard Operating Procedures (SOP's) for the laboratory are an obvious starting point for identifying SET. However, it is not unusual to discover a number of procedures during the workplace characterization that are not well documented. The best method of cataloging SET may be to interview the staff while they are in their laboratory, asking them to step through the steps required to complete the procedure. This provides the CHO with a good qualitative understanding of the potential risks associated with each step in the procedure.

A SET may be defined as a complete procedure, or as a subset of the overall procedure. For example, an extraction process may involve various steps, such as sample preparation, loading room-temperature solvent, unloading solvent that may still be at ana elevated temperature, and solvent disposal. The exposure potentials associated with each of those steps may vary significantly, and the CHO may decide to classify each of those steps as a separate SET. A SET may be defined based on the parameters included in Table 4.

TABLE 4. Definition of a Similar Exposure Task (SET)

Facility	[Site 01]	Apparatus	[Soxhlet]
Building	[Bldg. 100]	Procedure	[Extraction]
Location	[Lab 200]	Sub-Task	[Unloading]
Analyte	[BNA]	Hazard	[n-Hexane]
Sample Matrix	[Water]	Exposure Control	[Fume Hood]

This definition allows laboratory tasks performed in different facilities, different laboratories, and at different times to be identified as either the same or different SET. For example, the same

procedure may be performed in two separate facilities, but it may be performed on the bench top in one facility and in a fume hod in the second facility. In that instance, since the exposure controls were different, these would be identified as two separate SET.

The "Task", or the individual steps in a laboratory procedure, may not seem relevant during the initial inspection. However, the various tasks performed as part of a SET should be recorded, since the exposure potential of each step in a procedure may have to be assessed. As an example, an extraction apparatus may be loaded by one person, unloaded by a second person, and disposal and bulking may be performed by a third person. Therefore, characterizing the exposure potentials of each task results in a more usable database. In addition, the exposure potential of only one of several steps in a procedure may require controls.

It is important that the information in Table 4 reflect actual work practices. The exposure potential assigned to a SET during the initial inspection may not conform to the actual exposure potential if the parameters in Table 4 are not recorded correctly. For example, an extraction procedure using separatory funnels may be reported as occurring in a fume hood. However, observation may reveal that the chemist actually performs this task while pacing in front of the fume hood. Therefore, it is advisable to conduct the initial inspection by (a) interviewing workers while they are in their laboratory, (b) asking them to walk through the steps required to complete the SET, and (3) using professional judgment to anticipate actual work practices.

In addition, some SET may not be identified during the initial inspection, especially if the inspection is performed by someone who is not familiar with a particular facility. Generally speaking, if you do not ask, you will not be told - so ask. If 90 % of the SET are identified during the initial stage, that is an excellent result. Of course, this also implies that one should be prepared for some surprises, in the form of unscheduled sampling, when collecting samples.

Chemical Hygiene Plan

The OSHA Laboratory Standard (29 CFR 1910.1450) requires that a CHO be appointed, and that a Chemical Hygiene Plan (CHP) be implemented.[1] Various responsibilities may be assigned to managers, laboratory supervisors, senior scientists, and laboratory workers as part of the CHP. For example, the CHO may be responsible for assuring that periodic health and safety audits are performed; laboratory supervisors may be responsible for determining that laboratory operations performed in their work areas are performed safely; and workers may be responsible for developing and maintaining good chemical hygiene practices (work practices).

Exposure assessments would be more effective in contributing to a healthy workplace if they were (1) integrated into the CHP, (2) made a part of the audit procedure, and (3) encouraged the participation of personnel at all levels. The following requirements are related to exposure assessments, and could be incorporated into the CHP. The CHO and/or HSC might be expected to ensure that:

- A qualitative assessment and baseline quantitative assessment are performed for all regulated hazardous chemicals used in the facility.[37]
- A qualitative and/or quantitative assessment is performed for chemical, physical, and biological hazards.
- A qualitative assessment is performed for all operations at least annually.
- A quantitative assessment is performed based on the findings of the most recent qualitative assessment.
- Exposures to chemical, physical, and biological hazards can be demonstrated to be acceptable based on documentation.
- A database system for associating employee information with exposure assessment results is developed, implemented, and maintained.
- The interpretation of exposure assessment results is understood by the CHO, and the results are effectively communicated to the workers.
- A qualitative assessment is incorporated into periodic laboratory inspections.

The laboratory supervisor might ensure that:

- A qualitative assessment is performed for all new or modified operations as part of a New Procedure approval process.
- New workers develop and maintain good chemical hygiene practices, including contractor or guest workers.

Medical Surveillance Program

Many organizations may not be aware that the Occupational Safety and Health Administration (OSHA) Laboratory Safety Standard (29 CFR 1910.1450) actually requires an exposure assessment to be performed in laboratories.[1] Besides assessments for regulated chemicals, a Medical Surveillance Program (MSP) is also required. However, the majority of organizations may provide their employees with a medical screening, which provides periodic medical examinations to employees.[12] The purpose of a medical screening program is the early detection of disease rather than the prevention of disease, and may not fulfill the intent of a MSP.

A MSP is intended to prevent disease by identifying risk factors that are present in the workplace, and allowing those factors to be moderated before a disease state develops. It is the primary tool for the prevention of disease. The purpose of a MSP, as discussed in the OSHA

Laboratory Standard (29 CFR 1910.1450), is:

- To determine if adverse health effects are present in the workplace;
- The systematic collection and evaluation of health-related data; and
- The identification of exposure trends or patterns in the workplace.[3]

A database assembled using the EASL protocol can provide the basis for implementing a cost-effective Medical Surveillance Program.

The CHO is defined as "an employee who is qualified ... to provide technical guidance in the development and implementation of ... the Chemical Hygiene Plan (CHP). To the extent that a medical surveillance program is required, this could be interpreted as making the CHO responsible for implementing an exposure assessment strategy at their facility.

In that event, the CHO and/or HSC may be expected to ensure that:

- A baseline assessment of exposure potentials is performed for (at a minimum) all regulated hazardous chemicals used in their facility;

- Exposure potentials are assessed for all chemical, physical and biological hazards on a periodic schedule, or prior to the initiation of new tasks;

- The interpretation of the assessment results is understood by the CHO, and the results can be effectively communicated to the staff;

- Personnel exposures to chemical, physical and biological hazards can be demonstrated to be acceptable based on documentation;

- Exposure trends in the workplace can be identified and evaluated by establishing an electronic database system *that associated employees with exposures*.

The CHO should also be able to justify requests for health & safety resources, and prioritize the allocation of those resources.

OSHA requires a medical surveillance program to be implemented for all regulated hazards, and also as part of the compliance with 29 CFR 1910.1450. Some of the agents with an OSHA medical surveillance requirement are listed in Table 5.[12]

Table 5. Regulated Chemical Agents with an OSHA Medical Surveillance Requirement.

AGENT	REFERENCE	AGENT	REFERENCE
Noise	29 CFR 1910.95	Cadmium	29 CFR 1910.1027
Acrylonitrile	29 CFR 1910.1045	Ethylene oxide	29 CFR 1910.1047
Asbestos	29 CFR 1910.1001	Formaldehyde	29 CFR 1910.1048
Arsenic	29 CFR 1910.1018	Lead	29 CFR 1910.
Benzene	29 CFR 1910.1028	Methylene chloride	29 CFR 1910.1052
1,3-Butadiene	29 CFR 1910.1051	Vinyl chloride	29 CFR 1910.1017

However, many organizations have a medical screening program rather than a medical surveillance program. The purpose of a medical screening program is the early detection of disease. It can only detect what has already occurred, and is therefore a tool for the diagnosis of an occupational disease. It has limited potential to prevent the disease from occurring.

A medical surveillance program, however, is intended to *prevent adverse health effects from occurring by identifying risk factors that are present in the workplace, and addressing those factors before a disease state develops.*[(1)] The methods for achieving this goal include the:

- systematic collection and evaluation of exposure data;
- identification of patterns or trends in exposures; and
- evaluation of current health effects information.

These methods describe the essentials of an exposure assessment strategy; and strongly support the need for implementing an EAS in laboratories.

CHAPTER 3: MEASURES OF EXPOSURE

Occupational Exposure Limits

Exposure monitoring can be used to assess do-not-exceed Ceiling Values (CV), Short-Term Exposure Limits (STEL), average daily exposures (PEL, TLV), or long-term average exposures (LTA).[8, 9] These are generically referred to as Occupational Exposure Limits (OEL).[13]

The OEL should be viewed as the maximum allowable exposure, not the average allowable exposure.

Exposures are "in control" when they are in a range that is acceptable for regulatory compliance and/or to minimize the risk associated with exposure. However, are exposures in control if the average concentration of an agent is equal to the OEL? Probably not. If the OEL is viewed as the average allowable concentration, then, on average, 50 % of exposures will exceed the OEL, resulting in a 50 % chance of not being in compliance with the exposure standard.

As a rough guide, exposures are probably "in control" if the average concentration is about ½ or less of the exposure limit. This guidance assumes that exposures in the workplace should not exceed the exposure limit more than 5 % of the time. This example illustrates the condition in which the OEL is viewed as the maximum allowable concentration. In this instance, the chance of not being in compliance with the exposure standard is reduced to 5 %. Therefore, in order to maximize both regulatory compliance and worker protection, it is prudent to view the OEL as the maximum allowable concentration, not the average allowable concentration.

The "exposure potential" of a SET may be unacceptable, uncertain, or acceptable. For example, SET with a maximum exposure that was less than 10 % of the OEL were classified as "acceptable" in LEAP.[2, 3] This may seem overly conservative, but the assessment of exposure potentials is often based on small sample sizes and incomplete data. In reality, the 10 % value turns out to be a reasonable criterion.

Exposures may be compared to an OEL, such as the PEL or TLV values, when they are available for an agent. However, it's not unusual for a large corporation to employ 50,000 or more chemicals in their various processes; and one significant limitation of consensus exposure standards is that they are only available for about 1,000 chemicals worldwide. Therefore, many organizations have developed internal exposure guidelines; or simply have a policy of minimizing exposures.

Time-Weighted Average Exposure

The 8-hour time-weighted average (TWA) exposure is calculated using Equation [2], which is the standard form for the equation.[7]

[2] TWA = (concentration x time of exposure) / (8 hours)

TWA = (40 ppm x 2 hours) / (8 hours) = 10 ppm

The terms in Equation [2] can be arranged as in Equation [2a]. This form allows the TWA to be calculated using an exposure rate.

[2a] TWA = (concentration / 8 hours) x (time) = (Exposure Rate) x (time)

TWA = (40 ppm / 8 hours) x (2 hours) = (5 ppm / hour) x (2 hours) = 10 ppm

The Exposure Rate (ER) is equal to the average concentration measured for a SET divided by the 8-hours in a standard work day. The ER has the units of parts per million per hour (ppm/hr). The ER for a SET, as calculated using Equation [2a], is expected to be a relatively "static" parameter, and it is included in the EASL database.

The TWA exposure for an individual assigned to a specific SET can be calculated if both the average ER for the SET and the average time of exposure (completion time) are known. One significant advantage of EASL is that this calculation can be performed before the exposure occurs. This empowers the supervisor, as well as a worker with access to the data, to take a more proactive role in evaluating the exposure potentials of daily work schedules.

The exposures within a SET can also be reported as a percentage of the OEL (%OEL). One advantage of using this form is that the user does not need to remember the various OEL values, which is more convenient for non-IH's. The TWA can be reported on a percentage basis using Equation [3]. This example assumes the OEL is 25 ppm.

[3] %TWA = (TWA)(100%) / (OEL) = [(ER) x (time) / (OEL)] x 100 %

%TWA = [(5 ppm / hr) x (2 hours) / (25 ppm)] x 100 % = 40 %

When communicating exposure data to management and staff, it is recommended that the data be presented and discussed in terms of percentages, and not in units of concentration. Most laboratory staff do not known what the OEL is for the agents they commonly use. For example, telling someone their exposure was 10 ppm, through experience, was found to be a good way to create confusion and anxiety.

Telling workers (or management) that the exposure was 40 % of the OEL conveys more information than simply stating the exposure was 10 ppm. Therefore, exposure data in EASL have been expressed as a percentage of the OEL whenever possible.

Maximum Percent of the OEL

The exposure potential of a SET can also be reported as the maximum percentage of the OEL that was detected for the SET (MAX %OEL). The calculation is based on the minimum OEL (Action Level, PEL, or TLV) for that agent in EASL. The minimum OEL is used in the calculation because it provides the most conservative estimate of exposure potential, although any OEL value may be selected as the basis for the assessment.

For example, assume three samples are collected for a SET, and the concentrations of agent are 2 %, 7 % and 20 % of the minimum OEL for that agent. The MAX %OEL would be 20 % for that SET.

In addition, if the personal sample with the highest concentration within a SET results in an exposure that is 10 % of the PEL and 20 % of the TLV, then the MAX %OEL for that SET would be reported as 20 % in EASL.

The advantages of the MAX %OEL is that it is a simple concept, easily calculated, provides a conservative estimate of exposure potential, avoids the need for statistical calculations, and can be applied to SET with small sample sizes. This last characteristic is especially important, since the sample sizes for the majority of the SET in the LEAP database were too small for statistical analysis.

Over 70 % of the SET in the LEAP database had a sample size of 3 or smaller, making statistical calculations practically useless. Therefore, non-statistical parameters, such as MAX %OEL values, which were available for every SET, were more useful in providing guidance concerning the exposure potentials of SET. The LEAP database contained 126 SET involving exposures to chemical agents. Table 6 is the distribution of MAX %OEL values for the 126 SET.

Table 6. Distribution of MAX%OEL Values

RANGE for MAX %OEL	PERCENT of SET	CUMULATIVE PERCENT	EXPOSURE POTENTIAL
MAX %OEL <= 1%	34 %	34 %	Very Low
1% < MAX %OEL < 10%	46 %	80 %	Low
10% <= MAX %OEL < 25%	10 %	90 %	Moderate
MAX %OEL => 25%	10 %	NA	High

These data suggest that exposures from 80 % of the common laboratory procedures that were monitored were well controlled [MAX %OEL < 10 %], and exposures were moderate for an additional 10 % of the SET. Either exposure controls or a Task Review were only warranted for approximately 10 % of the 126 SET.

A sample size of four was the minimum for which statistical parameters were calculated. Since it may be difficult to collect four or more samples for most SET, Tables 7a through 7c contain estimated statistical parameters based on the MAX%OEL for a SET. These values have been calculated by assuming sample sizes of 5, 4 and 3. The calculations assume a GSD of 3.0, since the LEAP data had an average GSD of 3.2 for chemical agents.

Table 7a. Evaluating MAX %OEL Values as Exposure Criteria for n = 5.

SYMBOL	SET 1	SET 2	SET 3	SET 4	SET 5
MAX %OEL	55 %	35 %	25 %	20 %	10 %
GM	14 %	12 %	9 %	6 %	3 %
F	3.5 %	2.5 %	1.5 %	0.6 %	0.05 %
C_{95}	84 %	71 %	56 %	38 %	15 %
UCL_C_{95}	290 %	245 %	194 %	132 %	53 %
MVUE	22 %	18 %	14 %	10 %	4 %
AM	21 %	17 %	13 %	9 %	4 %

AM - Arithmetic Mean
GM - Geometric Mean
F - Fraction Exceeding OEL
C_{95} - 95th Percentile Conc.
MVUE - Maximum Likelihood Estimator of the Mean
UCL_C_{95} - Upper Confidence Limit for C95
UCL_MV - Upper Confidence Limit for MVUE
UCLG_M - Upper Confidence Limit for GM

Table 7b. Evaluating MAX %OEL Values as Exposure Criteria for n = 4.

SYMBOL	SET 1	SET 2	SET 3	SET 4	SET 5
MAX %OEL	55 %	35 %	25 %	20 %	10 %
GM	17.0%	13 %	9 %	7 %	3 %
UCL_GM	98 %	73 %	54 %	37 %	17 %
F	5.4 %	3.0 %	1.5 %	0.6 %	0.1 %
C_{95}	104 %	78 %	57 %	40 %	18 %
UCL_C_{95}	563 %	420 %	307 %	213 %	99 %
MVUE	26 %	19 %	14 %	10 %	5 %
UCL_MV	149 %	111 %	81 %	56 %	26 %
AM	25 %	18 %	13 %	9 %	5 %

Table 7c. Evaluating MAX %OEL Values as Exposure Criteria for n = 3.

SYMBOL	SET 1	SET 2	SET 3	SET 4	SET 5
MAX %OEL	55 %	35 %	25 %	20 %	10 %
GM	17 %	11 %	9 %	4 %	2 %
F	5.4 %	2.3 %	1.4 %	0.1 %	0.05 %
C_{95}	104 %	68 %	54 %	23 %	11 %
AM	25 %	16 %	13 %	5 %	3 %

The data in Table 7b, for example, may be interpreted as follows. A SET with a sample size of 4, a GSD of 3.0, and a MAX %OEL value of 10 % would be expected to result in exposures with the following characteristics:

- Less than 0.1 % of exposures exceeding the OEL (F);
- 95 % of exposures that are less than 18 % of the OEL (C_{95});
- An arithmetic average concentration that is 4.5 % of the OEL (AM);
- An estimated mean concentration that is 4.5 % of the OEL (MVUE)[36];
- An upper confidence limit for the MVUE that is 26 % of the OEL (UCL_MV);
- An upper confidence limit for C_{95} that is 99 % of the OEL (UCL_C_{95}).

Notice that UCL_C_{95} is 99 % of the OEL in this example. This was the basis for selecting 10 % as the control value for the MAX%OEL.

Short-Term Exposures

The STEL is intended to detect very high exposures that only occur for relatively short periods of time.[7] This situation frequently occurs in laboratories. For example, when loading and unloading extraction vessels, or when handling sensory irritants like inorganic acids

The STEL and CV were not measured for most SET because these parameters were frequently too resource-intensive to measure.[14] However, those that were evaluated suggested that using resources to measure short-term exposure limits was not very productive.

The measured concentration was used to estimate short-term exposure potentials for SET when the estimated STEL or CV either exceeded the OEL or was a significant fraction of the OEL. These estimated values provided at least some guidance on short-term exposure potentials.

The STEL is calculated with reference to the time limit specified for a particular agent, which is typically 15 minutes.

STEL = [concentration] x [sampling time] / [15 minutes]

If the measured concentration of an agent were 90 ppm, and the sampling period was 8 minutes, the STEL concentration would be 48 ppm.

STEL = [90 ppm] x [8 minutes] / [15 minutes] = 48 ppm

Some SET actually required less than 15 minutes to complete. However, the STEL concentrations that were estimated based on sampling times of less than 30 minutes were relatively low. The %PEL and %STEL were calculated for ten dichloromethane (DCM) [methylene chloride] samples collected from a bench top extraction procedure.

The first four samples had sample collection times between 7 and 18 minutes. The estimated %STEL for these samples was 5 % to 20 %, and the estimated %PEL was less than 5 %. None of these samples indicated that exposures were out of control (unacceptable). However, the six samples that had sample collection times between 30 minutes and 64 minutes resulted in %STEL from 20 % to 85 %, and %PEL from about 5 % to over 60 %. The STEL for sampling times exceeding 15 minutes was estimated by using the actual measured concentration. Five of the %STEL values out of the six long-term samples exceeded 25 %; and four of the %PEL values exceeded 25 %. These data suggest that collecting samples of less than 30-minutes duration may not be very useful in the laboratory environment.

The data for a separatory funnel extraction are plotted in Figure 1. The real-time concentrations of dichloromethane (DCM) [methylene chloride] were measured with a Pocket Photoionization Detector (PID) [Rae Systems, Inc.]. These data were used to calculate the 15-minute STEL values for this SET. In addition, the average concentrations for the first and second extraction cycles are also indicated. Although peak concentrations were almost 80 ppm during the second cycle, the maximum STEL value was 20 ppm, only slightly greater than the average value of 18 ppm.

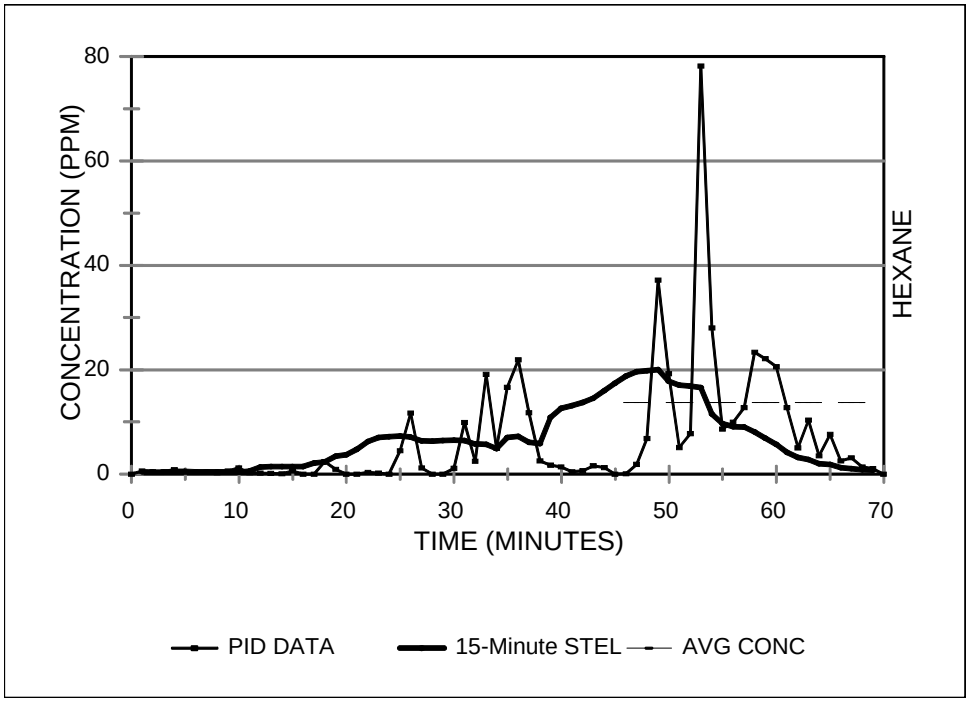

Figure 1. Short-term Exposure Limit Values for a Separatory Funnel Extraction.

The data in Figure 2 are n-hexane concentrations measured while sample vials were being filled on the bench top from an open beaker. The concentration-time profile, the calculated STEL values, and the average concentration are illustrated. As indicated, the maximum STEL value (18 ppm) was only slightly greater than the average concentration of 14 ppm.

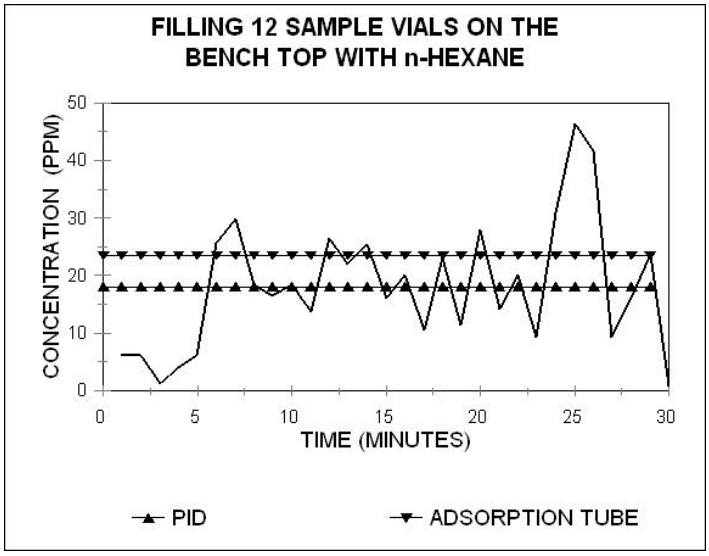

Figure 2. Short-term Exposure Limit Values for Filling Sample Vials.

The data in Figures 2 suggest that short-term exposures, in general, may not be a significant problem in laboratories. This assumption is consistent with the high ventilation rates typical of laboratories, which would be expected to moderate peak concentrations in the breathing zone of the worker. However, approximate values were reported for short-term exposures whenever conservative estimates were available.

Data for a bench-top extraction using DCM in accelerated continuous one-step extractors resulted in the same conclusion. Two of the seven sample times were 17 minutes or less, with acceptable STEL values of 13% and 11%, which were acceptable. However, the measured concentrations for the four samples with longer sampling times resulted in estimated STEL values ranging from 39% to 86% of the OEL. Although the actual STEL values may be higher, the STEL values estimated using the longer sampling times were sufficiently high to recommend that a Task Review be performed for this SET.

A third example involved personnel counting organisms preserved in 4 % formaldehyde solution using a bench-top microscope. The estimated STEL values ranged from 0.8% to 26% of the OEL, and might not result in a Task Review. Although the Ceiling value was not measured directly, the peak concentrations estimated using the measured concentrations ranged from 5% to 175% of the Ceiling. These estimates, which were probably conservative estimates of the actual Ceiling, were sufficiently elevated to classify the short-term exposure potential of this SET as unacceptable.

It was difficult to obtain data describing short-term exposures. First, it was difficult for a consultant who was not familiar with the steps in a laboratory procedure to select an appropriate short-term interval to sample. In addition, a 15-minute sample was easily biased by telephone calls, consultations with other personnel, or the need to leave the laboratory to obtain supplies.

It has been suggested that little effort should be devoted to the evaluation of short-term peak exposures.[15-18] A similar conclusion may be drawn from an analysis of the LEAP database. The sample times in Figures 3 through 6 that were 17 minutes or less tended to underestimate the short-term exposure potentials for those SET compared with estimates based on longer sampling times for the same SET.

These data supported the recommendation that measuring short-term exposures may not be an optimum strategy.[15] However, the long-term average (LTA) exposure to chronic agents was an important measure of exposures in LEAP. But, before we discuss LTA exposures, we have to first discuss contact time (CT).

Contact Time

Contact time is a conservative estimate of the number of hours persons performing a SET are expected to be exposed during a period of one year. The information required to calculate the CT for each SET is collected during the initial site inspection.

CT = [(maximum estimated task completion time)
x (maximum estimated frequency task is performed in a week)
x (50 weeks per year)]

For example, assume that, when interviewed, a chemist estimates that it takes 30-60 minutes to complete a SET, and that during the typical year the SET is performed an average of 3-5 times per week. The CT would be calculated using the maximum duration of 60 minutes and the maximum frequency of 5 times per week. For reference, a task performed an average of 1 hour per day, 5 days per week, and 50 weeks per year has a contact time of 250 hours per year.

CT = [(1 hr/day) x (5 days/wk) x (50 wks/yr)] = 250 hrs/year

An analysis of contact times (reported in hours per year) is provided for 11 laboratory tasks in Table 8. The minimum and maximum contact hours in Table 8 were the lowest and highest values reported for each task in the nine EPA facilities. For example, filtration procedures were characterized 17 times, with contact times ranging from 10 hours to 600 hours per year, with an average contact time of 195 hours per year.

Table 8. Hours per Year Spent Performing Various Laboratory Tasks.

TASK DESCRIPTION	NUMBER OF SET	MINIMUM HOURS	MAXIMUM HOURS	AVERAGE HOURS
Washing Glassware	15	20	800	188
Filtration	17	10	600	195
Chromatography, Colm	10	25	450	206
Disposal, Acids	10	20	750	207
Concentration (S-evap)	30	10	1250	251
Acid Digestion	32	20	750	254
Extraction, Loading	37	20	800	259
Sample Preparation	63	10	1750	261
Distillation, Recovery	10	50	1200	434
Analysis, Personal	41	25	1500	514
Analysis, Instrumental	24	20	1500	713

Ten percent of the tasks included in the database had average contact times of 25 hours or less, and 25 % had average contact times of 90 hours or less. The distribution of contact times is illustrated in Figure 3.

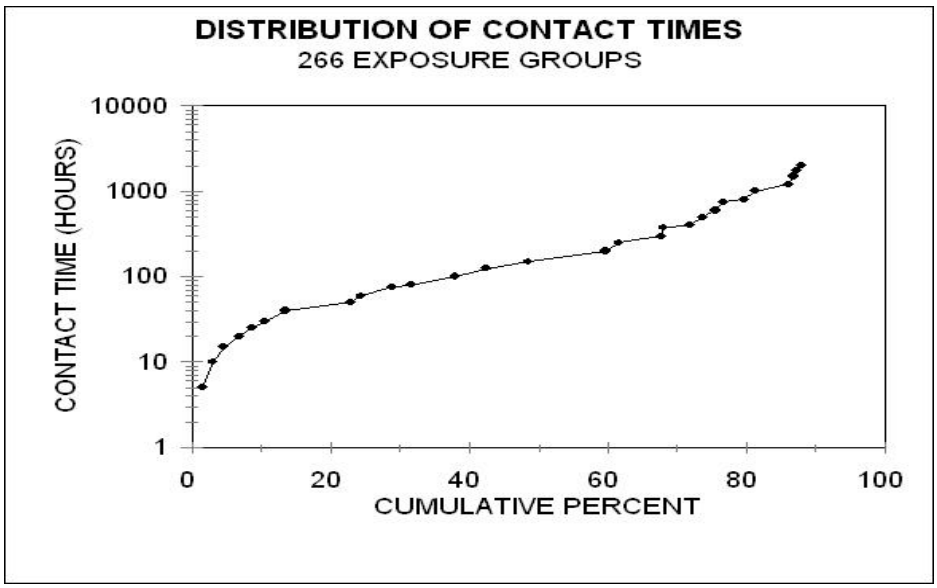

Figure 3. Distribution of Contact Times for Laboratory Procedures.

Laboratory workers were asked to estimate the range of completion times (task duration) for SET during the initial inspection. The upper limit of the reported range was used to calculate the estimated yearly contact times for that SET. Therefore, the upper limit of the reported duration range was an important parameter that was included in both LEAP and EASL.

The actual time that it takes to complete a SET was recorded during the collection of samples. This information allowed the reported contact times to be compared with the actual completion times for 84 SET selected from three laboratory facilities. The results of this comparison are illustrated in Figure 4.

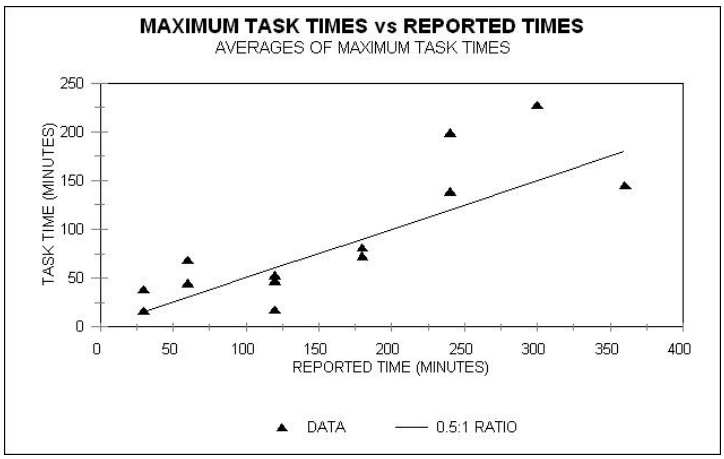

Figure 4. Actual Task Times versus Reported Task Times.

The coefficient of correlation (r) between actual and reported times was 0.834 ($r^2 = 0.70$). The comparison was accomplished by first averaging the actual completion times for each reported duration range. The average task times were then compared to the upper limit of the duration range. The actual time the worker was exposed to significant concentrations of the chemical agent during performance of the SET was, on average, 54 % of the upper limit of the reported duration range. In general, the estimated maximum durations exceeded the actual durations of exposure by a ratio of about 2 to1. However, some of the average task times were more than 80 % of the reported times. These data suggested that the upper limits of the reported duration ranges were an adequate basis for estimating the task completion time. This ratio was large enough to be conservative, but small enough to have utility.

Long-Term Average Exposure

The first objective of most organizations is to achieve regulatory compliance, which is evaluated based on the 8-hour TWA exposure. However, minimizing the risks associated with long-term exposures to chronic toxicants should also be an important organizational objective.

The long-term average (LTA) exposure is used to prioritize the implementation of response actions for SET based on "dose" rather than "concentration". The LTA exposure, rather than the 8-hour TWA exposure, is therefore a better descriptor of the risk associated with exposures to chronic exposure hazards, such as carcinogens.[15, 18, 19]

The LTA included in EASL is referred to as the "Yearly Percent OEL" (Y%OEL). This parameter is an estimate of the LTA exposure, reported as a percentage of the OEL for an averaging period of one year. The Y%OEL is calculated using Equation 4.

[4] $Y\%OEL = (((C \times CT)/2000)/OEL) \times 100\%$

The Y%OEL is calculated in the same way as a TWA, but instead uses the yearly contact time (CT) instead of the daily contact time, and an averaging period of 2,000 hours/year instead of 8 hours/day. However, other averaging periods may also be selected. For example, academic institutions might select a semester as the averaging period.

The OEL for long-term exposures, referred to as the LTA_OEL, is often set at ¼ to ⅓ of the 8-hour TWA.[19] This is equivalent to a Y%OEL of 25% or 33%, respectively. The Y%OEL is used to prioritize the exposure potentials of SET based on dose rather than concentration. Those SET with a Y%OEL exceeding 25 %, for example, should be subject to either a formal task review or the implementation of controls.

As an example, assume the average concentration for a SET was 12 ppm, the contact time was 1,500 hours per year, the OEL was 25 ppm, and the agent was a suspected human carcinogen.

$Y\%OEL = \{[(12\ ppm) \times 1{,}500\ hrs) / (2{,}000\ hrs)] / 25\ ppm\} \times 100\ \% = 36\ \%$

Since the Y%OEL of 36 % exceeds both the 25 % and 33 % criteria for the LTA_OEL, the long-term average exposure potential for this SET would be classified as unacceptable. As the example in Table 9 illustrates, this SET was in compliance with the OSHA PEL, but still represented a significant long-term exposure risk. .

Table 9. Example comparison of TWA and LTA exposure potentials for a suspected human carcinogen.

SET	AVG CONC	CT	OEL (ppm)	PEL (%)	Y%OEL
1	50 ppm	75 hrs/yr	25 ppm	200 %	7.5 %
2	12 ppm	1,500 hrs/yr	25 ppm	48 %	36 %

The exposure potential of SET 1 is twice the PEL, and the SET is not in compliance with the regulatory standard. Therefore, in order to achieve regulatory compliance, a prudent management decision would be to allocate scare resources to preferentially control exposures in SET 1. In fact, the necessity of regulatory compliance mandates this decision.

The exposure potential of SET 2 is less than half the OEL, and the SET is in regulatory compliance. However, SET 2 actually poses the greater exposure risk, since the Y%OEL exceeds both the 25 % and the less conservative 33 % LTA_OEL.

The dose-based risk associated with long-term exposures to chronic toxicants can only be assessed using the LTA exposure, which is represented by the Y%OEL in EASL. Unfortunately, in the task-based work environment typical of laboratories, simply achieving regulatory compliance based on an 8-hour TWA exposure may not represent an adequate degree of safety.

Long-Term Average OEL

The SET in Table 10 are laboratory procedures that had maximum Y%OEL values exceeding 20 %. Since the chemicals listed in Table 10 are chronic agents, the concept of the LTA_OEL is applicable. As discussed previously, the goal s to maintain exposures below a Y%OEL of 33 %, and preferably 25 %.

The maximum Y%OEL value for four of the nine SET exceeded 33 %, and those SET should be subjected to a Task Review and/or exposure controls. However, the upper confidence limits for the data in Table 10 were not calculated as part of the LEAP database. Therefore, to be conservative, all the SET in Table 10 should probably be subjected to at least a Task Review, if not controls.

Table 10. SET with Maximum Y%OEL Values Exceeding 20 %.

FACILITY	APPARATUS	CHEMICAL	CONTROL	Y%OEL
F	Acc. Cont. 1-Step	DCM	Bench Top	89.1
E	Continuous 1-Step	DCM	Bench Top	75.1
F	Sample Vials	DCM	Bench Top	51.0
E	Microscope, Counting	Formaldehyde	Bench Top	47.0
D	S-Evap, Concentration	DCM	Bench Top	28.4
C	Soxhlet, Mini	DCM	Bench Top	24.0
B	Separatory Funnel	DCM	Bench Top	23.0
C	Spinning Band Still	DCM	Bench Top	21.6
E	S-Evap, Concentration	DCM	Bench Top	20.7

Chronic exposure issues in the six facilities that were sampled, which included 126 SET, were limited to very few chemical agents; only the two listed in Table 10. The LEAP data suggested that identifying the agents responsible for chronic exposures at many facilities may not be a burdensome task.

Risk Assessment

Risk may be thought of in terms of the probability that an exposure will occur, and the consequences of that exposure if it does occur. The application of the Y%OEL to risk assessment is illustrated by discussing potential exposures to DCM, since it is classified as a B2 carcinogen (probable human carcinogen).[20]

The lifetime excess cancer risk for DCM has been estimated by OSHA to be 0.9×10^{-3}, or 0.9 excess cancer deaths per 1,000 exposed workers, at an average chronic exposure of 6.25 ppm.[20] For chronic exposures at the PEL of 25 ppm, the estimated risk is 3.62×10^{-3}. If the yearly average exposure to DCM were 6.25 ppm, this would be equivalent to a Y%OEL of 25 % [6.25 / 25 x 100 %].

A Y%OEL value of 25 % is therefore equivalent to a risk of 0.9×10^{-3}, or approximately 1×10^{-3}. Dividing the Y%OEL value for a SET involving DCM by 25 % is an estimate of the long-term exposure risk associated with that SET. However, it is emphasized that this discussion is only intended to illustrate a concept. The Y%OEL is not a measure of cancer risk, just as a TWA is not a measure of risk. It is simply a tool that allows the concept of dose to be included in the assessment of exposure potentials.

The example Y%OEL values contained in Table 11 may be compared, although only in concept, to the lifetime cancer risk associated with the indicated levels of exposure. Both the measured

risk and the risk based on estimates of the upper confidence limits (UCL) on exposures are included in the table. The OSHA estimates of risk are based on the UCL.[20]

Table 11. OSHA Estimates of the Lifetime Cancer Risk for Exposures to DCM.

SET	Y%OEL	RISK (Measured)	RISK (UCL)
1	90	3.6×10^{-3}	25×10^{-3}
2	75	3.0×10^{-3}	21×10^{-3}
3	50	2.0×10^{-3}	14×10^{-3}
4	33	1.5×10^{-3}	10×10^{-3}
5	25	0.9×10^{-3}	7×10^{-3}
6	20	0.8×10^{-3}	6×10^{-3}

Hazards Lacking Exposure Guidelines

Consensus exposure guidelines are available for less than about 1,000 chemicals, although possibly more that a 100,000 chemicals are used in industrial processes. Second, mixtures of chemicals that are not well characterized, such as those encountered in industrial process streams, environmental samples, or research activities can be a source of exposure in many laboratories. If the mixture is not fully characterized, only a qualitative assessment of the exposure potential may be possible.[10, 21, 22]

Finally, relative comparisons may have to be used to assess exposures for some samples. For example, the results from wipe samples or airborne microbial samples may have to be assessed on a comparative basis. Surface wipe samples were collected in a containment area where soil samples were analyzed for lead content using a portable X-ray Fluorescense (XRF) Analyzer. Figure 5 contains data for wipe samples collected inside the containment area, in the metals laboratory at the analyst's work station, and on the analyst's desktop in his office. These data suggest that the analyst's personal hygiene practices were adequate to prevent the transport of lead from containment to other work areas.

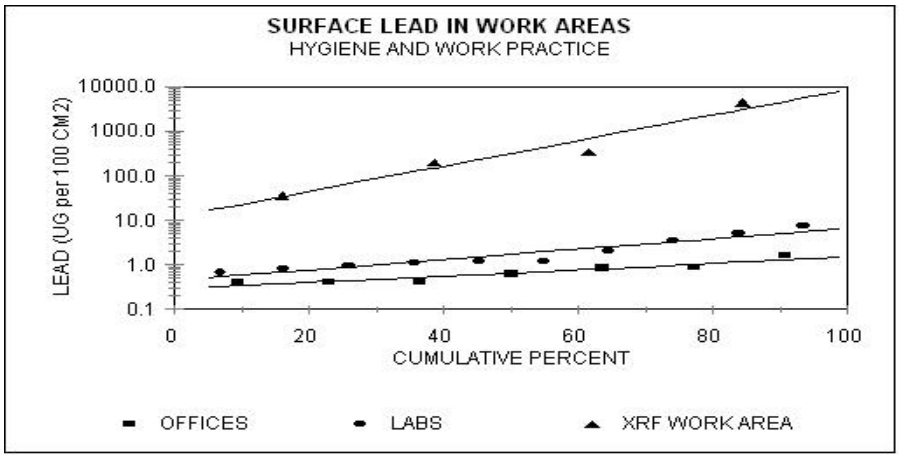

Figure 5. Lead Wipe Samples

A second example involved facilities with large floor-mounted seawater tanks, 6 to 8 feet in diameter; as well as shelf-mounted aquariums for culturing fish and other aquatic species. Since these containers were aerated, they were a potential source of airborne fungi and bacteria. Figure 6 contains data for airborne *Penicillium sp.* in one such laboratory, and the adjacent hallway outside the laboratory. These data indicate that not only were concentrations of *Penicillium* elevated inside the laboratory, but the adjacent hallway was also affected.

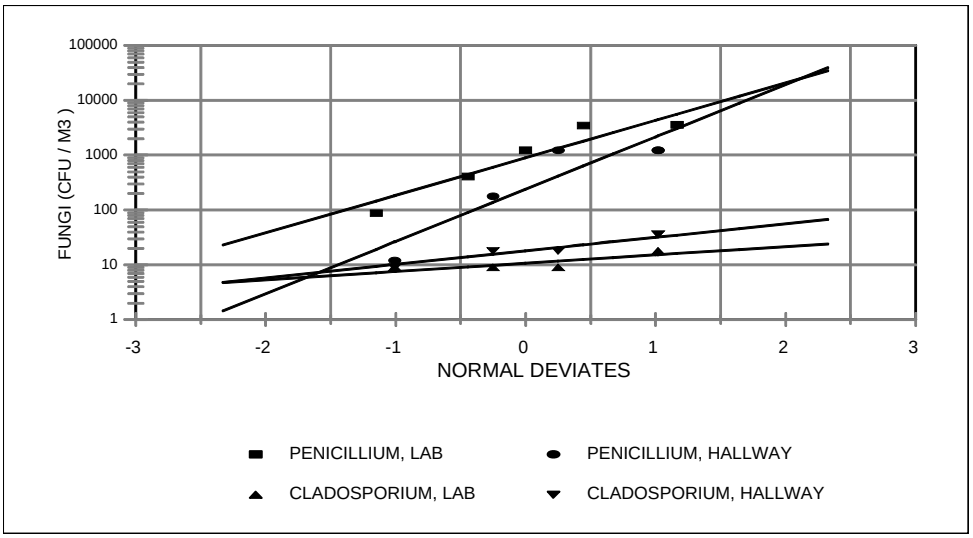

Figure 6. Airborne *Penicillium* from Aerated Aquatic Tanks.

The data also indicate the benefits of at least preparing log plots when assessing sample results. The log plots for both sample locations were right-truncated (flat at high concentrations). This

was an indication that the sampler (N6 Impactor, 2 minute samples) was saturated in both locations. Therefore, the actual airborne concentrations were probably much higher than reported. The individuals working in this laboratory reported frequent cold and flu-like symptoms, and the supervisor reported an increase an issue with the number of sick days.

A third example involved acid neutralization tanks that were not capped, which can be a source of high humidity and possibly fungal amplification. The concentrations of airborne fungi from various locations are compared in Figure 7. The concentration of airborne fungi was relatively low in the control area in the facility. However, concentrations in the space housing the uncapped acid neutralization tanks were elevated. Keeping the tanks capped reduced the humidity and controlled the fungal concentrations.

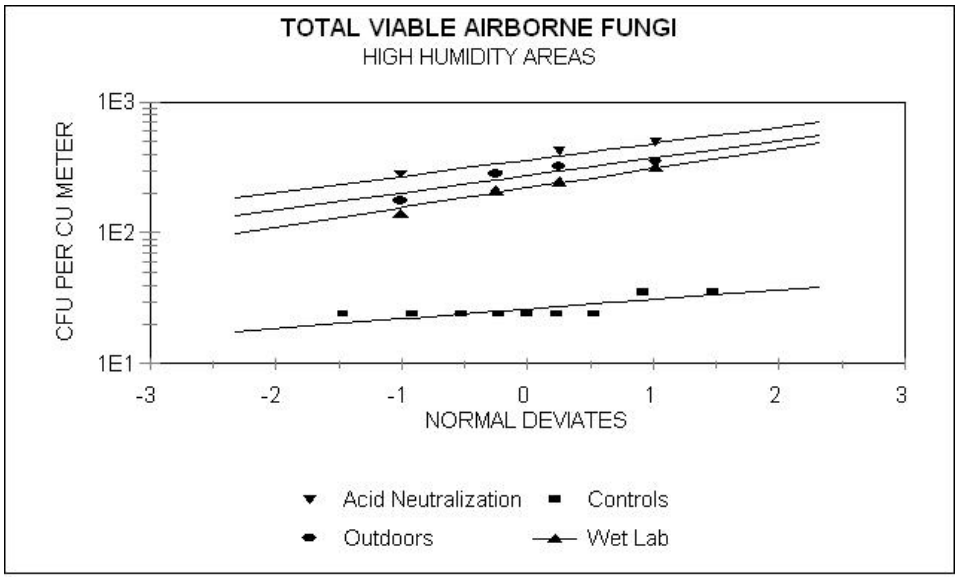

Figure 7. Airborne Fungi from Aerated Neutralization Tanks.

CHAPTER 4: SITE INSPECTIONS AND SAMPLING

An exposure assessment strategy describes and documents the methodology and decision logic that will be used to assess worker exposures. Examples of the generic elements included in a typical exposure assessment strategy are summarized in Table12.

Table 12. Elements of an Exposure Assessment Strategy.

Organizational Commitment	Data Interpretation and Decision Criteria
Workplace Characterization (WC)	Recommendations and Reports
Qualitative Assessment (QLA)	Program Integration (CHP)
Quantitative Assessment (QNA)	Program Maintenance

In practice, these elements are typically performed in the following order:

- An initial protocol for the QLA is developed;
- A limited number of laboratories are then selected for an initial WC;
- The QLA protocol is optimized based on the information collected during the initial WC;
- Once the QLA is finalized, the actual WC is performed;
- The initial phase of the QNA is implemented by collecting a small number of samples from as many SET as possible;
- The QLA protocol is used to prioritize SET for sampling;
- Larger sample sizes are collected for priority SET during the second phase of the QNA.

During the initial phase of the exposure assessment, the emphasis is on performing a preliminary assessment of the exposure potentials of SET. The objective is to limit, based on rational decision criteria, the amount of sampling that will be required to assess exposures. The emphasis in the second phase of the strategy shifts to a more detailed assessment of exposure distributions, but only for those SET with elevated exposure potentials.

The QLA protocol should be a written document that describes in detail the minimum information that has to be collected during the WC. In my opinion, it is the core element of the exposure assessment strategy; and a hastily prepared and inadequate QLA protocol may limit the overall utility of the exposure assessment. It describes:

- How similar exposure groups will be identified;
- The decision criteria for assessing exposures;
- The minimum information that must be collected for each SET;
- The detail in which the field parameters have to be described;
- How the field data will be analyzed and reported; and
- The database fields and structure.

Only two of the elements listed in Table 12, the WC and the QNA, involve the collection of field data. The other elements are essentially derived from these activities. The WC is based on the visual inspection of the laboratory facility. Conceptually, this is a simple task, but it requires both attention to detail and a basic knowledge of laboratory procedures. The objective is to identify, document and characterize all the potential sources of exposure present in the work environment.

There are two primary limitations placed on the WC. First, the information has to be documented in sufficient detail to allow exposure potentials to be assessed systematically. Since the QLA is performed after leaving the facility, the information gathered during the WC determines the both the quality and the utility of the exposure assessment.

Second, the field data have to be collected in a consistent manner, both between facilities and over time. This requires everyone assigned to the project to be trained, and to understand the concepts embodied in EASL. Unless this consistency is maintained, the quality of the database may be less than adequate.

The only other field activity in EASL is the QnA, the sampling strategy. This step includes:

- Selecting the sampling methods and media;
- Assembling sufficient equipment and supplies;
- Developing the field forms;
- Training personnel to collect the data in a consistent manner;
- Coordinating with facilities to prepare a sampling schedule; and
- Collecting the samples (probably during several sampling campaigns).

WORKPLACE CHARACTERIZATION

Purpose

The purpose of the initial site visit to a facility is to perform a Workplace Characterization.[4,5] The WC is used to document the current status of the workplace, describe operations, identify and classify exposure groups , obtain anecdotal information relating to potential exposures, and plan the quantitative assessment.

Not all of the 126 SET in the LEAP database were described in the initial WC. A number of SET that were not identified during the WC were discovered during the initial QNA, for example. This problem might be of less concern when the WC is performed by in-house personnel rather than outside consultants.

Field Data

The use of standardized field forms, especially in multi-facility organizations, is strongly recommended.[1] In order to perform an exposure assessment, the information collected during the WC has to be associated with the exposure data collected during the QNA..[23, 24] Therefore, standard forms should be developed and used to collect the field data.[21, 25] This increases the probability the required data will be collected, and allows exposure data to be associated with specific SET. Developing and using standard field forms also promotes the use of a standardized approach over time and between facilities.

Although the ultimate objective is to estimate the exposure of an individual, this is accomplished by summing the exposure potentials of individual SET. Therefore, the objective during the WC is to obtain a detailed description of each SET that is performed at a facility.

The minimum information recommended for collection during the WC is described in Table 13. This information identifies the specific facility, department, and laboratory that is being assessed. Second, it identifies the specific SET that is being assessed. Finally, the factors related to exposure potential are recorded.

Table 13. Minimum Information to be Collected during The WC.

Date	Analyte	Chemicals/Hazards
Facility	Sample Matrix	Duration, Range
Building	Apparatus	Frequency, Range
Department	Procedure	Scale, Range
Section	Tasks (Optional)	Exposure Controls
Laboratory or Room	Physical hazards	Work Practices

A preliminary list of similar categories should be developed prior to the first site visit, and then modified, as required, until a final list is established that is specific to a particular organization. The fields in some categories, such as sample matrix, reflect the fact that the LEAP data were collected in environmental laboratories. In addition, some categories, such as Exposure Source, may not be useful, and may be deleted. However, the table offers a starting point for preparing a similar table that is site-specific.

The data fields included on the EASL field sheets were limited to those that could be included on a single page. These data fields were the minimum required to both define a SET and estimate its exposure potential. Other information, such as the mole fractions of solvent mixtures, solvent temperatures, etc. was not collected, but may have been useful to know. Although these (and other) parameters are important, many of them can be estimated from a review of the written Standard Operating Procedure (SOP) for a SET. What information is readily available from existing documentation, and what has to be recorded, should be determined prior to the field

survey. However, in general, as much descriptive information as possible - relevant to exposure potential - should be recorded.[10, 11]

Work Practices

One of the main benefits of performing an exposure assessment is that it requires trained H&S personnel to observe how procedures are performed, and individual work practices, in a systematic way.[2-5] Observing work practices is often all that is required to minimize exposures.

For example, the SET in the LEAP database that had significantly elevated exposure potentials often shared a common (and critically important) characteristic - trained observers were able to predict the high exposure potentials of those SET prior to sampling by simply observing the procedure and the work practices. In general, those SET were sampled to simply confirm the obvious.

However, the fact that a SET had an elevated exposure potential was not always obvious from the WC. One reason was that the actual exposure controls and/or work practices may have been different from those reported during the WC. The only way to gauge those effects was to observe the procedure during the sample collection. Therefore, it is strongly recommended that at least some samples be collected for all SET in a baseline survey in order to validate the assessment methodology.

Figure 8 is a plot of the Dichloromethane (DCM) [methylene chloride] concentrations measured during the breakdown of several soxhlet extractors and the unloading of the solvent. The extraction vessels were mounted on the bench top, and the concentration was measured continuously with a Pocket Photoionization Detector (PID).

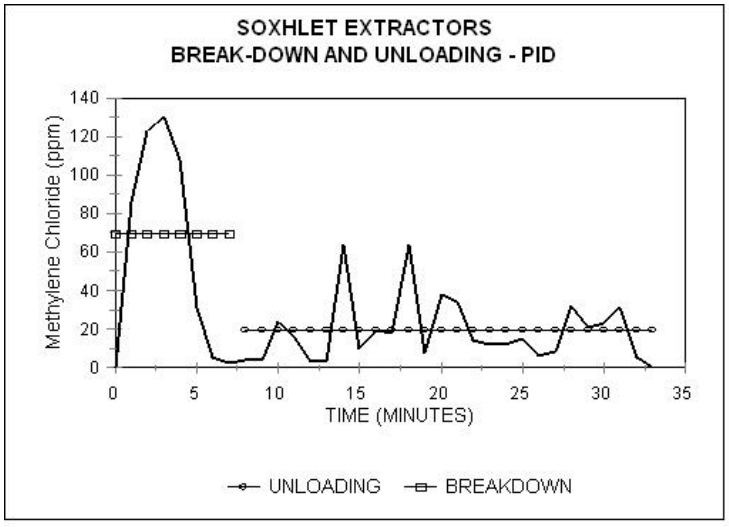

Figure 8. Solvent vapor concentrations during the breakdown of an extraction apparatus.

Excessive exposures are often associated with a specific task that is performed as part of a procedure. During the sampling, it was observed that the chemist turned off the heating mantle, turned off the water to the condenser, immediately separated the condenser from the extraction vessel, and transferred the vessels to the fume hood for processing. This procedure resulted in a concentration peak during the breakdown, as indicated in Figure 9.

This one 7-minute task resulted in a 54 % increase in the average exposure for the SET. When it was suggested that the condensers be left in place for 15 minutes, letting the solvent cool before the breakdown, the concentration peak was eliminated. The exposure potential for this SET was minimized by simply being present and observing work practices.

As a second example, a solvent disposal task involving separatory funnels only lasted 20 minutes, but resulted in up to 17 % of the daily allowable exposure. Observation revealed that the separatory funnels were too large to place them over the waste container, which was kept in a fume hood. The workers had to lift the container out of the fume hood, place it on the floor, empty the funnels, then lift the container back into the fume hood. Therefore, this was actually a bench-top procedure, although it had been described in the WC as a fume hood procedure. Obviously, ergonomic factors were also an issue.

Work practices might be especially important in situations involving students, interns, graduate students, guest scientists, or newly hired employees, for example. These individuals may lack experience, or their frequent rotation through the workplace may result in safety-related issues. For example, an adequate safety indoctrination can minimize the situation in which a guest scientist departs, leaving behind a number of flasks and bottles containing chemicals labeled only in a foreign language.

Pressure Differentials

One of the parameters measured during the WC was the differential pressure (DP) between the interior of a laboratory and the adjoining hallway; or between the laboratory and administrative modules. The possible value of this parameter for assessing exposure potentials was not appreciated during the initial phases of LEAP. Therefore, measurements were only collected in five of the nine facilities evaluated during LEAP. The DP was simple to measure, and measurements could be completed in a 50,000 square-foot facility in about 30 minutes.

The DP for a laboratory was made by standing in the hallway and extending the tubing attached to one port of the micro-manometer into the laboratory. The laboratory door was held open (about ½ inch) so that the tubing was not crimped, and the DP was recorded. The instrument was zeroed periodically during the collection of the measurements. The DP was also measured between office modules and laboratory modules when appropriate.

The maximum DP measured in laboratories varied by laboratory usage, as indicated by the data in Table 14. Biological and inorganic laboratories generally had the lowest DP, while organic

laboratories had the highest DP.

Table 14: Maximum Differential Pressures by Laboratory Usage

TYPE OF LABORATORY	MAXIMUM DIFFERENTIAL PRESSURE
Biological	-5 Pa
Inorganic Analysis	-10 Pa
Chemical Store Room	- 13 Pa
Inorganic Sample Preparation	-14 Pa
Organic Analysis	-16 Pa
Organic Sample Preparation	-19 Pa

Exposure Potentials and Differential Pressures

Figure 9 is a plot of the average %OEL recorded at each DP value for those laboratories where the measured concentration of a chemical agent exceed 1 % of an OEL. The data suggest the DP may be related to exposure potential in a general way. The average values are plotted to reduce the variance and improve the correlation. The Coefficient of Determination (r^2) was 0.87, with a Coefficient of Correlation (r) of -0.93.

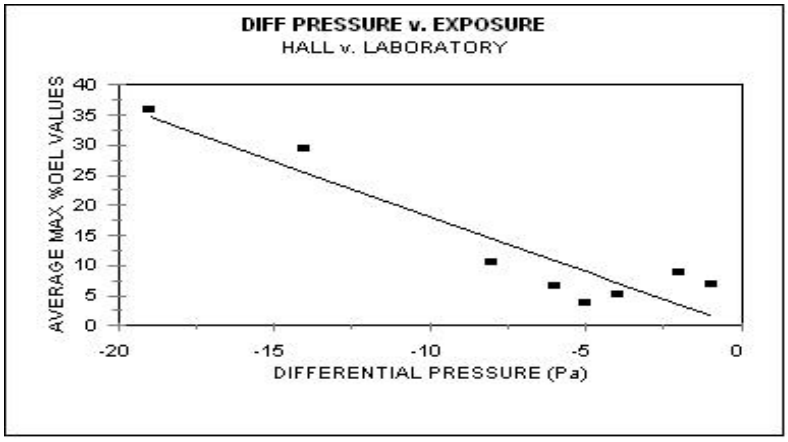

Figure 9. Relationship between The MAX%OEL and Differential Pressures.

The data in Figure 9 suggest a qualitative relationship between the MAX%OEL and DP. For example, the DP in laboratories in which the MAX%OEL exceeded 10% was generally -8 Pa or less; and generally did not exceed 10 % in laboratories where the DP was greater than -8 Pa. These data suggest there may have been a relationship between exposure potentials and DP.

It is not suggested that this was a causal relationship. If one assumes that the air supply to a laboratory remains constant (doors closed) but the exhaust volume is increased, then the DP in that laboratory will increase (become more negative). It may be reasonable to assume that an attempt may have been made to increase exhaust volumes in those laboratories where exposures were suspected of being elevated. Whatever the explanation, this was a rapid and inexpensive method for identifying "hot spots" within an unfamiliar facility.

Two basic facility designs were evaluated as part of LEAP. Four facilities had staff offices in the laboratory module, while seven facilities had offices located in a separate administrative wing. Figures 10a and 10b are plots of the DP measured in office spaces in the two designs.

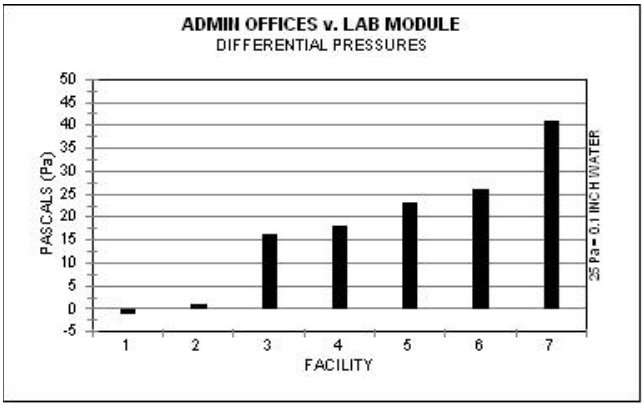

Figure 10a. Differential pressures measured in offices located in separate administrative areas.

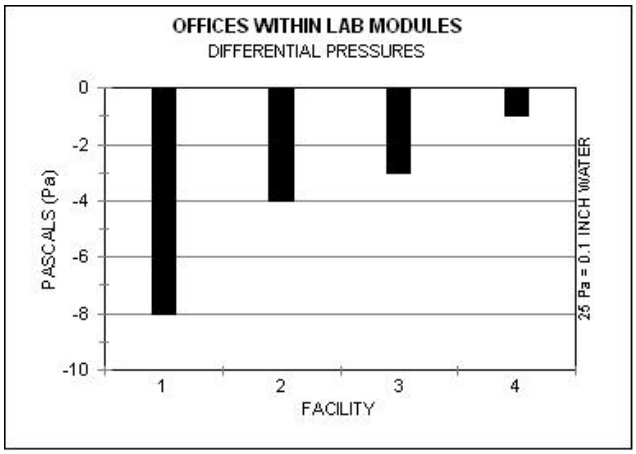

Figure 10b. Differential pressures measured in offices located within laboratory modules.

The DP between the administrative wing and laboratory module was neutral in two of the seven facilities, and exceeded 15 Pa in five of the facilities. In general, offices located in a separate wing outside the laboratory module were within a positive-pressure environment. The four offices in Figure 11b that were located within the laboratory module were either neutral or negative to the adjacent hallway.

Ventilation Guidelines

The verification of fume hood face-velocities is not included in the LEAP protocol. This parameter, although a health & safety function, was outside the scope of an exposure assessment. However, observation of airflow indicators and the application of professional judgment suggests that face velocities were generally adequate (range of 80 - 120 fpm) in most laboratories.

The ANSI Z9.5 American National Standard for Laboratory Ventilation, Section 5.7, states that "each fume hood shall maintain an average face velocity of 80 - 120 fpm with no face velocity measurement more than $\pm$ 20% of the average". In addition, this standard states that an "offset" of about 10 % should be used for laboratory design, and that DP should not be used as part of the design criteria. An offset of 10 % means that 90 % of the exhaust air would be supply air and 10 % would be from leakage into the laboratory. If the actual offset significantly exceeded the design value, a negative pressure would be expected to develop in the laboratory.

Appendix A to the OSHA Laboratory Standard [29 CFR 1910.1450], Section C (The Laboratory Facility), states that:

- Paragraph [f] *Performance* - "4 - 12 room air changes per hour is normally adequate ... primary method of control"

- Paragraph [g] *Quality* - "*fume* hood face velocity should be adequate (typically 60 - 100 lfm)".

Prudent Practices in the Laboratory (NRC, 1995), Section 8.C.2, states that "In most cases, the recommended face velocity for a fume hood is between 80 and 100 feet per minute".

The above standards, as well as NFPA 45, restrict the range of face velocities for fume hoods. Based on the results of the DP measurements, however, it may be desirable to explore these standards. Exposure potentials may be better controlled by balancing the air supplies to individual laboratories based on either (1) measured exposure potentials, or (2) laboratory usage. If the range of DP is from 0 Pa to -20 Pa (the measured range), a target value of -10 Pa for all laboratories (for example) may reduce exposure potentials by putting the supply air where it is needed most.

The objective would be to adjust average face velocities according to the exposure potentials in each laboratory if the supply air was limited. For example, rather than having a face velocity of 100 fpm in all laboratories, it may be preferable to have face velocities of 80 fpm in Inorganic Analysis laboratories and 120 fpm in Organic Sample Preparation laboratories.

QUANTITATIVE ASSESSMENT

The LEAP protocol included a dual-phase quantitative assessment. The purpose of the phase 1 QNA was to collect a few samples each for a large number of SET. The phase 2 QNA was included to allow larger sample sizes to be collected at a later date.

The dual-phase QNA was included in the sampling strategy for several reasons. First, an effective exposure assessment strategy for laboratories did not exist, and one had to be developed in the initial stages of LEAP. Therefore, the initial objective was to obtain exposure data, although limited, on as many SET as possible, and as fast as possible. These data were necessary to begin formulating the qualitative assessment protocol. In addition, the phase 1 QNA provided a quick assessment of the magnitude of the exposure problem.

Second, the type of sampling included in the phase 1 QNA was suitable for campaign sampling (intensive sampling over a short period of time). In addition, it allowed facility staff to be introduced to exposure assessments through management briefings, short training sessions, and observation of the protocols.

The phase 2 QNA was intended to provide a more detailed assessment of exposure potentials, but for a limited number of SET. This type of sampling was not felt to be suitable for campaign sampling. Therefore, the phase 2 QNA was intended as a facility responsibility. However, the SET included in the phase 2 QNA would be limited to those SET with elevated exposure potentials. Therefore, this sampling strategy was a cooperative effort that provided an efficient use of both "headquarters" and facility resources.

The quantitative assessment (QNA) in EASL has been structured into two phases, an initial phase and a completion phase. The initial phase is a preliminary or "screening" assessment. The objective of the initial phase is to collect a small number of samples from as many SET as possible. These data, combined with the qualitative assessment methodology, allows the SET to be prioritized for the more extensive sampling conducted in the completion phase.

Once the initial sampling has been completed, the data are provided to the facility's CHO, who is then responsible for evaluating the data. The CHO has the option of either (1) collecting additional exposure data for those SET with elevated exposure potentials during the completion phase, or (2) bypassing additional sampling and performing a Task Review on each of those SET.

The emphasis during the completion phase of sampling is on obtaining sufficient data to assess the exposure distributions for those SET having potentially elevated exposure potentials. The assessment of "exposure distributions" infers a minimum sample size (n => 4) sufficiently large to calculate statistical parameters.

Observing Work Practices

One factor that affects the decision concerning the exposure potential of a SET is work practices. However, these are not actually observed until the QNA. Figure 11 illustrates the exposure profile for the extraction of samples using n-hexane. The extraction was performed using 3-liter separatory funnels in a fume hood. The first two cycles of a three-cycle extraction were sampled using an adsorption tube. In addition, a Personal Photoionization Detector (PID) (Rae Systems, Inc.) was used to continuously measure n-hexane concentrations during all three extraction cycles.

Figure 11 illustrates several potential problems associated with performing task-based exposure assessments: (1) the period sampled may not be representative of the total exposure, (2) the "observer", at least initially, may influence work practices and the measured exposure, and (3) assigning an exposure potential to a SET should be based on an evaluation of actual rather than reported work practices.

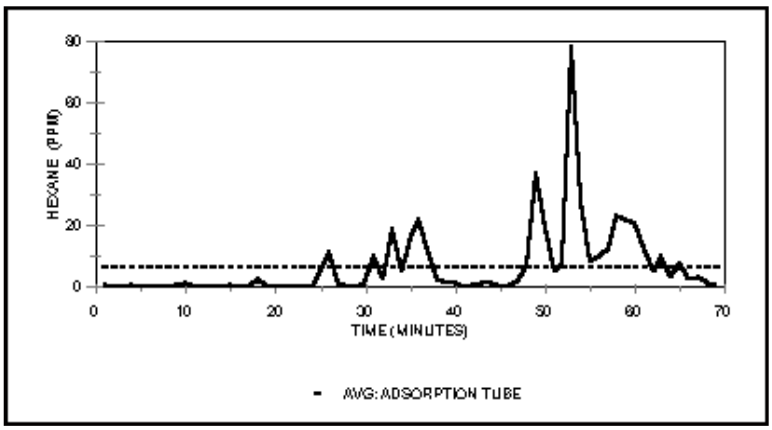

Figure 11. Two Extraction Cycles using Separatory Funnels in a Fume Hood: Personal Photoionization Detector and Charcoal Adsorption Tube.

Although sampling did not begin until the chemist indicated the procedure was starting, exposures did not occur during the initial third of the procedure. This period was devoted to retrieving additional glassware and consultations with other chemists, which may or may not be typical for the SET, but were reported as atypical.

The average concentration, as measured by adsorption tube samples, was 12 ppm for the first extraction cycle, 18 ppm for the second extraction cycle, and 6.6 ppm for the entire sampling period. These data demonstrate both a weakness and a strength of the EASL strategy.

One weakness in the LEAP data is that samples were not always collected throughout the performance of a SET. This limitation resulted from productivity requirements associated with the use of campaign sampling (there were more SET to sample than people to sample them). However, as in the above example, individual samples were frequently collected for each “task”, such as each extraction cycle.

Second, the initial cycle reflects an awareness of being observed. During the initial extraction cycle, both chemists stood in front of the fume hood and held the 3-liter separatory funnels inside the fume hood with arms extended. However, the data for the second cycle probably reflects both the ergonomic stress and the boredom associated with this activity [comment: poor ergonomics should be evaluated as a factor contributing to laboratory exposures].

During the second extraction cycle, the chemists performed the extraction while talking and pacing in front of the fume hood, which was typical of actual work practices as determined by further observations. Therefore, based on professional judgment, the exposure level associated with the second extraction cycle (18 ppm per cycle) was assumed to be typical for this SET.

The knowledge that exposures for a SET may be elevated often served as a catalyst for reducing exposure potentials. Experience suggests that once the laboratory worker is aware that exposures may be elevated, they are often able to suggest process modifications that eliminate the problem quickly, with minimal cost, and without impacting productivity.

In a second example, a SET involved counting aquatic organisms preserved in 4 % formaldehyde using a bench-top microscope. A series of 15-minute samples for this SET indicated that exposures were as high as 172 % of the CV. The supervisor, upon reviewing the sample results, suggested rinsing the organisms in water prior to counting. This simple modification of the process reduced formaldehyde concentrations to below the LOD.

In a third SET, a solvent extraction procedure performed on the bench top exhibited elevated exposures during the unloading of the extraction vessels. Upon observation, the industrial hygienist determined that the worker:

- Shut off power to the heating mantle;
- Shut off the cooling water to the condensers;
- removed the condensers from the extraction vessels; and
- moved the extraction vessels into a fume hood.

This example is almost elementary, but illustrates an important point; that productivity is as much an issue in laboratories as in any workplace. The exposure potential of this SET was discussed with the worker performing the SET, and a 15 minute delay in shutting off the condenser water was suggested, allowing time for the solvent to cool before disconnecting the condensers. The chemist was well aware of this simple solution, but did not feel comfortable suggesting it. However, once the recommendation was made in writing by the industrial hygienist, the modification was implemented. This simple solution may have been missed if the exposure potentials of the loading and unloading tasks had not been evaluated separately. However, it would positively have been missed if the procedure had not been observed and a simple qualitative assessment performed.

One of the more memorable worker exposure issues occurred because of contractor productivity requirements. An on-site contracting firm had recently been hired by EPA, and was obviously the low bidder in order to have won the contract. Due to the low bid, they felt that only one chemist could be assigned to a laboratory previously employing three chemists, but they did not reduce the work load. This resulted in work practices that, to say the least, were subject to improvement.

Even though the contractor had an independent laboratory health& safety program, EPA decided that they were responsible for the work space, and suggested that the working conditions be improved. Not only could those work practices affect the health & safety of contractor employees, but also EPA staff. This example illustrates why <u>all</u> facility personnel should be included as part of an exposure assessment strategy.

Censored Data

Samples with concentrations that are below the limit of detection (LOD) for the analytical method are referred to as censored data..[26, 27] A significant number of samples collected in the initial phase of the assessment were censored. One reason was that all SET were included in the initial baseline sampling, even those expected to have low exposure potentials. This was necessary to validate the decision logic used in the QLA, which required sampling even those SET expected to have low exposure potentials. In addition, the short duration of many SET resulted in small sample volumes, and therefore sample concentrations that were below the LOD for the analytical method. These data can not be entered directly into the database, since the log of zero is undefined. However, several methods are available for including censored data in the analysis of lognormal distributions.[19, 28-31]

Censored data are typically entered into the database as some fraction of the LOD, such as the LOD/$\sqrt{2}$ or LOD/2, although this may not always result in the minimum bias.[19, 32] Entering censored data as the LOD/2 may be preferable if the geometric standard deviation (GSD) is greater than 3.[19] The average GSD for the data in the LEAP database was 3.2. Therefore, entering censored data as the LOD/2 was an appropriate choice for the LEAP data, and a single approach was used for simplicity.

The mean value for a lognormal distribution is expected to be independent of averaging time.[19] However, many of the samples in the LEAP database were censored. Therefore, the sample times that are used to collect data for a specific SET should be similar in order to minimize the effects on censored data. This may require some coordination when similar procedures are performed in different facilities, sample collection is performed by different individuals, or samples are collected over widely separated time periods.[10]

Therefore, both the LOD reported by the analytical laboratory and the variation in the sample volume are important parameters. The fact that many of the collected data may be censored requires the sample volumes within a particular SET to remain relatively constant ($\pm$ 15%). If this condition is not met, the values entered for the censored data will simply reflect the sample volumes.

This means a trend line will be observed when it didn't exist, which can result in the over-estimation of exposures if the data are not interpreted correctly. Although this error is "conservative" and overestimates exposures, it can result in the application of scarce resources to a nonexistent problem if the data are improperly interpreted.

When using adsorption tubes, for example, the analyte concentration (ug/m^3) is calculated by dividing the weight of the analyte (ug) detected in the tube by the sample volume (m^3). However, the results for a significant number of samples may be below the LOD for the analytical method. This is going to be a constant weight for that analytical method.
The lower plot in Figure 12 would result if a variable sample volume had been used to collect the

samples (constant weight divided by a variable volume). In this example, the information that some of the data are censored is not readily apparent from the log plot. Once these data are entered as numbers into a database, this fact is even less apparent. Therefore, the variation in sample volumes within a SET should be minimized.

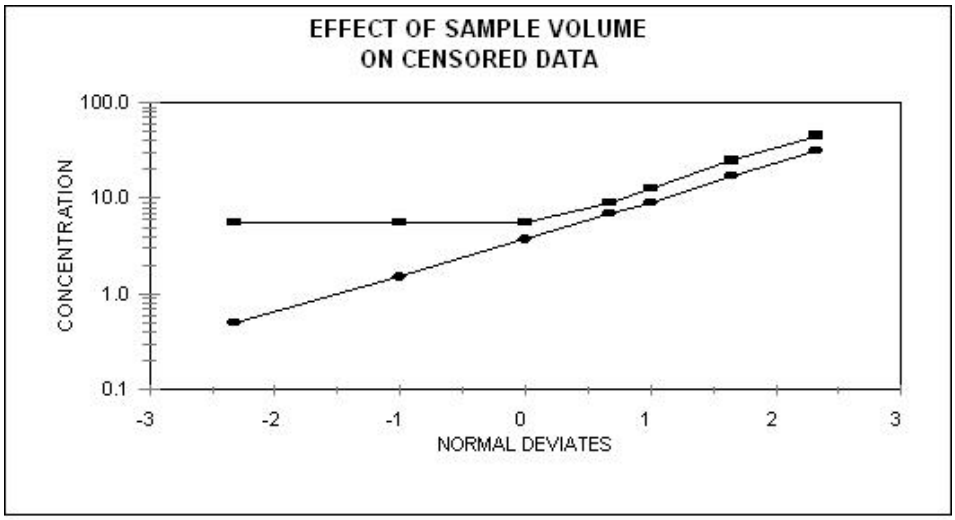

Figure 12. Effects of variable sample volumes on censored data.

For example, a constant sample volume will result in a horizontal log-plot with a geometric standard deviation (GSD) of 1.0. A variation in sample volumes will result in a log-plot with a positive slope and a GSD > 1.0, which may be difficult to distinguish from "real" data. Keeping the variation in sample volumes within a SET to $\pm$ 15% results in a GSD of about 1.2 or less.

An analysis of censored data in the LEAP database was performed by selecting 40 laboratory procedures with the largest sample sizes. Each of the 40 procedures were a combination of the same SET, but from multiple facilities. These procedures were described by 400 personal samples, and represented 62 % of the personal samples collected as part of LEAP.

All the samples for 15 of the procedures (38 %) were censored, while none of the samples were censored for 6 procedures (15 %). Therefore, the exposure potentials for 53 % of the 40 procedures were not affected by the method used to enter censored data into the database. Only seven of the 40 procedures (17.5 %) contained censored data and also had MAX %OEL values that exceeded 10 %. The degree of censorship for these procedures ranged from 20.4 % (10 of 49) to 71.4 % (5 of 7). However, only the two procedures described in Table 15 had MAX %OEL values exceeding 20 %. This suggests that using a single method to enter censored data in the database would not be expected to result in significant errors in the decision criteria.

Table 15. Procedures Including Censored Data and Having MAX %OEL Values of 25 % or Greater.

APPARATUS	CHEMICAL	SAMPLE SIZE	PERCENT CENSORED	MAX %OEL
S-evap	Methylene Chloride	33	27.3 %	35 %
Separatory Funnel	Methylene Chloride	49	20.4 %	25 %

THE SAMPLING STRATEGY

Sample Documentation

The minimum information to be collected during the QNA is described in Table 16. This includes the facility information, the SET description, and the exposure parameters required to calculate the partial-period exposure.

Table 16. Minimum Information to be Collected during the QNA.

Date	Analyte	Chemicals Sampled	Sample Volume
Facility	Sample Matrix	Time: Start	Exposure Control
Building	Apparatus	Time: Finish	Task Scale
Laboratory	Procedure	Time: Sample	Name, SSN
Sample Number	Task	Sample Flow Rate	Field Notes

The “total time” referred to in Table 3 (Finish - Start) is the time it takes the person to complete the SET; the task completion time. The “sample time” is the time the SET was actually sampled. Both times should be recorded; and they are frequently different.

- The task completion time is used to calculate the TWA exposure for the SET;
- The sample collection time is used to calculate the concentration of airborne agent.

For example, an extraction procedure using separatory funnels may involve three extraction cycles, each lasting two hours, for a total time of six hours. However, the industrial hygienist may have only sampled one two-hour cycle due to productivity requirements.

The sample documentation included on the data collection forms is listed below.

- The SET evaluation forms and field sampling forms are used to enter the data into the EASL database. Therefore, it is important that the same forms are used at all facilities within the organization during the qualitative and quantitative exposure assessments.

General Information: Facility description, Analyte name, Reference method, Sample date, Lab number, Sample media, Sample number, Procedure, Field notes, Report number, Activity

Exterior Sampling: Temperature, Humidity, Wind direction, Wind speed, Cloud cover

Airborne Chemicals: Sample type, Sample volume, Last name, First name, SSN, Start time, Flow rate, Sample time, Analyte weight (mg), Analyte concentration

Wipe Samples: Surface type, Sample area, Analyte weight (ug)

Random Sampling

One objective of EASL was to collect data so that it could be used to determine the exposure distribution of a SET by simply adding to the existing database during subsequent sampling campaigns. Every effort was made to collect samples as randomly as possible within the constraints of campaign sampling. Therefore, only one personal and one area sample were collected each time a SET was performed.

Exposure samples may be collected randomly in order to estimate the typical exposure; or during periods of peak exposure to estimate "worst case" exposures for regulatory compliance. The sampling strategy used in EASL may be described as the "stratified sampling of peak exposures"; a "worst case" scenario. Furthermore, many of the samples will probably be collected by directed sampling during sampling campaigns. Therefore, to the extent this description is accurate, a goal of truly random sampling will not be met.

The autocorrelation between sample results has been raised as a potential problem when campaign sampling is used.[33] Since detecting autocorrelation requires large sample sizes, the effects could not be evaluated for this study. However, it has been suggested that the high ventilation rates in laboratories makes autocorrelation between samples unlikely.[19]

In addition, other studies have suggested that relatively little autocorrelation was observed when campaign sampling was used, especially if sampling times were adjusted to task times.[11, 33] Finally, every effort was made to only collect one personal and area sample per day for each SET, which further minimized autocorrelation.[19]

The EASL protocol is based on the concept of Similar Exposure Tasks (SET). These are exposure groups that are defined and identified so that they are mutually exclusive. The concept of SET implies the use of a stratified sampling strategy rather than a simple random sampling strategy. The above terminology is described as follows:

- Stratified Sampling: Professional judgment is used to separate, or stratify, the sources of exposure into SET. Not all SET may be sampled, with an emphasis on sampling those SET with potentially significant exposures.

- Random Peak Sampling: The standard approach to industrial hygiene sampling is to choose sampling periods randomly throughout the work period. However, the objective of EASL is to characterize the exposure potentials of SET. Therefore, only "peak" concentrations are sampled, although the periods during which a SET is sampled are chosen as randomly as possible within the constraints of campaign sampling.

- Campaign Sampling: Intensive sampling over a short period of time, such as one week. Much of the EASL data will likely be collected during short periods rather than over an extended time period.

Campaign sampling may be the strategy of choice, since it would be difficult to keep personnel on stand-by, waiting to find out when a specific SET was being performed. It would be more typical, and more productive, to mobilize resources for intensive sampling during a one- or two-week period.

The proposed sampling strategy has several advantages, including the following:

- The assumption is made that all personnel within a SET are subject to the same distribution of exposures. Therefore, a smaller number of samples may be required to characterize exposures.

- It is cost effective. The protocol minimizes the life-cycle cost of performing industrial hygiene surveys by adding to the existing data rather than replacing it each time a survey is performed.

- The statistical "power" of the database increases as new data are added to the existing database.

- The data may be presented in a graphical format that is easier to communicate than statistical tables. This allows management to more easily observe exposure trends in the work place, improves communication between technical and nontechnical personnel, and aids in the transfer of information.

The sampling strategy determines whether or not the data (1) are representative of employee exposures, and (2) can be analyzed in such a manner that the objectives of EASL are met. The sampling strategy includes the:

- sample documentation;
- sample types;
- sampling methods;
- sampling parameters;
- sampling frequencies;
- sampling locations;

- analytical methods, and
- quality assurance considerations.

Sampling Schedules

A preliminary sampling schedule is discussed with the laboratory management, supervisors, and team leaders during the initial visit. This allows the quantity of sample media and the required number of persons to be estimated. However, a final schedule is generally prepared on the first day of the sampling period. The final schedule is dictated by vacations, training, equipment breakdowns, work loads, etc. Once a final sampling schedule is available, areas of responsibility can be assigned to the project personnel.

When campaign sampling at a remote site, one may plan on arriving on a Sunday, for example, and spending the entire week at the site. Monday would then be spent unpacking, labeling sample media, calibrating equipment, coordinating with laboratory management, and some sampling. Tuesday, Wednesday, and Thursday would be the most productive days for sampling, while Friday might be used for a combination of sampling, packing, the exit briefing, and travel.

Although one person may collect 30 samples on a good day, it should be assumed for planning purposes that each person will collect 15 samples per day. With two persons, a hundred or more samples may be collected during each week of sampling. If the sampling schedule allows sufficient flexibility, no more than one set of samples per day should be obtained for a SET to minimize auto-correlation effects.

The nomenclature relating to the sampling schedule contains the following terms:

- Primary Sampling - sampling conducted during the first full week of sampling; expected to result in the collection of 40-50% of samples.

- Secondary Sampling - sampling conducted during the second full week of sampling; expected to result in the collection of 30-40% of samples.

- Completion Sampling - spot sampling conducted by local personnel as the laboratory work schedule permits; expected to collect the final 10-15% of samples.

- Maintenance Sampling - future sampling campaigns to be conducted at scheduled intervals; designed to keep the database current.

In LEAP, it was preferable to assign an individual to a specified area of the facility for the entire sampling period. For example, one person was responsible for sampling the laboratories in Corridors A and B, while a second person was responsible for the laboratories in Corridors C and D. This allowed that person to become familiar with the activities in those areas, and usually resulted in additional procedures being discovered and added to the sampling schedule.

Sample Types

The types of samples that are collected as part of EASL, and their typical sampling locations, are illustrated in Table 17.

Table 17. Sample Types and Typical Sampling Locations.

SAMPLE TYPE	SAMPLE LOCATIONS
Personal	Breathing Zone
Area	Bench Top, Work Stations
Environmental	Outside, Hallway, Lunch Room, Office
Wipe	Bench Top, Hoods, Weighing Tables, Apparatus
Noise	Sonicators, Hoods, Shops, Mechanical Rooms
Differential Pressure	Lab vs Hall, Fume Hoods
Tracer Gas	Containment Labs, Solvent Storage

Field Blanks. A minimum of two field blanks were submitted for each sample media during each sampling campaign in LEAP. The media were opened and briefly exposed to the ambient environment. The sample was then sealed and included with the other samples.

Personal Samples. Personal samples for airborne contaminants are collected within the breathing zone of laboratory personnel. A small low-volume personal sampling pump is generally placed inside the pocket of the laboratory coat, and the sampling media suspended from the lapel with a clip. The sample pump used for obtaining personal samples should be as small and light as possible.

Table 18. Example guidelines for the collection of personal samples.

SAMPLE CLASS	MEDIA	SAMPLE TIME	FLOW RATE
Airborne Chemicals	Adsorbent Tubes	30 minutes	100 cc/minute
Airborne metals	37 mm MCE closed Cassette	30 minutes	2,000 cc/minute

Area Samples. Area samples for airborne contaminants are generally collected between the source and either the nearest analyst or the closest point of exhaust (fume hood). The sample media are placed just above the level of the bench top or at the approximate level of the breathing zone. Work stations situated within a laboratory, which are often occupied by persons not involved in performing the SET that is being sampled, are good locations for area samples.

Table 19. Example guidelines for the collection of area samples.

SAMPLE CLASS	MEDIA	SAMPLE TIME	FLOW RATE
Airborne Chemicals	Adsorbent Tubes	120 minutes	25 cc/minute
Airborne metals	37 mm MCE closed Cassette	120 minutes	500 cc/minute

Environmental Samples. Environmental airborne samples may be collected for TVOC's or other chemicals. However, the LOD for TVOC is 0.1 mg by the NIOSH 1500 method. This limitation made this particular method too insensitive for most background studies in LEAP.

Table 20. Example guidelines for the collection of environmental samples

SAMPLE CLASS	MEDIA	SAMPLE TIME	FLOW RATE
Airborne Chemicals	Adsorbent Tubes	240 minutes	100 cc/minute

Wipe Samples. Wipe samples are obtained by marking an area of surface material with masking tape or similar procedure. A gauze pad or other specified media is removed from the container using rubber gloves, wetted with an appropriate solvent, and the sample area wiped twice, in perpendicular directions. The media is folded and placed in the labeled container.

Table 21. Example guidelines for the collection of wipe samples

ANALYTES	METALS, PESTICIDES, HERBICIDES, PCB'S, PCP
MEDIA	GAUZE PADS, FILTER PAPER, SWABS
SOLVENT	DEIONIZED WATER, n-HEXANE, TOLUENE, METHANOL

- The objective is to obtain random samples of the surfaces to detect the presence of latent hazards. Obvious spills, unless representative for the area, should not be specifically sampled (but noted for response).

- Multiple smaller areas may be combined to achieve the desired area, rather than obtaining the entire sample from a single area. This protocol provides a more representative characterization of the surfaces in the workplace.

Sampling Methods

- Using different sampling methods can result in different estimates of exposure.

- Validated (NIOSH) sampling methods may be preferred for estimating exposures.

- Continuous sampling methods may be preferred for associating peak exposures with specific tasks.

Most airborne samples were collected using standard methods described by the National Institutes of Occupational Safety and Health (NIOSH), while a small portion were collected using standard OSHA methods.[14,15] Although adsorbent tubes were the primary media used for sample collection, diffusion badges, filter cassettes, and treated filter cassettes were also used for selected airborne agents. In addition, a Pocket Photoionization Detector (PID) (Rae Systems, Inc.) was used to continuously measure the concentrations of solvent vapors.

The previous Figure 4 is a plot of n-Hexane concentrations measured continuously with a Pocket PID inserted in the breast pocket of the chemist's lab coat. The SET involved 12 open 50-ml beakers, each containing 10 ml of solvent. The average personal concentration for the 30-minute period was also measured using a charcoal adsorption tube.

The PID recorded an average concentration of 18 ppm, while the average concentration for the adsorption tube was 24 ppm. Even using the higher value obtained with the adsorption tube as the basis for comparison, this was a 25 % difference in the two sample collection methods.

Each of these methods has its advantages. The adsorption tube is a validated method and is expected to provide a reliable estimate of exposures. It also provides a single average concentration that can be entered directly into a database. This method would be preferred if the exposures associated with specific tasks within a SET are expected to vary significantly.

However, continuous measurement methods provide much more detail, allowing peak exposures to be associated with specific tasks within a procedure. These methods should be considered if multiple tasks, each having a different exposure potential, are contained within a SET.

Sample Collection Times

Since LEAP was developed for task-based work environments, sample collection times were kept within the completion time of each SET.[10, 14] This resulted in a database that was "static" (the data could be used to estimate future exposures), and had maximum utility.

Exposure data are often collected over the majority of a work shift (8 hours) in order to estimate the Time-Weighted Average (TWA) exposure of an individual, which is used to assess regulatory compliance. However, collecting full-shift samples in a task-based work environment may not be an efficient use of resources, and may actually result in a database with limited utility.

The full-shift exposure of an individual is not measured in EASL, but rather the exposure potential of a SET. The logic behind this approach is that an 8-hour TWA exposure for an individual is only valid for the processes, activities, and work regimen the employee participated

in during the sampling period, and the exposure data are “nontransferable” to other days or work routines (the data are “dynamic” rather than “static”).

In order to associate a quantitative level of exposure with a specific SET, the maximum sample collection time has to be limited to the completion time of the SET. If the sample collection time were longer than the completion time of the SET, and especially if those sampling times varied from day to day, the analytical results reported by the laboratory would not reflect the exposure potential of the SET.

Documenting the exposure potentials of SET actually provides information that is more useful to management. For example, suppose the 8-hour TWA exposure is measured for an analyst on day 1; and the analyst participated in activities A and B during the sampling period. On day 2, while monitoring was not performed, the analyst participated in activities B and C. The analyst’s exposure could not be estimated for day 2 without obtaining a second set of samples.

However, if the levels of exposure that were produced by activities A, B and C were known, and the analyst’s work schedule was known, the analyst’s exposure could be estimated for any combination of those activities that were performed on any day. This information allows management to:

- Use administrative controls to prevent excessive exposures before they occur;
- Evaluate the level of personal protective equipment required for each SET;
- Minimize the need for sampling (and the cost).

In fact, if 8-hour TWA samples were collected, an impractical number of samples would have to be collected in most laboratories to simply demonstrate regulatory compliance.

The emphasis on the exposure potentials of SET rather than full-shift exposures allows the exposure data to be used for more than just compliance monitoring. The advantages of this approach include the following:

- A “static” rather than a “dynamic” database is created. Laboratory tasks (extraction, digestion, etc.) which have definable exposure distributions provide a logical basis for assigning individuals to exposure groups; and exposures can be associated with these groups.

- Specific tasks in a procedure (loading, unloading, disposal) with the greatest exposure potential can be identified;

- The potential exposure associated with assigned work schedules can be estimated before the tasks are performed. This allows administrative controls (modification of daily work assignments) to be used to avoid excessive exposures before they occur.

- The need to track 8-hour TWA exposures is limited to those workers assigned to SET with "unacceptable" exposure potentials [a small fraction of the total].
- It allows long-term average (LTA) exposures, and therefore chronic toxicity, to be estimated for SET (but not necessarily for individuals).
- Provides information for use in the design of new facilities; and
- It allows a management metric (Facility Exposure Index) to be calculated, which can be used to track exposure trends within and between facilities.

The disadvantages of this approach are:

- Individual 8-hour TWA exposures are estimated rather than measured directly.
- Estimating daily 8-hour TWA exposures requires the individual to keep a record of the assigned SET and contact times for each work day. However, this is only required for personnel assigned to SET with "unacceptable" exposure potentials, which were a small fraction of the SET in the LEAP database, and therefore a manageable task.

Sample Size

The collection of a minimum of six personal samples is recommended when the objective is to determine the distribution of exposures for a similar exposure group.[2, 3, 13, 32, 34, 35] A less ambitious goal of collecting a minimum of four area and four personal samples for each SET was established during the pre-planning for LEAP.[5] However, even this goal was not often attained. The reasons for the small sample sizes included:

- The samples were collected during one-week sampling campaigns, during periods when some SET were not performed.
- The number of times an active SET was performed during a one-week period was limited.
- Equipment malfunctions and scheduling conflicts further limited the number of samples that were collected for each SET.
- Limited resources, which forced a choice between sampling SET that were performed during the same time period.

In addition, prior experience with similar SET that had been sampled in other facilities often indicated a low exposure potential, and resulted in a low sampling priority for a SET. Therefore,

the exposure potentials of many SET were assessed based on small sample sizes, with the final assessment considering the QAR value of the SET.

An analysis of sample sizes was made for 420 exposure series from 25 Dutch industries, including 1,837 individual measurements.[20] About 59 % of the exposure series had a sample size between 3 and 6, while only 10 % of the series had a sample size greater than 6 samples. In comparison, 38 % of the LEAP data had a sample size between 3 and 6, and only about 5 % of the SET had a sample size greater than 6 samples. The relatively small sample sizes associated with the LEAP data, which were collected over a period of six years, indicate the difficulty of collecting exposure data in laboratories.

For example, an initial QNA was performed for 126 SET involving airborne chemicals, including SET with both negative and positive QAR values. Approximately 1,500 samples were collected for these SET; including 650 personal; and 850 area, environmental (outside, hallways, administrative areas), and microbiological samples. The number of personal samples collected in each facility ranged from a minimum of 22 (incomplete assessment) to a maximum of 156. The number of SET with an initial QnA and the number of personal samples collected from each facility are contained in Table 18. As indicated in Table 22, fewer than 25 SET were sampled in any one facility, with an average of 79 personal samples collected per facility.

Table 22. Number of SET for each Facility with an Initial Quantitative Assessment

FACILITY	SET	PERSONALS	FACILITY	SET	PERSONALS
A	18	68	F	15	73
B	14	156	G	9	47
C	17	72	H	10	50
D	8	22	I	23	75
E	22	92	- -	- -	- -

The frequency distribution of personal samples collected per SET is contained in Table 23. The sample sizes range from a minimum of 1 to a maximum of 20 for the 126 SET.

Table 23. Frequency Distribution of Sample Sizes for Personal Samples

SAMPLES PER SET	NUMBER OF SET	PERCENT OF TOTAL	CUMULATIVE PERCENT
1	34	26.9	26.9
2	36	28.8	55.7
3	21	16.4	72.1
4	17	13.7	85.8
5	9	6.9	92.5
6	3	2.1	94.7
7 - 20	8	6.2	100

Approximately 72 % of the SET were described by 3 or fewer personal samples; a sample size that precluded an effective statistical analysis.[2, 3, 31] Furthermore, 92 % of the 126 SET were described by 5 or fewer personal samples. Therefore, performing a statistical analysis was not possible for 72 % of the SET involving airborne chemical hazards; and would have resulted in measures of exposure with broad confidence intervals for an additional 20 % of the SET.

The data in Table 23 illustrate a significant reason for developing the QAR. The exposure potentials of only 11 of the 126 SET in Table 12 were described by six of more samples. This is the minimum sample size per SET recommended by AIHA.[2, 3] The QAR was developed once it became obvious that sampling was going to be of limited utility.

These data illustrate why a qualitative assessment methodology is required. Not only is sampling expensive, but it is very difficult to collect a sufficient number of samples for statistical analysis. Therefore, professional judgment is often the default method of assessing exposure potentials. That requires the development of a formalized decision logic that can be defended, which is the exposure assessment strategy.

However, one of the reasons only one or two personal samples were collected for many of the SET was the low exposure that was initially measured for those SET. If the maximum exposure was less than 10 % of the MAX%OEL, then those results were correlated with the QAR value for the SET. If the QAR value confirmed the expectation for a low exposure, sampling resources were diverted to other SET in subsequent facilities.

VARIABILITY OF EXPOSURES

In a published study, exposures for workers performing the same task using chemical solvents were monitored over six days.[4] Concentrations were found to range from 13 ppm to 78 ppm. Therefore, exposures within similar exposure groups that have been constructed based on observation are not expected to be “homogeneous”, nor conform to definitions of “controlled exposures”.[15, 18, 22, 25, 32] This variability also applies to the SET as defined in EASL, and the variability of exposures within a SET were frequently significant.

Task Duration and Concentration

Both the measured concentrations and the task times for a SET are distributions. The variability associated with several of these distributions is illustrated in Table 24. The relative standard deviations (RSD) [standard deviation divided by the mean] were calculated for various SET selected from one facility. The data in each column are for one SET, but were collected while several persons performed the SET.

These variations are representative of many of the SET included in the LEAP database.
In addition, since the 8-hour TWA is proportional to the product of the concentration and the task time, the variability for TWA exposures was even more variable than either the time or the

concentration.

Table 24. Relative Standard Deviations for Task Times and Concentrations for Selected SET.

Apparatus	Acc. 1-step Extractor	Acc. 1-step Extractor	Cont 1-step Extractor	Bulking, Wastes	S-Evap, Concen.
Task	Load	Unload	Load	Load	Load
Hazard	DCM	DCM	DCM	DCM	DCM
Sample Size	8	5	6	7	5
Task Time	71.9 %	57.6 %	40.1 %	111.4 %	37.7 %
Concentration	67.5 %	88.3 %	40.9 %	38.1 %	54.0 %
Exposure Rate	67.5 %	88.3 %	40.9 %	38.1 %	54.0 %
8-hour TWA	104.2 %	146.6 %	83.0 %	131.6 %	69.2 %

Variability of Data within SET

- Measuring exposures on any one day may result in a biased view of the exposure potential of a SET.

- Characterizing the distribution of exposures for a SET, not measuring one or two exposures, is the objective.

The exposure data in Table 25 were collected from the same procedure, performed by the same chemist, on eight different days The bench top extractions, using Dichloromethane (DCM), were sampled during three different one-week periods of campaign sampling. The Action Level for DCM was 12.5 ppm, the PEL was 25 ppm, and the STEL was 125 ppm. The data in Table 25 are reported as percentages of those OEL.

Table 25. Solvent extraction procedure using dichloromethane; performed by the same chemist on eight different days.

DATE	AL (%)	PEL (%)	STEL (%)
09-09	28	14	13
09-10	46	23	61
09-11	18	9	20
10-29	56	28	76
11-04	6	3	17
11-25	124	62	86
11-26	82	41	62
11-27	4	2	11
Average	46 %	23 %	43 %
Exceedance Fraction	62 %	31 %	6 %

The DCM exposure was less than 15 % of the PEL on four of the eight days, and 20 % or less of the STEL. Only one exposure exceeded the AL, and none of the exposures exceeded the PEL or STEL. The average exposures were 46 % of the AL, 23 % of the PEL and 43 % of the STEL.. These data might lead the CHO to classify the exposure potential of this SET as acceptable.

Therefore, if only one sample had been collected from this SET, there would have been better than a 50 % chance that the CHO would have concluded that exposures were less than 15% of the PEL. This could have resulted in a decision that exposures were in control when they were actually not in control.

The intra-worker variability was significant, with exposures varying between 2 % to 62 % of the PEL for methylene chloride, with a GSD of 4. The estimated STEL exposures varied from 11 % to 86 %, with a GSD of 2.3.

The measures of exposure for this SET were:

- Average exposure was 17.7 % of the PEL;
- The 95th percentile concentration was 71.6 % of the PEL;
- The MAX %OEL was 123 % of the Action Level; and
- The Y%OEL was 89 %.

Several of these measures of exposure were significant, including the Action Level, 95th percentile concentration, and Y%OEL; and indicated the need for a Task Review and/or additional control measures. The exceedance fraction (f) is the percentage of exposures expected to exceed an OEL. Exposures may be considered to be "in control" if, for example, exposures are not expected to exceed the OEL more than 5 % of the time. This condition is equivalent to an f of 5 % or less. Using this criterion, the exposure potentials of SET with an exceedance fraction greater than 5 % would not be acceptable. The f values for the SET in Table 25 were 62 %, 31 % and 6 %, respectively, again indicating an unacceptable exposure potential.

Geometric Standard Deviations

The geometric standard deviation (GSD) is a measure of the variability associated with data that can be described as a lognormal distribution.[32] It is an important parameter. However, estimating the GSD for a SET based on a small sample size (< 30) may result in large negative errors in both the estimated GSD and the estimated fraction of exposures exceeding the OEL.[32]

It has been suggested that a reasonable range of GSD values for environmental samples collected outdoors is approximately 2.5 to 3.5, with a typical value of 2.7.[32] The ventilation rates in laboratories are typically 4 to 12 air changes per hour, which may be more representative of the outdoors than typical indoor conditions. Therefore, the variability in the exposure data collected in laboratories, represented by the GSD, was compared to the variability of data collected outdoors.

Statistical parameters, including the GSD, were calculated for about 100 SET in the LEAP database. The median GSD for 93 of these SET involving airborne chemicals was 2.4, with a mean GSD of 3.2. These values were consistent with the reported value of 2.7.[32] The distribution of GSD values for airborne chemical samples, ranged from a low of 1.2 for totally censored SET to a high of 6.9.

The range of GSD values for exposure to benzene for 19 job groups in refineries has been reported.[23] Approximately 58 % of the 19 GSD values were less than 4. In comparison, about 65 % of the 93 GSD values that were calculated using the LEAP database were less than 3, and 77 % were less than 4. The possible association of GSD values with values of the geometric mean (GM) was evaluated by examining 64 SET for chemical agents. The coefficient of correlation (r) for these SET was 0.195. Therefore, the GSD did not appear to be highly correlated with the level of exposure for chemical agents.

However, for airborne fungi, there was some indication that the GSD was associated with the degree to which the sampled environment was contaminated, as illustrated in Figure 13. The range for airborne microbiological samples was from 1 to 9. A GSD of 2 or less was associated with control areas, while a GSD of 3 or greater was associated with areas of microbial amplification.

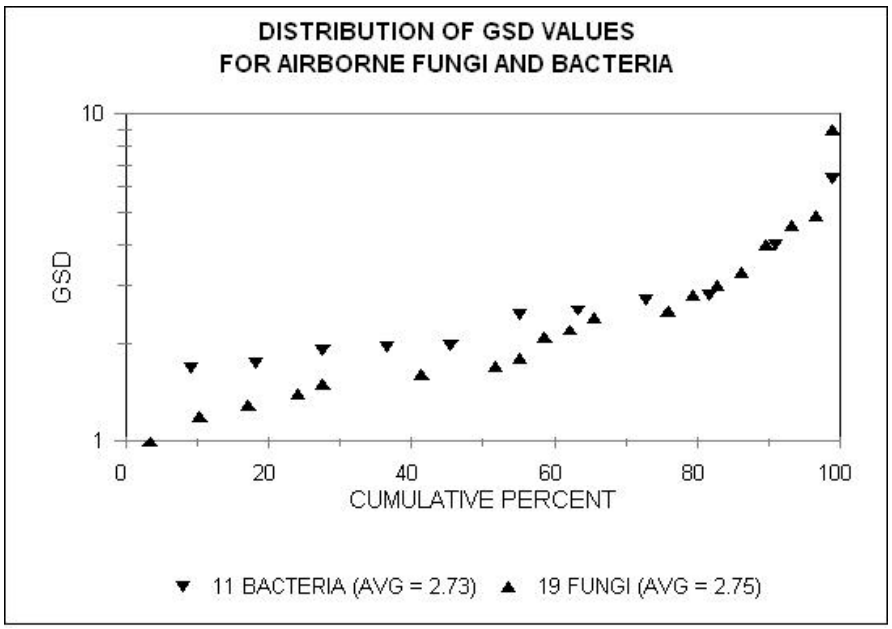

Figure 13. Rank Order of Fungal and Bacterial GSD Values.

An association between the GSD and GM for microbial contaminants might be expected. A 10-fold variation in the concentration (100 - 1,000 spores/m³, for example) of airborne fungi would result in a GSD of 2, while a 40-fold variation (200 - 8,000 spores/m³, for example) would be

required to result in a GSD of 3. Therefore, higher GSD values might be expected to be associated with contaminated environments.

SAMPLE ANALYSIS

Laboratory Data

An AIHA certified laboratory was used to analyze the field samples. Field samples were submitted along with field blanks. Multiple analytes may be collected on a single medium if the sample preparation steps are compatible (confirm with the laboratory performing the analysis). The analytical laboratory included blanks, duplicate samples, and recovery controls, as required.

Analytical Methods

Standardized laboratory methods were used. The sampling and analytical protocols were based on NIOSH methods whenever possible. If required, EPA and OSHA methods were also specified. A minimum of one field blank for each analyte was included along with each days field samples.

It is important for the field personnel to assist the analytical laboratory by submitting clearly written field sheets and sample custody sheets. Otherwise, significant data losses can occur.

The limit of detection (LOD) and/or limit of quantification (LOQ) are reported by the analytical laboratory. The LOD was used to include censored data in the data tables.

CHAPTER 5: ASSESSING EXPOSURES

Objectives

The Qualitative Assessment (QLA) is simply the application of a decision logic to the information obtained during the WC and the QNA. That information is used to assign an expected exposure potential to each SET.

The objective of the QLA is to limit the time and resources, both monetary and personnel, required to perform the assessment. Therefore, the QLA serves two purposes. First, it is a cost-effective method for documenting exposure potentials (but not exposures). If adequately documented, the QLA protocol may be used to satisfy the requirements of the OSHA Laboratory Safety Standard.

Second, the QLA prioritizes SET for sampling. Specifically, the QLA is used to limit sampling to the extent possible. If the estimated exposure potential is high, the SET is either scheduled for additional sampling or a task review is performed. If the estimated exposure potential is low, the final assessment may be based on an evaluation of qualitative factors using professional judgment.

The WC and QLA were critical components of the LEAP strategy. Their importance is supported by other exposure assessments performed in research facilities.[10] In fact, limiting the assessment of exposures to a QLA may be appropriate for some operations.[10, 21, 22] This makes the validation of a QLA methodology for laboratories an important goal.

Demonstrating that SET with low exposure potentials can be identified during the WC and subsequent QLA provides the CHO/HSC with a cost-effective method for performing the initial exposure assessment.[2] The ability to place a greater reliance on the QLA during the initial assessment process would reduce sampling requirements, resulting in lower overall costs for the exposure assessment. This would allow assessments to be performed in a larger number of laboratory facilities and/or with a greater frequency.[23]

Exposure Potentials

An exposure assessment has been defined as *the systematic identification, evaluation and documentation of exposure potentials in the workplace*. The next step is to define exposure potential in terms of risk. Risk is a function of the *probability* of an exposure and the c*onsequences* of that exposure. The CHO has to be able to describe these factors for each SET in order to assess their exposure potential.

The factors affecting the probability of an exposure may be summarized into the following categories:

- exposure controls;
- process controls;
- laboratory design; and
- work practices.

There are several schemes that have been proposed for assigning an exposure probability rating to exposure groups.[3, 21, 25] Examples include those based on the frequency and level of exposure (Table 26a), the potential for exposure (Table 26b), and prior knowledge of exposure data (Table 26c).

Table 26a. Assessing Exposure Probabilities based on Frequency and Level of Exposure.

RATING	FREQUENCY and LEVEL
1	No contact
2	Infrequent contact at low concentrations
3	Frequent contact at high concentrations
4	Frequent contact at high very concentrations

Table 26b. Assessing Exposure Probabilities based on Potential for Exposure.

RATING	POTENTIAL FOR EXPOSURE	EXAMPLES
1	Closed system	Glove box
2	Partially open system	Fume hood
3	Open system with exhaust	Local exhaust
4	Open system without exhaust	Bench top

Table 26c. Assessing Exposure Probabilities based on Existing Exposure Data.

RATING	EXISTING EXPOSURE DATA
1	Exposure < 10 % of the OEL
2	10 % <= Exposure < 50 % of the OEL
3	50 % <= Exposure < 100 % of the OEL
4	Exposure => 100 % of the OEL

Time constraints during the initial workplace characterization in LEAP only allowed an average of 15 minutes to be spent in each individual laboratory. The question was, what could be learned about exposure probabilities in 15 minutes or less? This constraint made a system based on the potential for exposure, as illustrated in Table 26b, a reasonable choice for assessing the probability of exposure.

Second, as indicated in the examples, the concept was easily adapted to coincide with typical exposure controls employed in laboratories. Therefore, this was the approach that was selected to initially assess the exposure potentials of SET. Once exposure data have been collected and analyzed, then the approach illustrated in Table 26c becomes a viable option for assessing exposures.

The factors affecting the consequences of an exposure may be summarized into the following categories:

- time of exposure;
- frequency of exposure;
- level of exposure; and
- agent toxicity, acute or chronic.

Similar systems are also commonly available to assess the consequences of exposure. Examples include those based on descriptive phrases (Table 27a), toxicological testing (Table 27b), and hazard description and/or exposure limits (Table 27c).

Table 27a. Assessing Consequences of Exposure based on Descriptive Phrases.

RATING	DESCRIPTIVE PHRASE
1	Minor reversible injury; Slight irritation
2	Temporary reversible injury; Moderate irritation
3	Major injury; Severely irritating; Corrosive
4	Permanent damage from single exposure

Table 27b. Assessing Consequences of Exposure based on Descriptive Phrases.

RATING	AGENT TOXICITY
1	Inhalation LD_{50} > 20 mg/L (Rat)
2	2 < Inhalation LD_{50} <= 20 mg/L (Rat)
3	0.2 < Inhalation LD_{50} <= 2 mg/L (Rat)
4	0.2 < Inhalation LD_{50} (Rat)

Table 27c. Assessing Consequences of Exposure based on Descriptive Phrases.

RATING	HAZARD DESCRIPTION	EXPOSURE LIMIT
1	Minimal Hazard	OEL => 100 ppm
2	Moderate Hazard	50 ppm <= OEL < 100 ppm
3	Serious Hazard	5 ppm <= OEL < 50 ppm
4	Severe Hazard	5 ppm < OEL

Whenever possible, the consensus OEL was used as a surrogate for the consequences of

exposure. This was the simplest approach, as well as being consistent with regulatory compliance.

Exposure Assessment Criteria

The QLA methodology used in EASL, and the decision logic used to estimate exposure potentials, was based on the criteria in Table 28.

Table 28. Criteria for Classifying the Exposure Potentials of SET.

CRITERIA	QAR*	PRIMARY CONCERN	SECONDARY CONCERN
Activity Rating	AR	Sample Preparation	Sample Analysis
Compliance Rating	CR	OEL <= 50 ppm	OEL > 100 ppm
Exposure Control Rating	ECR	Bench Top	Fume Hood
Hazard Rating	HR	Organic Solvents	Acids, Metals, etc.
Task Frequency	Y%OEL	3 - 5 Times per Week	< 1 Time per Week
Task Duration	Y%OEL	=> 30 Minutes	< 15 Minutes
Task Scale	NA	Solvent Volume => 1 liter	Solvent Volume < 0.1 liter

*Qualitative Assessment Rating

The numerical limits included in Table 28 were derived by analyzing the results of the approximately 1,500 area and personal samples in the LEAP database, and are therefore descriptive (of those data) rather than predictive (of new data). Although the specific values in Table 28 provide general guidance, the reader is strongly advised to evaluate the applicability of these values to a particular facility.

The significance of Table 28 is that an assessment of exposure potentials could be performed for the majority of SET in the LEAP database using simple qualitative criteria that were easy to obtain, and without collecting a large number of samples. In fact, once the criteria in Table 28 had been validated, sampling was suspended for a significant percentage of the SET.
Several constraints were placed on the QLA methodology that was developed for EASL, including:

- The required information had to be simple to understand;
- The parameters had to be readily obtainable during the WC; and
- The exposure potentials of SET had to be ranked.

The criteria in Table 28 reflect these constraints, for example:

- The criteria are simple in concept, and the information can be acquired without having specialized knowledge.

- The criteria in Table 4 (except exposure limits) can typically be obtained during a brief visit of 15 minutes or less (The OEL values could be obtained either before or after the site visit).

The limited number of criteria in Table 28 were adequate for describing the exposure potentials of the majority (90 %) of the SET in the LEAP database; and (except for task scale) could be used to calculate a Qualitative Assessment Rating (QAR). The QAR was used to numerically rank the exposure potentials of the SET.

The criteria in Table 28 are subdivided into primary and secondary concerns. The conditions listed as primary concerns were typical of SET that had elevated exposure potentials. Significant exposures were defined as those that equaled or exceeded 10 % of the minimum OEL. SET described by the conditions listed as secondary concerns generally had low exposure potentials. However, the values in Table 28 are discontinuous. This was done to emphasize the need for professional judgment in performing exposure assessments.

Qualitative Assessment Rating

The Qualitative Assessment Rating (QAR) was the criterion that was used to prioritize SET according to their expected exposure potentials. For example, since resources were limited, those SET with negative QAR values were assigned a low sampling priority. Resources could then be focused on those SET with the greatest potential for producing excessive exposures.

Once the high-priority SET had been adequately assessed, then the low-priority SET were scheduled for sampling. However, even then, only enough samples were collected from low-priority SET to validate the calculated QAR value. To the extent that the QAR concept can be validated for a facility, small sample sizes (n <= 3) combined with negative QAR values could be used to identify SET with low exposure potentials

The qualitative assessment of a SET's exposure potential was based on the first four ratings in Table 28; the exposure controls, the type of hazard, the type of activity, and the OEL of the agents associated with the SET. These factors have been combined into the QAR, which is used to calculate a numerical rating for the SET.

A QAR was calculated for each SET using Equation [1]. The component ratings, in one form or another, can be found in numerous ranking methodologies related to exposure assessments.[2-4, 21, 25] These individual ratings are defined in the following sections of this chapter.

[1] QAR = Ln[(ECR x AR) / (CR x HR)]

ER - Exposure Control Rating	CR - Compliance Rating
AR - Activity Rating	HR - Hazard Class Rating

Equation 1 was developed by empirically correlating the parameters in Table 28 with Ln(%OEL) values. Therefore, as previously emphasized, the QAR is only descriptive, not predictive.

The natural logarithm was included in the equation to convert the values to a simple numeric scale with a range of -8 to +6. The QAR results in a numerical rating of a SET based on the criteria in Table 28, and may be interpreted as follows:

- SET with negative QAR values have characteristics similar to those SET in the LEAP database that were never associated with exposures greater than 10 % of the minimum OEL.

- SET with negative QAR values are expected to have similar exposure potentials to those in the LEAP database that could have been excluded from sampling.

- Those SET with positive QAR values are similar to SET in the LEAP database that *sometimes* produced elevated exposures.

- A positive QAR value does not indicate that excessive exposures will be detected, but it does indicate that SET with similar characteristics have produced excessive exposures.

The initial Sampling Decision (SD) for a SET was arrived at by applying the following decision logic to the QAR value:

- If QAR < -0.25, then SD is “Exclude SET from sampling”;
- If -0.25 <= QAR <= 0.25, then SD is “Uncertain” (use professional judgment);
- If QAR > 0.25, then SD is “Include SET in sampling”.

Compliance Rating

The Compliance Rating (CR) was defined as the minimum OEL for those agent with consensus exposure limits. For example, the minimum OEL for dichloromethane is the OSHA Action Level (AL) of 12.5 ppm rather than the PEL of 25 ppm. This provides the most conservative assessment of exposure potential. However, either the TLV or the PEL could have been used as the CR. Parameters for agents with OEL’s expressed as ppm and mg/m^3 were calculated separately.

Various methods have been described for assigning a toxicity rating to chemical agents.[2, 21, 25] However, EASL emphasizes the regulatory consequences of exposure by referencing exposures to consensus OEL values.

Exposure Control Rating

A variety of rating systems have been suggested for assessing the effectiveness of exposure controls.[3, 21, 25] The Exposure Control Rating (ECR) used in EASL is based on the openness of the system, and therefore the potential for coming in contact with airborne agents. This system, which is illustrated in Table 26b, is simple and directly applicable to laboratories.

The ECR was assigned the values contained in Table 29 for the work locations common to many laboratories. Again, it is emphasized that the actual values were derived empirically. The rating values in Table 29 simply illustrate the methodology, and should be validated for a particular facility.

Table 29. Suggested Exposure Control Ratings for Typical Work Locations

Exposure Control	Rating	Example
Closed system	0.05	Glove box
Partially open system	2	Fume hood, Vented exhaust
Open system, with exhaust	15	Local exhaust systems
Open system, no exhaust	50	Bench top, Floor

Table 29 suggests a “protection factor” of 25 for procedures performed in fume hoods compared to those performed on the bench top. This ratio was determined by comparing exposures for similar SET performed under both conditions. Although these comparisons resulted in a range of ratios, 25 was selected as a representative value.

Once the ratio of 25 had been selected, the specific rating values of 2 and 50 for SET performed in fume hoods and on bench tops, for example, were selected to reflect the values in Table 30.

Table 30. Minimum OEL Values Resulting in a Positive QAR for a SET

ACTIVITY	BENCH TOP	LOCAL EXHAUST	FUME HOOD
ANALYSIS	4 ppm	0.5 ppm	0.05 ppm
SAMPLE PREP	35 ppm	10 ppm	5 ppm

The conditions resulting in a negative QAR value for a SET are summarized in Table 30. That is, exposures exceeding 10 % of the minimum OEL were not detected under those conditions. For example, Table 30 indicates that

- An instrumental analysis procedure performed on the bench-top, and involving a chemical agent with a minimum OEL of 4 ppm or greater, is not expected to result in a positive QAR value (low potential for significant exposure).

- A sample preparation procedure performed on the bench-top, and involving a chemical agent with a minimum OEL of 35 ppm or greater, is not expected to result in a positive QAR value (low potential for significant exposure).

These data indicate that a sample preparation procedure involving benzene (TLV = 1 ppm), even when performed in a fume hood, sometimes resulted in an exposure that was greater than 10 % of the minimum OEL. Conversely, procedures involving an agent with a minimum OEL greater than 5 ppm, when performed in a (functioning) fume hood, could probably be assigned a low sampling priority during the initial phase of the assessment.

Activity Rating

The Activity Rating (AR) is a variable that allows professional judgment to be included in the decision logic. It is included in the QAR to account for variables such as the degree of contact with the agent, work practices, etc.

For example, consider two procedures performed on the bench top. The first might be an extraction procedure using liter quantities of a solvent; while the second procedure might involve the injection of microliter quantities of that same solvent into a gas chromatograph. Although the exposure potentials for these two procedures are intuitively different, both procedures would have identical QAR values if the AR were not included in the calculation.

Typical values for the AR might range between 0.1 and 10, although any value may be chosen. Examples of AR values included in EASL are indicated in Table 31.

Table 31. Suggested Activity Ratings for Common Laboratory Procedures

ACTIVITY	RATING	EXAMPLES
General	0.1	Shipping & Receiving
Analysis, Instrumental	0.1	GC, AA, Autoanalyzer
Analysis, Personal	1	Microscope, Stds. Prep.
Sample Preparation	1	Extraction, Filtration
Wastes and Bulking	1	Solvent Recovery, Transfers

The term “personal analysis” is used to refer to SET where the person is directly exposed to the agent during the analysis. Common examples include the preparation of standards, microscopic analysis, manual titration, etc. These activities often place the individual in close contact with vapors or other airborne agents.

Sample preparation activities refer to typical laboratory procedures involving multi-liter quantities of solvents, such as filtration, extraction, concentration, distillation, etc.

Hazard Rating

The Hazard Rating (HR) is an empirically derived constant that allows the QAR, and the decision logic for the Sampling Decision, to be applied to various classes of chemical agents. For example, the various classes might be organic solvents, airborne metals, pesticides/ herbicides/PCB's, particulate matter, etc. Examples of HR values that were used in EASL are contained in Table 32.

Table 32. Suggested Chemical Class Ratings for Airborne Agents

CLASSIFICATION	UNITS	RATING	EXAMPLES
Solvents, Organics	ppm	1	n-Hexane, Acetonitrile
Metals, Airborne	mg/m^3	5	Lead, Cadmium
Acids, Mineral	mg/m^3	10	Nitric acid, Sulfuric acid

Excessive exposures due to mineral acid vapors were never detected, even in laboratories where the metal cabinets were heavily rusted.

Task Scale

Variations in exposures are expected to be related to changes in the: (1) generation rate of the contaminant, (2) rate of contaminant dilution, and (3) positioning or mobility of the worker.[14, 28] The association between the level of exposure and task scale (number of extraction units, volume of solvent) was only evaluated for a small number of SET.
However, the relationship between exposure level and task scale varied from being proportional for some SET to being inversely proportional for other SET; a consistent relationship was not obvious. Therefore, it was concluded that task scale was not a good predictor of exposure potential, and this parameter was not included in the QAR.

A review of the LEAP data suggests that environmental conditions in many laboratories effectively controlled exposures (placement of air supply diffusers, air changes per hour, placement of work stations relative to sources and exhausts). However, detailed information on environmental parameters in each laboratory was not included in the assessment strategy, since this information was not readily obtainable during the WC.

The high ventilation rates encountered in laboratories did not appear to increase the variability of the data for airborne chemicals. The high air exchange rates probably tended to suppress peak concentrations, reducing the GSD. This effect is illustrated in Figure 14, which is a log plot for airborne lead concentrations inside containment. The containment, maintained under negative pressure, was used to analyze soil samples. The high ventilation rate was able to control the airborne concentration of lead to less than about 150 ug/m^3 as indicated by the right-truncated log plot.

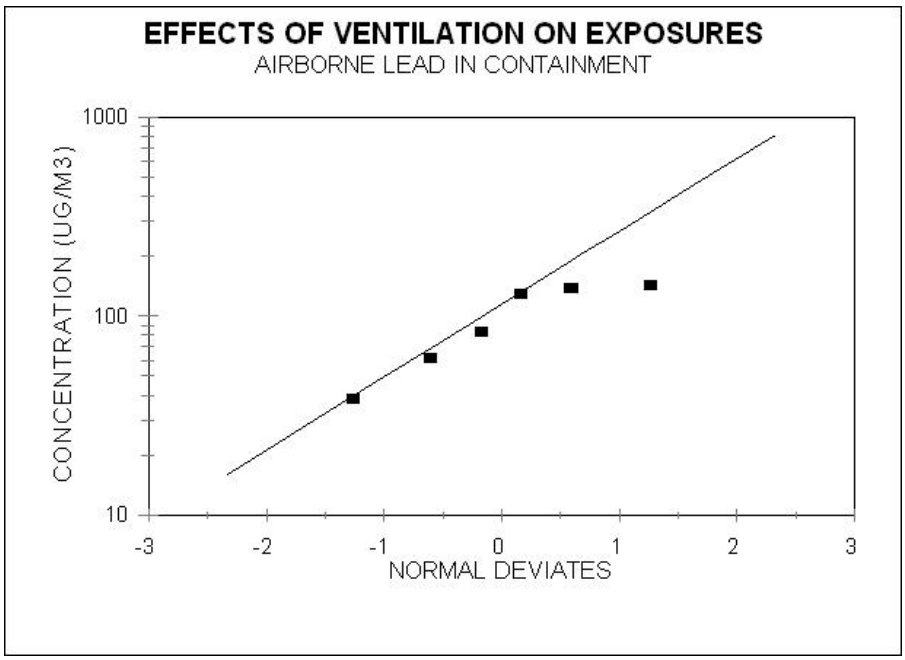

Figure 14. Concentrations of Airborne Lead in Containment.

Application of the QAR

Although sampling data for only 126 SET performed in six facilities are contained in the LEAP database, a QLA was performed for a total of 365 SET in 9 laboratory facilities. The types of activity associated with the 365 SET in the LEAP database are illustrated in Table 34. The SET described as "miscellaneous" were generally those that did not have consensus OEL.

Table 33. Types of SET in the LEAP Database with Qualitative Assessments.

PROCEDURES	NUMBER	PERCENT
Miscellaneous	25	7 %
Analysis, Instrumental	55	15 %
Analysis, Personal	68	18 %
Sample Preparation	217	59 %

The QAR calculated for these SET were compared with their measured exposure potentials, as represented by the MAX %OEL for each SET. The MAX %OEL values included the PEL, TLV, and conservative estimates for the STEL and CV whenever possible.
The 126 SET involving airborne chemical hazards that are contained in the LEAP database have a QAR range of about -8 to +5. All SET with a QAR of less than -0.25 had a MAX %OEL of less than 10%, and were assigned a Sampling Decision of "Exclude from sampling".[3, 4, 21, 25]

Figure 15 is a plot of the MAX %OEL versus the QAR for 52 SET that were performed on the bench top, and which did not contain censored data. The coefficient of correlation was 0.77 (r^2 = 0.60).

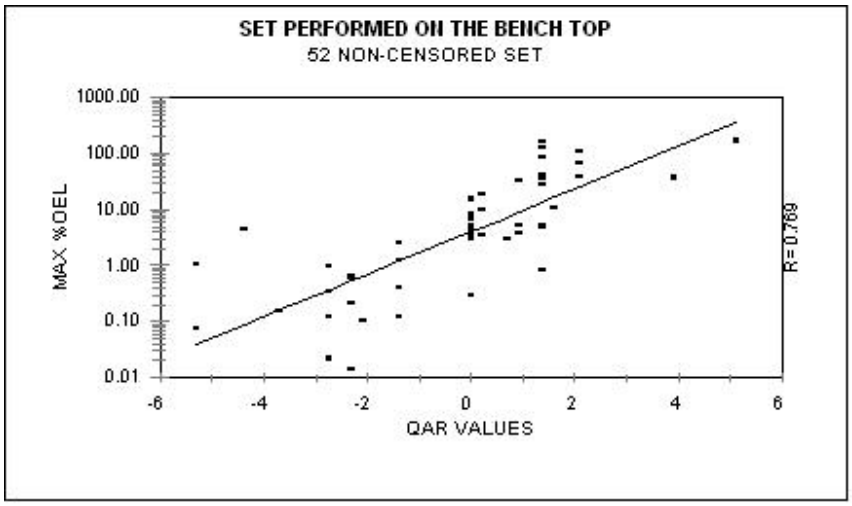

Figure 15. Maximum %OEL Values as a Function of the QAR for Bench Top Procedures.

The QAR values for the SET summarized in Table 34 resulted in the following sampling decisions: Exclude = 35 %; Uncertain = 21 %; and Include = 44 %. Therefore, based on the QAR, less than half the SET performed on bench tops were expected to result in exposures exceeding 10 % of the minimum OEL.

Table 34. Summary of Sampling Decisions for SET Performed on the Bench Top.

SAMPLING DECISION	QAR RANGE	SET	AVERAGE (MAX %OEL)	MAXIMUM (MAX %OEL)
Exclude	QAR < -0.25	35 %	0.7 %	4.3 %
Uncertain	-0.25 <= QAR <= 0	21 %	5.5 %	15.4 %
Include	QAR > 0	44 %	47.4 %	171.6 %

Bench-top SET with a positive QAR had MAX %OEL values ranging from 0.01 % to 172 %. Therefore, a positive QAR value indicated that a SET:

- May or may not have a high exposure potential; but
- Did have characteristics that could result in a high exposure potential.

The MAX %OEL versus the QAR for 23 SET that were performed in a fume hood did not contain censored data. The coefficient of correlation was 0.76 ($r^2 = 0.57$). The QAR values for the SET performed in fume hoods and summarized in Table 35 resulted in the following sampling decisions: Exclude = 87 %; Uncertain = 4 %; and Include = 9 %.

Table 35. Summary of Sampling Decisions for SET Performed in Fume Hoods.

SAMPLING DECISION	QAR RANGE	SET	AVERAGE (MAX %OEL)	MAXIMUM (MAX %OEL)
Exclude	QAR < -0.25	87 %	4.1 %	18.3 %
Uncertain	-0.25 <= QAR <= 0	4 %	8.1 %	8.1 %
Include	QAR > 0	9 %	3.7 %	6.6 %

The highest MAX%OEL value for SET with a QAR of less than -0.25 was 18.3 %. However, the unusually elevated exposure potential for this SET was due to the fact that the apparatus was too large to fit entirely inside the fume hood. Therefore, the SET was not actually performed inside the fume hood, a situation readily identified as requiring professional judgment during the WC.

However, one should be aware that poor work practices, or atypical conditions, could result in elevated exposures even for SET with a negative QAR. In addition, it must be emphasized that small sample sizes should only be used with either (1) a substantial amount of professional judgment, or (2) in combination with a QlA methodology that has been validated by the user for their particular workplace.

Estimating Sampling Priorities for SET

Once data were available from the initial phase of the quantitative assessment, the exposure potentials of SET were assessed using the decision criteria contained in the qualitative assessment. Instead of assessing the exposure distributions of SET using statistical parameters, the exposure potentials of SET were assessed using decision criteria based on a combination of their (1) QAR value, (2) existing sample size, and (3) MAX %OEL value.

The decision criteria were:

- If the QAR for a SET was positive, a minimum of 4 personal and 4 area samples were scheduled to be collected.

- If the QAR for a SET was negative, and at least one sample had been collected, the decision logic in Table 36 was used to assign a sampling priority to the SET.

Table 36. Sampling Priority for SET with a Negative QAR.

MAXIMUM %OEL	SAMPLES COLLECTED	SAMPLING PRIORITY
MAX %OEL < 1 %	=> 2 < 2	Low High
1 % <= MAX %OEL < 10 %	=> 3 < 3	Low High
MAX %OEL => 10 %	=> 4 < 4	Low (Statistical Analysis) High

For example, if the QAR for a SET was negative, two samples had been collected, and both samples were less than 1 % of the minimum OEL [the OSHA Action Level for methylene chloride, for example], then the exposure potential was considered to be of minimal concern, and the sampling priority was "low".

Based on the criteria in Table 37, 80% of the 126 SET included in the LEAP database required three or fewer samples to describe their exposure potentials. Therefore, EASL is expected to be an "efficient" strategy in that it should allow a rational sampling decision to be based on a limited number of measurements.[15]

If the MAX %OEL for a SET exceeded 10 %, and a minimum of 4 samples had been collected, statistical parameters similar to those in Table 39 were calculated for the SET. Obviously, the more samples that are collected for a SET, the more confidence one has in the results. If the resulting confidence intervals were too wide to effectively assess the exposure potential, then: (A) additional samples were collected; or (B) a Task Review was performed.

Table 37. Example statistical parameters calculated for a SET.

Minimum	Geometric Mean	MVUE of mean	95 %-tile concentration
Maximum	95 % UCL/LCL on GM	95 % UCL/LCL on MVUE	95 % UCL/LCL on C_{95}
Average	Geo. Std. Deviation	MLE of mean	Cumulative percent distribution

CHAPTER 6: MANAGING EXPOSURES

Response Actions

Those SET with an elevated %OEL or Y%OEL require a response action by the CHO/HSC. Example response actions based on the Y%OEL, as one example, are contained in Table 38.

Table 38. Suggested Response Actions based on the Maximum Yearly Percent OEL

Response Action	Y%OEL <= 10 %	10% < Y%OEL <= 25 %	Y%OEL > 25 %
Exposure Potential	Acceptable	Uncertain	Evaluate
Administrative Priority	Low	Moderate	High
Sampling Priority	Exclude	Uncertain	Include
Work Schedule	Exclude	Include	Include
Engineering Controls	Acceptable	Uncertain	Evaluate
Evaluation Frequency	Upon Change	36 Months	12 Months
Risk Communication	OSHA Notification of results	OSHA Notification + Task Meeting	OSHA Notification + Task Meeting + Task Review
Medical Surveillance	Exclude	Uncertain	Evaluate

The factors evaluated during a task review might include, for example, (1) process modifications, (2) work schedules and practices, (3) the need for exposure controls, and (4) environmental conditions.

Medical surveillance of laboratory workers, and even administrative workers, can represent a substantial economic burden to an organization. Table 10 provides a decision logic for assessing the need for medical surveillance. It provides a rationale for the selection criteria, and may make the process more transparent to concerned workers.

Work Schedules

EASL recommends that individuals assigned to work on one or more SET with a MAX %OEL greater than 10 %, or a Y%OEL greater than 25 %, should be included in a subsequent risk assessment conducted by the CHO/HSC. These “trigger” values were derived empirically by interviewing laboratory workers, and then assessing the impact of the reported work schedules on their TWA exposures.

Since many laboratory workers participate in multiple SET during any one day, the anticipated exposures from each SET can be summed to calculate their TWA exposure. This calculation can be performed by the supervisor, or the worker if they have access to the database, for a proposed

work schedule. As examples, modifying work schedules to achieve a maximum daily %OEL of less than 75 % and a maximum daily Y%OEL of less than 60 % would be reasonable goals based on the LEAP database.

Table 39 demonstrates the procedure for estimating daily exposures for individuals; and for demonstrating how individuals could be empowered to estimate potential exposures before they occur. The first two columns in Table 39 describe two tasks that were performed within the same laboratory procedure, a solvent extraction using separatory funnels. The last two columns describe bulking waste solvent involving exposure to two chemicals.

Table 39. Average Exposure Parameters for Two Laboratory Procedures.

SET	1 ((DCM)	2 (DCM)	3 (DCM)	3 (n-Hexane)
Time_ [hr]	2.3	0.25	0.5	0.5
ER_[ppm/hr]	3.1	30.0	16.8	10.3
%OEL	29	30	33	10

Time = Task Completion Time (hours)
ER = Exposure Rate (ppm/hr)
CONC = Concentration (ppm)

Suppose a worker was assigned both of these procedures during a single work shift. Since the information in Table 39 is contained in the EASL database, their supervisor, or a worker with access to these data, could estimate the average exposure associated with the proposed work schedule. In fact, since the database includes the range for these parameters (minimum & maximum), the expected range of exposures could also be easily calculated.

In this example, the average exposure associated with this work schedule would be 102 % [29 + 30 + 33 + 10], which exceeds the assumed maximum allowable exposure of 75 %. Since the proposed work schedule resulted in an estimated exposure that was of concern, the worker could discuss the proposed work schedule with their supervisor. This could (1) avoid excessive exposures before they occurred, and (2) allow exposures to be controlled using inexpensive administrative controls..

When interviewed during the WC, laboratory workers generally knew what their work schedule was going to be for a particular day; and it was not unusual for them to know their work schedule for the coming week. Therefore, the modification of work assignments to avoid excessive exposures should not be a burdensome task

Comparing Facilities

Some organizations will have laboratories housed in one or more buildings at one geographic location, while other organizations will have laboratory facilities that are dispersed over a broad

geographic area. EASL attempts to provide a metric that ranks facilities by their "total exposures". The objective was to provide management with a method for allocating H&S resources between facilities, so that worker health & safety could be maximized throughout an organization.

Since the focus was on controlling exposures to chronic toxicants, the Y%OEL was used to calculate an "exposure ranking" for a facility. This parameter is referred to as the Facility Exposure Index (FEI). The FEI can be used to compare exposures between departments, buildings in one facility, or between geographically dispersed facilities. The FEI is a management metric that was designed to prioritize needs and allow cost-benefit analysis to be applied to the health and safety function in a simple way.

The FEI can be used to (1) identify facilities with the greatest needs and prioritize the implementation of exposure controls, (2) set yearly goals for reducing total exposures for each facility, and (3) track the variation in "total exposures" for a facility over time.

Facility Exposure Index

The FEI is calculated as follows:

- SET with Y%OEL values exceeding 1 % are listed for the entire facility (Table 40);
- Those Y%OEL values are summed to calculate a SEI for the facility (Table 40);
- A CEI is calculated by substituting the Target Y%OEL for each Y%OEL that exceeds the Target Y%OEL and summing these numbers (Table 40);
- The FEI is calculated by dividing the SEI by the CEI (Table 41).

The SET Exposure Index (SEI) for a facility is calculated by summing the Y%OEL values exceeding 1 % for the SET performed in that facility. This provides a measure of the "total exposures" in a particular facility, but does not consider the size or level of activity of a particular facility. Smaller facilities, with fewer SET performed, might have a lower SEI, for example.

In order to calculate the FEI, a target value for the Y%OEL is selected. This is the LTA_OEL, such as a Y%OEL of 25 % or 33 %, which is then applied to all participating facilities. The goal is to eventually reduce exposures for each SET in each department, building or facility to the target Y%OEL or less. The Compliance Exposure Index (CEI) is calculated by substituting the Target Y%OEL for each individual Y%OEL value that exceeds the Target Y%OEL and summing these numbers. The CEI is a measure of what the "total exposure" for a facility would be assuming the Y%OEL values for all SET had been reduced to the Target Y%OEL.

The FEI is calculated by dividing the SEI for a facility by the CEI for that facility. This is a measure of "uncontrolled exposures" at that facility. In addition, the FEI is "standardized" and accounts for differing activity levels between facilities.

The data in Tables 40 and 41 are example data, and not actual LEAP data. The example calculations were performed for Target Y%OEL of 25 %. The example in Table 40 indicates that SET 4, 5 and 6 are in compliance with the LTA_OEL of 25 %, and no further response is required for those SET. However, SET 1, 2 and 3 have LTA exposures that exceed the LTA_OEL of 25 %.

It is assumed that the goal is to reduce those exposures to at least the LTA_OEL. When that goal has been achieved, the value of the SEI will have been lowered to the value of the CEI, which would then indicate that all SET were in compliance with the LTA_OEL of 25 %.

Table 40. Example Exposure Indices Calculated for Facility E.

SET	Y%OEL	25 % LTA_OEL
1	75 %	25 %
2	47 %	25 %
3	28 %	25 %
4	17 %	17 %
5	10 %	10 %
6	8 %	8 %
TOTALS	SEI = 185 %	CEI = 110 %

Table 40 contains data for six example SET, which refer to facility E in Table 41. The FEI for facility E was calculated by dividing the SEI of 185 % by the CEI, resulting in an FEI of 1.68 for an LTA_OEL of 25 % and 1.43 for an LTA_OEL of 33 %.

Table 41. Calculated FEI Values for Example Facilities.

FACILITY	SEI	CEI (25 %)	FEI (25 %)
A	63 %	63 %	1.00
B	77 %	77 %	1.00
C	96 %	70 %	1.37
D	142 %	52 %	2.73
E	194 %	110 %	1.68

The FEI for facilities A and B in Table 41 were both 1.0. This indicates that all of the SET in those two facilities were in compliance with an LTA_OEL of 25 %. The other three facilities had FEI values exceeding 1.0, indicating that one or more SET in those facilities were not in compliance.

Facilities C, D and E had SET with Y%OEL above the target Y%OEL, and additional controls would have been beneficial in those facilities. The greatest reduction in LTA exposures could be obtained by bringing facility D into compliance, followed by E, and then C.

Cost Analysis

The primary utility of the FEI is on ranking facilities based on total exposures. However, it may also provide a simplistic method for performing an initial cost-benefit analysis for evaluating competing control methods.

As an example, assume a soxhlet extraction procedure is performed on the bench top. Based on comparisons with similar procedures performed in other facilities, it might be estimated that the Y%OEL can be lowered from 49 % to 10 % by moving this SET into a fume hood. This would reduce the FEI from 2.8 to 1.3, achieving a 53 % reduction in “total exposures” for that facility.

In addition, assume that installing the new fume hood would cost $ 50,000. The relative cost of this response would be the equipment cost of $ 50,000 divided by the change in the FEI (1.5), or $ 33,333 per unit reduction in the FEI. This approach allows the cost of various control measures to be compared per unit-reduction in exposure.

CHAPTER 7: QUALITY ASSURANCE PLAN

Purpose

It has been emphasized that EASL is based on the results and experience obtained in applying the strategy to environmental laboratory facilities. The basic processes and procedures described in this document should be viewed as an initial starting point for developing a site-specific strategy. This chapter has been included to provide a starting point for developing a quality assurance plan. It presents several concepts that may be included in such plans, but it is certainly not an exhaustive list. These elements should be modified as experience is gained.

The purpose of the Quality Assurance Plan (QAP) is to provide guidance on (1) planning and implementing, and (2) assessing the effectiveness of EASL. The QAP describes the quality assurance requirements of EASL, and how those requirements will be met.

The goal of EASL is to:

- Develop an exposure assessment strategy suitable for task-based work environments such as found in laboratories,
- Remain both cost- and time-effective when implemented,
- Allow exposure trends to be assessed within facilities, between facilities, and over time,
- Be accepted as a model program by personnel within the organization and within the broader industrial hygiene community.

The QAP shall clearly identify:

- What is and is not included;
- The specific tasks that are to be accomplished;
- The specific methods that will be used to accomplish those tasks;
- The organizational division or individual who will accomplish each task;
- The specifics of the electronic database in which the data will be maintained;
- A method for reporting and communicating the results..

The information in the QAP should be sufficiently detailed to satisfy the requirements of a peer-reviewed scientific journal.

Applicability

This program shall be implemented in accordance with the organizations's approved procedures and policies. It shall be used to:

- Assess the exposures of employees, interns, on-site contractors, and guest scientists;
- Demonstrate compliance with the OSHA Laboratory Safety Standard;
- Serve as input into the Chemical Hygiene Plan, Personal Protective Equipment Plan, and the Medical Surveillance Program;
- Establish a central database that shall serve as a repository of industrial hygiene data.

Limitations

Hazards. Only those potential hazards that are identified can be included in the exposure assessment.

The scope and utility of an exposure assessment are dependent upon the quality of the initial facility inspection. The H&S personnel performing the workplace characterization may not be familiar with the specific operations that occur in a facility. In addition, not all procedures will be operational during the initial walk-through inspection. The locations, procedures, and analytes included in an exposure assessment are therefore dependent not only upon the visual observation and professional judgment of the assessors, but also the information provided by facility personnel.

Interviewing the staff in as much detail as possible is a critical element in identifying SET. Some of the most difficult SET to identify are those that are performed infrequently. Conversely, an attempt to hide procedures

Potential hazards that have consensus OEL, such as PEL and TLV values, are the simplest to assess. If consensus guidelines are not available for an agent, then the CHO/HSC shall use professional judgment in assessing exposure potentials.

Personnel. All individuals working in laboratory spaces controlled by the organization shall be subject to inclusion in EASL.

Contractor employees may perform many of the same procedures as employees. In addition, (1) their activities and work practices may directly affect the potential exposures of employees, and (2) the organization may want to document that their exposures were acceptable while they were on-site. As a practical matter, the objective is to characterize potential exposures that are associated with a particular standard operating procedure (SOP) or otherwise defined SET, regardless of who is performing the procedure.

Sample Matrix. The toxicological properties of the sample matrix are often poorly characterized.

One significant issue that is not easily addressed in EASL is the sample matrix. The strategy is limited in its ability to characterize exposures resulting from this source. Samples received for analysis by an environmental laboratory, for example, may contain a variety of toxic contaminants other than the analyte of interest. Many of these contaminants are unknowns, and are never characterized. Many process streams in manufacturing facilities are also poorly characterized.

The CHO is encouraged to assess the contribution of the sample matrix during the qualitative exposure assessment. The importance of disregarding this factor in the exposure assessment strategy will obviously vary. However, at least one serious exposure incident involving the sample matrix was documented.

Therefore, it may be appropriate to consider the sample matrix, unless fully characterized, to be "highly toxic" when designing and implementing controls. This is especially pertinent for samples that are either acidified, dried without adequate venting, or contain significant quantities of volatile chemicals.

Work Practices. Individual work practices can be an important exposure factor.

A second significant issue not directly addressed by EASL is work practices. The interaction between the individual's actual work practices and prescribed procedures is a variable that may significantly affect both personal (analyst) and area (co-worker) exposures. As more data are collected and added to the database, and inter-laboratory comparisons become possible, the importance of this variable for a SET will become better defined.

ORGANIZATIONAL NEEDS AND REQUIREMENTS

The following are the specific organizational needs and requirements that will be met by implementing EASL.

01. Development of an accessible and easily maintained industrial hygiene database to:

- Assess exposures of employees and contractors to potential hazards,
- Identify potential for excessive exposures before they occur,
- Establish decision criteria governing the necessity of medical surveillance,
- Show compliance with the OSHA Laboratory Safety Standard,

- Evaluate the exposure potentials of new or modified procedures,
- Evaluate waste minimization procedures;
- Address the need for an epidemiological database.

02. The need to present exposure data in a format that minimizes confusion and can be interpreted by management and staff. If the exposure data are reported in a manner that is user friendly, their effectiveness as a management tool will be increased.

- The industrial hygiene data shall be interpreted for the laboratory manager, and the potential exposures shall be classified as Acceptable, Uncertain, or Unacceptable.
- Recommended actions and sampling schedules are associated with each exposure classification, and are included in the facility report.
- EASL uses an approach that is visual to the extent possible. Rather than simply calculating tables of statistical data, a log-plotting procedure may be used that allows the user to interpret the data visually as well as statistically.

03. The need to integrate exposure data obtained over time. These are often not effectively utilized because the field methods and results are not internally consistent, there is no easy way to combine the data collected from poorly defined SET, and historical data may not survive personnel changes.

- EASL requires the CHO/HSC to adopt a standardized sampling plan and protocols for obtaining and interpreting exposure data, promoting greater consistency within the exposure database.
- The data should be maintained in an electronic database or spreadsheet, which can survive the departure of key personnel. In addition, this keeps EALS actively within the control framework of the CHO/HSC, so that it is not as easily neglected.
- The database is designed so that new data can be easily combined with existing data, increasing the statistical “power” for each SET over time. The EASL protocol also provides an indication as to whether or not the new data can be combined with the existing data, or whether the distribution has changed (log plots).
- Sample data that are more than (for example) 3 years old may not reflect current practices, procedures, or controls. The characteristics of an electronic database allows the user to maintain historical data while confining analyses to current data..

04. The need to integrate newly acquired exposure data with existing data. An industrial hygiene survey often requires the collection of an entirely new set of exposure data to characterize the workplace as it then exists. This approach only provides a "snapshot" of the current conditions; and, requires management to obtain entirely new data each time an exposure survey is required.

- The EASL protocol blends newly acquired data with existing exposure data. This provides a broader chronological perspective on exposures, and allows the comparison of historical exposures, current exposures, and exposure trends.

- Since EASL utilizes the existing data as well as the new data, the overall cost of subsequent exposure surveys is minimized. Subsequent surveys may require 50% or less, often as little as 10 %, of the data collected in the initial survey.

05. The need to define similar exposure groups in a manner that is consistent with the way exposures occur in laboratories. These groups shall be defined on the basis of laboratory procedures and activities. Similar Exposure Tasks (SET) shall be used as the basis for assessing exposures.

06. Sampling periods are confined to the period of the SET; and individual 8-hour TWA exposures are not measured.

It is initially assumed that most laboratory procedures (extractions, sample loading, etc.) will require 2 hours or less to complete, individuals perform multiple short-term tasks each day, and their daily work assignments often vary. Therefore, partial-period samples were chosen as having the greatest "information" content. This sampling strategy also provides the basis for an inter-laboratory comparison of competing procedures, work practices, waste minimization, etc.

MEASURES OF SUCCESS

EASL may be considered to have fulfilled its objectives if the following evaluation criteria have been met:

- The qualitative exposure assessment is thorough and identifies areas of concern. The relevant processes, procedures, and activities are captured during the assessment.

- The analytical results are representative of employee exposures (Appendix 9). The sample data are as random as possible, and results are suitable for their intended purpose.

- The database provides a mechanism for allocating resources for hazard reduction. It allows SET to be ranked according to exposure potential.

- The strategy includes a mechanism for assessing and encouraging progress in the

continued reduction of potential exposures. The database allow trends in the work place to be observed, and the data are used by management to evaluate progress.

- EASL serves as a communications tool between Organization/Facility/Staff. The database is used as a planning tool by the management.

- EASL is integrated into, and interfaces effectively with, the CHP, PPE Plan, and the Medical Surveillance Program.

- The EASL protocol reduces the life-cycle costs associated with exposure monitoring. New exposure data are added to previously collected data, and fewer data are required in future sampling campaigns to maintain the database.

- EASL establishes an accessible, user friendly electronic database that is used by supervisors and/or staff to evaluate daily work schedules to prevent excessive exposures before they occur.

- The laboratory managers acknowledge the program as containing valid data and conclusions, having value as a management tool, and being something they want to continue.

- Resources are made available to implement the program. Results are provided to laboratory supervisors, Health & Safety Committees, and Contractors for implementation.

QUALITY CONTROL REQUIREMENTS

Are management incentives consistent with project goals?

Facility management may decide to adjust personnel assignments so that the “best” personnel are performing the SET to be monitored; or reschedule a high-exposure SET so that it is not performed during the sampling period. This behavior may be counter-productive if the results of the exposure assessment are used to allocate H&S resources; and are certainly not in the best interest of the organization. However, it may be advisable to consider the incentives that might promote such behavior when implementing an exposure assessment strategy.

Have all project personnel been adequately trained?

The EASL protocol requires the field data to be collected in a consistent manner and recorded using a consistent format, both between facilities and over time. Otherwise, interpreting the results may be difficult. The sampling strategy required by EASL may not be familiar to practicing industrial hygienists, since it is not typically associated with the collection of industrial hygiene data. This can result in the loss of data if field personnel are not adequately

trained prior to implementing the program and initiating data collection. Experience suggests that between 10 % and 100 % of the data may have to be excluded from the database if this factor is ignored.

Has the proper equipment been specified ?

Standard low-volume pumps, low-flow controllers, and sorbent tubes are typically used to sample airborne contaminants. Other parameters are monitored using standard industrial hygiene equipment, such as sound pressure level meter, differential pressure micromanometer, and direct reading instrumentation.

Have the proper sampling methods and analytical methods been selected, and followed ?

Sampling methodology is based on standard NIOSH methods; or OSHA or EPA methods if NIOSH methods are not available. Sampling parameters are maintained within the limits specified in the standard method as well as in the sampling protocol for a SET.
The laboratory is certified or otherwise recognized as competent in the analysis of the subject analyte. To the extent possible, the laboratory's SOP's are included in the project documentation.

Are the sampling parameters within the guidelines of the methods ?

Sampling parameters such as flow rate and sample volume are maintained within the limits of the standard procedure that is used (this may be difficult if OSHA methods rather than NIOSH methods are specified).

Are the sample volumes (limits of detection) adequate ?

Sample volumes are adequate to determine the exposure assessment classification of the SET, but may not be adequate to determine that exposure levels are less than 10% of the occupational exposure limit (this factor requires evaluation).

Are equipment calibration records available ?

Equipment calibrations are documented and the documentation is maintained. Calibration of airflow devices is performed using either an electronic airflow meter or a calibrated 150 mm precision rotameter having an appropriate flow range. The area designated for a wipe sample is measured and objectively outlined using tape or similar method.

Have area samples been linked to personal samples ?

The starting times of all airborne samples are recorded. These data allow the CHO to associate personal samples with the corresponding area samples.

Are the sampling intervals appropriate ?

Full shift TWA data are not collected unless the SET is full-shift. Sampling intervals are equal to or less than the completion time of the task that is being sampled.

Are sample sizes adequate ?

Sample sizes may be limited due to time and operational constraints. Additional samples may have to be obtained during subsequent sampling campaigns to supplement the initial data.

Has the sampling distribution been properly identified ?

The sampling distribution has been identified as lognormal. This is consistent with published data and with the characteristics of similar data.

Are the flow rate, sample time, sample volume, chemical to be analyzed, and interferences supplied to the analytical laboratory ?

All of the above parameters, except interferences, are supplied to the analytical laboratory. Information on interferences shall be supplied when available.

Is the analytical laboratory certified by AIHA ?

The analytical laboratory is certified by AIHA.

Is the monitoring strategy described ?

The monitoring strategy is described in writing.

Is a rationale for follow-up monitoring provided ?

A follow-up monitoring schedule based on the exposure assessment classification of the each SET shall be included in the initial facility report.

Is adequate written documentation available describing the protocol ?

The exposure assessment strategy, the sampling protocols, and the decision logic are described in writing.

EXPOSURE ASSESSMENT PROGRAM

EASL is a multi-activity program that is divided into the following phases:

Phase 1: Development

- Develop an initial exposure assessment strategy and sampling protocol that are applicable to the specific site and work environment.
- Apply the strategy to a limited number of test laboratories.
- Modify the elements of the strategy to meet the needs of the specific work environment.
- Develop field sheets for collecting the required data fields.
- Develop a database that includes the required data fields.

Phase 2: Implementation

- Schedule site visits and collect the required data to populate the assessment database.
- Evaluate and interpret the data, report the results, and implement controls.
- Identify requirements for additional data and collect the data during scheduled site visits.

Phase 3: Maintenance

- Modify the CHP to include the elements of the strategy, and interface the database with the PPE Plan and the Medical Surveillance Program.
- Provide maintenance support for the database;
- Implement the strategy in multiple facilities within the organization.
- Reassess facilities on a scheduled basis.

Planning the Site Visit

Before conducting the initial site visit, the project coordinator shall:

- Develop the field sheets to collect the data;
- Develop an electronic database to archive the field data;
- Obtain a chemicals inventory (list of probable hazards);
- Summarize the OEL's for anticipated hazards;
- Develop quality control criteria and a quality assurance program;
- Train personnel to collect the data in a consistent manner; and
- Coordinate and schedule the site visit [Confirm that laboratory personnel are not all attending a regional conference the week you plan to be there].

Collecting exposure data in laboratories can be a difficult task. Some laboratory procedures are performed infrequently, or are associated with specific industrial products, process streams, or

sample matrices, for example. Therefore, scheduling issues can be critical, and close coordination with the laboratory director may be required to successfully complete this task.

In addition, many laboratory procedures are relatively short in duration, or involve relatively small quantities of chemicals. Therefore, the limits of detection (LOD) of the sampling/analytical methods are an important criteria. For example, a significant percentage of the LEAP samples were censored; or below the LOD. Experience with LEAP suggests that NIOSH methods are generally preferable to OSHA methods, for example, since NIOSH methods are typically more sensitive.

MEASURES OF EXPOSURE

Sample data collected over an extended period of time (such as an 8-hour TWA) represent an average value, and the Central Limit Theorem suggests these data are expected to be normally distributed. However, the data for samples obtained as grab samples, with short sampling times of one hour or less, are often lognormally distributed. This distribution is frequently encountered when dealing with environmental data, and it shall be assumed that the data in the EASL database may be described as a lognormal distribution..

A lognormal distribution has all positive values, is positively skewed, and is fully described by the geometric mean (GM) and the geometric standard deviation (GSD). For a lognormal distribution: mode < median = GM < mean.

The measure of dispersion is the geometric standard deviation (GSD). The GSD reflects the slope of the log-plot, and it can be estimated by dividing the 84% value by the 50% value. In addition, the GSD has a value of 1 if there is no dispersion about the GM. Therefore, GSD = 1 for a lognormal distribution is equivalent to standard deviation of zero for a normal distribution. Health effects from exposures to chronic toxicants are expected to be related to average exposures. However, the average exposure concentration can not always be reliably estimated for a lognormal distribution by simply averaging the data. The mean concentration for a SET can be estimated by calculating the minimum variance unbiased estimator of the mean (MVUM) or the maximum likelihood estimator (MLE).

The term unbiased is used when the mean of a sampling statistic is equal to the population parameter, indicating the MVUM is expected to provide an estimate of the mean that has a minimum bias. The MVUM is also expected to have the least scatter about the mean, providing an estimate of minimum variance. The MVUM is a function of the sample size (n) and the variance (Var) of the data. The MLE is a more robust estimate of the mean, and doesn't require the distribution to be specified.

Health effects from exposures to irritants are expected to be related to peak exposures. Unless the data have been collected using continuous monitors, the 95^{th} percentile concentration (C_{95}) may be a reasonable estimate of peak exposures.

THE DATABASE

Estimating TWA Exposures

In order to estimate an individual's total daily exposure, the following information would be required:

- The individual's work schedule for the day; the SET assigned to an individual on a particular work day (work schedule).
- The completion time for each of those SET (EASL database).
- The exposure potentials associated with each SET; agents, exposure rates, and maximum exposures (EASL database).

Data Usage

The exposure data entered into the EASL database may be used:

- To assess exposures of employees and contractors to chemical, physical and biological hazards;
- To show compliance with the OSHA Laboratory Safety Standard [29 CFR 1910.1450];
- As an input into the Chemical Hygiene Plans, Personal Protective Equipment Plans, and the Medical Surveillance Program; and
- To establish an accessible database that will serve as the repository for industrial hygiene data related to the organization's technical facilities.

The EASL database provides a means of evaluating and tracking employee and contractor exposures. These data may be useful for:

- Estimating past exposures;
- Minimizing future exposures;
- Performing inter-laboratory comparisons of work practices;
- Assessing the exposure potentials of new or modified procedures;
- Identifying the need for additional management or engineering controls;
- Health and safety training.

The EASL data shall be maintained in an electronic database or spreadsheet. It is recommended that the data be entered into the database by as few people as possible. This results in a greater

consistency in the format of the data.
The data from the initial baseline survey are entered into a primary data table using the original field sheets. The data are then separated according to SET, and standard statistical calculations may be performed on the stratified data. The calculated statistical parameters for each SET can be summarized in a statistical table, which is included in the final report. Finally, the data for each SET may be plotted, and the resulting log-plots included in the final report. The database is typically updated periodically as new surveys are performed. The new data, following evaluation, may be added to the existing data tables and graphs..

The data fields in the exposure assessment database identify the information that has to be collected, and determine the minimum content of the field sheets that will be used to collect the data. An exposure assessment program, once initiated, should be expected to continue for many years. During this time, new people may be hired, and some may retire, resulting in the loss of "organizational memory". The only thing that will survive this process is documentation.

Documenting the results of an exposure assessment may require several relational databases to be developed and maintained. A database program is more efficient for this purpose, but a spreadsheet is sufficient. Security is always an issue, since these databases will contain sensitive information.

The data fields in the database indicate the minimum amount of information that has to be collected. Therefore, a preliminary database design should be developed before the workplace characterization. In addition, these data fields dictate the minimum content of the field sheets that will be used to collect this information.

The data fields are provided as a starting point for the preliminary design of a database. The example database contains the exposure assessment records, decision logic, and response parameters. Once the field data begin to be collected, a final design will naturally evolve. Therefore, it's better to initially collect a small amount of data to evaluate the adequacy of the data fields, then modify the data fields, as required.

A second type of database is illustrated in Appendix 12, which is used to document the sample collection methods. The amount of detail included in this type of database will vary, but it is important to document how the samples were collected, how they were analyzed, and what the OEL were at the time the samples were collected.

This form can also be used for several other purposes. First, it indicates which analytes can be collected in the same sample. Collecting multiple analytes on the same sample can minimize costs. Second, it indicates the minimum and maximum values for the sampling parameters (rate and volume). Third, it can be used to determine the quantity of sample media that will be required.

REFERENCES

01. Young, J. A., Kingsley, W. K., Wahl, G. H.: Developing a Chemical Hygiene Plan. American Chemical Society, Washington, DC (1990).

02. Hawkins, N., Norwood, S., Rock, J., Eds.: A Strategy for Occupational Exposure Assessment. AIHA, Fairfax, VA (1991).

03. Mulhausen, J., Damiano, J.: A Strategy for Assessing and Managing Occupational Exposures; AIHA Press, Fairfax, VA., (1998).

04. Guest, I., et al: BOHS Technology Committee Working Group: Sampling Strategies for Airborne Contaminants in the Workplace. BOHS Technical Guide No. 11. H & H Scientific Consultnats Ltd., Leeds, U.K. (1993).

06. Keil, C. B.; Editor. Mathematical Models for Estimating Occupational Exposure to Chemicals; AIHA Press, Fairfax, VA; 1999.

07. Crystal Ball Software; Decisioneering, Inc., Denver, CO (www.crystalball.com).

08. American Conference of Governmental Industrial Hygienists; Guide to Occupational Exposure Values - 1998. Cincinnati, OH; 1998.

09. American Conference of Governmental Industrial Hygienists; 1998 TLV's and BEI's: Threshold Limit Values for Chemical Substances and Physical Agents. Cincinnati, OH; 1998.

10. Sharp-Geiger, R., et al: Development and Implementation of an Exposure Assessment Program in a Research-Based Facility: Phase 1. Appl. Occup. Environ. Hyg. 13(12): 839 (1998).

11. Smith, R. W., et al: Task-based Exposure Assessment: Analytical Strategies for Summarizing Data by Occupational Groups. AIHAJ, 58(6): 402 (1997).

12. Fairfax, Richard, Ed.; Making Sense of OSHA Standards with Medical Surveillance Requirements: Part 1; Appl. Occup. Environ. Hyg., 13(3): 144 (1998).

13. Lyles, R.H.; Kupper, L.L.: On Strategies for Comparing Occupational Exposure Data to Limits. AIHAJ. 57(1): 6 (1996).

14. Kumagai, S., Matsunaga, I.: Changes in the Distribution of Short-term Exposure Concentration with Different Averaging times. AIHAJ, 56 (1): 24 (1995).

15. Hewett, P.: Interpretation and Use of Occupational Exposure Limits for Chronic Disease Agents. Occupational Medicine: State of the Art Reviews. Hanley & Belfus, Inc.; Philadelphia, PA. (1996).

16. Tornero-Velez, R., et al.: Compliance Versus Risk in Assessing Occupational Exposures. Risk Analysis, 17(3): 279 (1997).

17. Hewett, P.: Mean Testing: 1. Advantages and Disadvantages. Appl. Occup. Environ. Hyg. 12(5): 339; (1997).

18. Rappaport, S.: Selection of the Measures of Exposure for Epidemiology Studies. Appl. Occup. Environ. Hyg., 6(6): 448 (1991).

19. Rappaport, S.: Assessment of Long-Term Exposures to Toxic Substances in Air. Ann. Occup. Hyg., 35(1): 61 (1991).

20. Part II, 29 CFR 1910, 1915, and 1926; Occupational Exposure to Methylene Chloride; Final Rule. Federal Register, pp. 1494-1619,;Friday, January 10, 1997.

21. Stenzel, M.: An Alternate Approach to the Exposure Assessment Strategy: Classification vs. Prioritization. Roundtable 240, American Industrial Hygiene Conference and Exposition, Dallas, TX; May 17-23, 1997.

22. Damiano, J.: Quantitative Exposure Assessment Strategies and Data in the Aluminum Company of America. Appl. Occup. Environ. Hyg. 10(4): 289 (1995).

23. Harris, R. L.: Guideline for Collection of Industrial Hygiene Exposure Assessment Data for Epidemiologic Use. Appl. Occup. Environ. Hyg. 10(4): 311 (1995).

24. ACGIH-AIHA Joint Task Group on Occupational Databases.: Data Elements for Occupational Exposure Databases: Guidelines and Recommendations for Airborne Hazards and Noise. Appl. Occup. Environ. Hyg. 11(11): 1294 (1996).

25. Mulhausen, J., et al: Comprehensive Exposure Assessment and Management at 3M: Results of a Feasibility Project. Roundtable 240, American Industrial Hygiene Conference and Exposition, Dallas, TX; May 17-23, 1997.

26. Hornung, R.W.; Reed, L.D.: Estimation of Average Concentration in the Presence of Nondetectable Values. Appl. Occup. Environ. Hyg. 5(1): 46 (1990).

27. Perkins, J., Cutter, G., Cleveland, M.: Estimating the Mean, Variance, and Confidence Limits from Censored, Lognormally-Distributed Exposure Data. AIHAJ. 51(8): 416 (1990).

28. Waters, M., Selvin, S., Rappaport, S.: A Measure of Goodness-of-Fit for the Lognormal Model Applied to Occupational Exposures. AIHAJ, 52(11): 493 (1991).

29. Seixas, N., Robins, T., Moulton, L.: The Use of Geometric and Arithmetic Mean Exposures in Occupational Epidemiology. Am. J. Ind. Med., 14: 465 (1988).

30. X. Zhou, Xiao-Hua: Estimating the Mean Value of Occupational Exposure. AIHAJ, 59(11) 785 (1998).

31. Ott, W.R.: Environmental Statistics and Data Analysis. Lewis Publishers, New York, N.Y. (1995).

32. Buringh, E., Lanting, R.: Exposure Variability in the Workplace: Its Implications for the Assessment of Compliance. AIHAJ. 52(1): 6 (1991).

33. George, D. K., Flynn, M. R., Harris, R. L.: Autocorrelation of Interday Exposures at an Automobile Assembly Plant. AIHAJ, 56(12): 1187 (1995).

34. Hewitt, P.: Sample Size Formulae for Estimating the True Arithmetic or Geometric Mean of Lognormal Exposure Distributions. AIHAJ. 56(3): 219 (1995).

35. Hewitt, P., Ganser, G.: Simple Procedures for Calculating Confidence Intervals Around the Sample Mean and Exceedance Fraction Derived from Lognormally Distributed Data. Appl. Occup. Environ. Hyg. 12(2): 132 (1997).

Acknowledgments

The Laboratory Exposure Assessment Project (LEAP) was initiated and supported by the US Environmental Protection Agency (EPA), Safety Health and Environmental Management Division (SHEMD), National Programs Branch (NPB). The collection and analysis of the exposure data was performed under contracts BCA94-99EP30012-089 with the Department of Health and Human Services, US Public Health Service, Division of Federal Occupational Health (DFOH). The LEAP was developed and implemented with the support and guidance of Julius Jimeno, Chief, SHEMD; Dennis Bushta, Chief, NPB; and Kathy Morring, Senior Executive, DFOH. In addition, the author would like to acknowledge the contributions of the various DFOH consultants who were involved in collecting the field data in the various regions.

Disclaimer

This document was written following the completion of LEAP. Neither the contents nor the various concepts described have been reviewed by either EPA or DFOH, nor do either of these organizations necessarily endorse the concepts, parameters, or products described. Mention of company names or products does not constitute endorsement.