Chapter 4 – Exposure Assessment Strategies

1. General

This chapter outlines procedures for assessing occupational exposures. Exposure assessment is part of the industrial hygiene (IH) survey where work processes and materials used are qualitatively assessed to determine exposure potential. At times, semi-quantitative methods may also be used initially. Based on these qualitative or semi-quantitative assessments, the processes and hazards that are deemed to have significant exposure potential and require quantitative assessment are identified.

When exposures and processes are stable, sufficient exposure monitoring data may be obtained to allow statistical analysis to assist in exposure assessment. The strategy presented here is based on the strategy presented in Reference 4-1 but is not identical to it. One of the major advantages of this strategy is to reduce the number of samples required for decision making by:

a. Recognizing that Similar Exposure Groups (SEGs) with employee exposures estimated to be significantly less than the Occupational Exposure Limit (OEL) (e.g., the 95th percentile exposure point estimate is “no detectable exposure” or “exposure is minor, < 10% of OEL”) do not necessarily require routine exposure monitoring just to complete exposure assessments, if there is strong evidence for anticipated negligible exposures (e.g., very low material quantities in use, very short work duration (may not be applicable if short term or ceiling OELs apply to the hazard), work methods unlikely to generate significant exposures, or low sampling results from similar processes) as well as high confidence in that qualitative or semi-quantitative exposure assessment. However, some hazards require at least initial monitoring by substance specific regulation such as Reference 4-2, and some SEGs may benefit from occasional exposure monitoring to validate the assessment. Additional monitoring is needed if administrative, work practice, or engineering controls are modified;

b. Recognizing that SEGs with employee exposures estimated to significantly exceed the OEL may be controlled without additional exposure monitoring, except in the case where particular periodic monitoring is required by substance specific regulation such as Reference 4-2, or when additional monitoring is needed to validate respirator protection factor selection or if administrative, work practice, or engineering controls are implemented/modified;

c. Recognizing that 6 to 10 samples may be sufficient to quantitatively assess many exposures, which is a significant reduction from the 11 to 29 samples recommended in previous sampling strategies; and

d. Recognizing that a sampling strategy may be designed to look for trends or be based on regulatory requirements.

However, for some Navy processes and hazards with potentially significant exposure potential, there are circumstances where other exposure assessment strategies may be needed (e.g.; when exposure monitoring opportunities may be too infrequent or the process may be too variable to allow collection of a statistically valid number of measurements, or when there is no OEL to which to compare to the 95th percentile exposure point estimate). In such cases, the industrial hygienist must exercise sound professional judgment, after considering the available information and make an exposure assessment with a well-documented rationale. Reference 4-1 should be consulted as it goes into details on guidance for other exposure assessment strategies such as Occupational Exposure and Control Banding and Rules, Guidelines to Facilitate Professional Judgement, Dermal Exposure Assessment, or Estimating Airborne Exposures by Mathematical Modeling.

2. Definitions

a. 8-hour Time Weighted Average (TWA)/8-hour TWA-OEL. The TWA concentration for a normal 8-hour workday and a 40-hour workweek, which cannot be exceeded. It is accepted to be a concentration to which nearly all employees may be repeatedly exposed, day after day, without adverse effects. The average level of a hazard over a specified time period, weighted for the length of time at each measured level. The measurement is usually a concentration of a chemical contaminant or a level of a physical agent (e.g., noise). The duration of the TWA must be specified. The most common IH TWA duration is 8 hours, which is the length of the most common workday. A TWA may be determined by a single sample (i.e., the averaging is done by the sampling device throughout the sampled period) or by mathematical combination of one or more consecutive samples.

b. Action Level (AL). One-half the 8-hour TWA value designated as the OEL unless a specific AL is established for an Occupational Safety and Health Administration (OSHA) Permissible Exposure Limit (PEL) adopted by the Navy (e.g., 60% of the OSHA PEL for inorganic lead). The AL may initiate the implementation of specific actions, such as periodic monitoring, training or medical surveillance if specified by a Navy safety and occupational health (SOH) or OSHA standard.

   The necessity for an employee exposure AL is based on variations in the occupational environment (i.e., variations in the employee's daily exposures). As such, the employer should attempt to prove with 95% certainty that no employee's true daily average exposure (i.e., 8-hour TWA) exceeds the standard. (References 4-3 and 4-4)

c. Ceiling (C)-OEL. A contaminant concentration that should not be exceeded during any part of the employee’s exposure. If instantaneous monitoring is not feasible, samples are collected and assessed as a 15-minute TWA exposure, except for those substances that may cause immediate irritation when exposures are short. (Reference 4-5).

d. Censored Data (Handling of). The techniques used to adjust data (usually concentration results) that is reported by the laboratory as less than the limit of detection (LOD) for a hazard. (These techniques also apply if Limit of Quantification (LOQ) is reported instead of LOD.) It is currently recommended to adjust all such values by dividing by the square root of 2.

e. Employee Exposure. The exposure to a concentration of an airborne contaminant that would occur if the employee were not using respiratory protection, or to noise without regard to attenuation provided by the use of personal protective equipment. (Reference 4-2)

f. Exceedance Fraction. The fraction of the exposure distribution above the OEL. It is also called the Probability of Noncompliance.

g. Excursion Limit (EL)-OEL. Peak exposure criteria. Only one hazard, asbestos, currently has an EL. The EL for asbestos was set as a TWA over a 30-minute period, distinguishing it from a Short Term Exposure Limit (STEL), which has a shorter averaging period. For substances that have an 8-hour TWA-OEL but no short term exposure limits, excursions in employee exposure levels may exceed 3 times the 8-hour TWA-OEL for no more than a total of 30 minutes during a workday, and under no circumstances should exceed 5 times the 8-hour TWA-OEL, provided the 8-hour TWA does not exceed the 8-hour TWA-OEL. (Reference 4-5).

h. Exposure Assessment. The process of defining SEGs, exposure profiles, and determining the acceptability of SEG employee exposures based on qualitative, semi-quantitative, or quantitative data.
   (1) Qualitative Exposure Assessment. This is an exposure assessment of a SEG that is based on professional judgment.
   (2) Semi-Quantitative Exposure Assessment. This is an exposure assessment of a SEG that is based on screening samples, Bayesian Decision Analysis, or limited (less than 6) IH sample data, etc.
   (3) Quantitative Exposure Assessment. This is an exposure assessment of a SEG that is based on the statistical analysis of usually at least six IH samples.

   Exposure assessment includes the classification of SEG employee exposures as acceptable, uncertain, or unacceptable. This classification is based largely on whether and how the confidence intervals around a SEG exposure profile point estimate and the OEL overlap or on the exposure effect rating (EER) and exposure profile certainty.
   (1) Acceptable Exposures. Exposures where there is no overlap of the SEG exposure profile and the OEL confidence intervals, and the OEL is greater than the 95^{th} percentile exposure point estimate and $UTL_{95\%,95\%}$ of the exposure profile; or a SEG with an EER of 1 or 2, and possibly 3 or 4 with high certainty about the exposure profile and the OEL; or where determined acceptable by other qualitative or semi-quantitative assessment methods.
   (2) Uncertain Exposures. Exposures where there is overlap of the SEG exposure profile and OEL confidence intervals, and the 95^{th} percentile exposure point estimate of the

exposure profile is less than the OEL, but the $UTL_{95\%,95\%}$ of the exposure profile is greater than the OEL; or a SEG with an EER of 3 or 4 with the upper tail of its exposure profile approaching the OEL; or when the available information is unable to predict with certainty whether overexposure will occur. When assigning classification during the SEG assessment in DOEHRS, uncertain is not an available option. The responsible industrial hygienist must choose either acceptable or unacceptable with Needs More Data.

(3) Unacceptable Exposures. Exposures where there is no overlap of the SEG exposure profile and the OEL confidence intervals, and the 95th percentile exposure point estimate of the exposure profile is greater than the OEL; or a SEG with an EER of 5. The employee exposures of these SEGs are expected to exceed the OEL and need to be controlled.

i. Exposure Assessment Priority (EAP). Priority for scheduling additional exposure monitoring/information gathering. EAP is a numerical rating, ranging from 1 to 125, which is obtained by multiplying the Health Risk Rating (HRR) times the Uncertainty Rating, with 1 being the lowest priority and 125 being the highest priority. This system is discussed in paragraph 4.e.(6)(b)4 and Figure 4.2 and Table 4.6 of this chapter.

j. Exposure Profile. A characterization of the day-to-day variability of exposures of a SEG. A qualitative exposure profile is based on professional judgment. A semi-quantitative exposure profile may be based on screening samples, Bayesian Decision Analysis, or limited (less than 6) IH sample data, etc. A quantitative exposure profile is based on exposure monitoring data and statistics, and includes measures of central tendency and measures of variability.

k. Exposure Effect Rating (EER). EER looks at the exposure frequency and likelihood of exceeding the OEL. EER is an estimate of 95th percentile exposure level relative to an OEL. It is a numerical rating with a scale from 1 to 5, with 1 being the lowest exposure effect and 5 being the highest effect. This system is discussed in paragraph 4.e.(5)(c)3.a and Table 4.2 of this chapter.

l. Health Effect Rating (HER). The expected health effect if the exposure level is at the OEL, and so is independent of the actual exposure. It is a numerical rating with a scale from 1 to 5, with 1 being the least health effect and 5 being the greatest effect. This system is discussed in paragraph 4.e.(6)(b)1 and Table 4.3 of this chapter.

m. Health Risk Rating (HRR). A numerical rating ranging from 1 to 25 which is obtained by multiplying the EER times the HER. This system is discussed in paragraph 4.e.(6)(b)2 and Table 4.4 of this chapter.

n. Long Term Average (LTA)-OEL. An occupational exposure limit with an averaging time of at least a week or more which is intended to protect against chronic effects.

o. Mean and Geometric Mean.

(1) Mean. The arithmetic average of a set of data. Arithmetic mean is the correct mean to use when evaluating cumulative exposure.

(2) Geometric Mean. The n^{th} root of the product of n values and the median of a lognormally distributed data set.

p. Minimum Variance Unbiased Estimate (MVUE). The value of the mean and the variance around a data set, believed to provide the best estimate of the true population mean and variance. The best estimate of an average (cumulative) exposure for a lognormal distribution is the arithmetic mean, not the geometric mean as is commonly believed. The MVUE is the preferred estimate of the arithmetic mean of a lognormal distribution.

q. Occupational Exposure Limit (OEL). Limits established to protect employees from workplace exposure to certain chemical substances or physical agents. A quantitative exposure assessment cannot be made without an OEL.

It is recognized that OSHA PELs may be less protective than exposure standards that reflect more recent medical evidence and promulgated by reputable organizations devoted to occupational health. Industrial hygienists are ethically bound to evaluate all recognized occupational health risks and provide professional recommendations to minimize or eliminate those risks. The Navy shall use the following hierarchy of OELs:

(1) Department of Defense (DoD) or Navy developed or adopted standards.
(2) OSHA PELs
(3) American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values® (TLVs) where OSHA PELs are not available. When the OSHA PEL is less stringent, the ACGIH TLVs shall be included in reports of data to supplement the OSHA PEL and provide additional context to aid the risk management process. The OSHA PEL remains the legally binding standard, however.
(4) Nationally recognized industrial hygiene best practices shall be used to supplement the OEL hierarchy. The industrial hygienist shall use professional judgement to recommend OEL guidelines, when appropriate, to aid the risk management process in a given situation. Sources include but are not limited to:
    (a) California Occupational Safety and Health Administration (Cal/OSHA) PELs
    (b) National Institute for Occupational Safety and Health (NIOSH) recommended exposure limits (RELs) or risk management limits for carcinogens (RMLs-CA)
    (c) Occupational Alliance for Risk Science (OARS) Workplace Environmental Exposure Levels (WEELs)

For further guidance on the appropriate applications of OEL, IH program office should contact their respective regional command or Navy and Marine Corps Public Health Center (NMCPHC) for assistance.

r. Percentile (%ile). The percentage of values in a population that are below a given value. For example, if exactly 95% of all zinc oxide fume exposures from a particular welding process are less than 4 mg/m^3, then 4 mg/m^3 is the 95^{th} percentile exposure point estimate level for zinc oxide fume for that process.

s. Probability of non-compliance (Exceedance Fraction). See Exceedance Fraction.

t. Processes (formerly Operations/Operation Codes (OPCODEs)). For years, Navy IH OPCODEs had been used to denote work operations and have been documented on IH sampling forms. These OPCODEs were provided in tabular format as the Navy IH Operation Codes Dictionary. With the advent and use of Defense Occupational Environmental Health Readiness System – Industrial Hygiene (DOEHRS-IH), processes now need to be defined by both a user defined Process Name and the DOEHRS-IH Process Category/Common Process/Process Method pick lists. DOEHRS-IH requires the choice of a Process Name for each work operation. The Process Name is user defined and is what the user typically sees. Since Process Name is user defined, care must be taken to use a business practice that ensures accurate and consistent Process Names are created. The DOEHRS-IH Process Category/Common Process/Process Method pick lists are in the form of a three tiered process pull down pick list and are the equivalent of the old OPCODEs. It is very important that proper selections are made from these DOEHRS-IH pick lists and that they are accurate and consistent for the process under consideration in order to facilitate data mining. A spreadsheet of the entire DOEHRS-IH Process pick list is available on the NMCPHC DOEHRS-IH webpage. Though some IH program offices still use the OPCODEs in house, the applicable DOEHRS-IH Process Name and the Process Method pick list choice should be included on any sampling forms in the Operation field.

u. Samples/Sampling. With respect to this chapter discussion of samples or sampling for exposure monitoring and exposure assessment is referring to personal sampling, unless otherwise specified (e.g., screening sampling).

v. Short Term Exposure Limit (STEL)-OEL. A 15-minute TWA exposure that should not be exceeded at any time during the workday. The STEL is often associated with an 8-hour TWA-OEL in cases where there are recognized acute effects from a substance whose toxic effects are primarily chronic. The STEL may also be a separate independent OEL. Exposures above the 8-hour TWA-OEL up to the STEL should not be longer than 15 minutes and should not occur more than four times per day. In addition, there should be at least 60 minutes between successive exposures in this range. (Reference 4-5).

w. Similar Exposure Group (SEG). A group of employees who experience such similar exposures to hazards, that if one of the employees was sampled, the results of the sampling could be used to predict the exposures of the remaining members of the group. Individuals within the group generally conduct the same processes, use the same equipment, have the same job description and are exposed to the same hazards at similar frequencies and durations. For Navy use, the initial definition of a SEG should be a shop-based SEG with a combination of a shop and process. However, keep in mind that SEGs can certainly include one or more shops and one or more processes, depending on the situation. Other identifiers such as job title, work task, work team, location and work shift can be used to differentiate and separate SEGs if needed. The definition of every SEG also includes one or more hazards. However, each hazard will often be assessed separately.

Some SEGs are considered critical SEGs and have exposure profiles near but below the OEL for a particular hazard. Critical SEGs are most at risk for misclassification and erroneous-assessment from inadvertent grouping of some employees having unacceptable exposures with other employees having acceptable exposures for the same hazard.

x. Standard Deviation and Geometric Standard Deviation.
   (1) Standard Deviation. The positive square root of the variance of a population. It is the measure of the spread of data set values around the mean.
   (2) Geometric Standard Deviation (GSD). The antilog of the deviation of log transformed data. It is the measure of variability for a lognormally distributed data set.

y. Uncertainty Rating. Consideration of the confidence in existing controls and exposure characterizations. It is a numerical rating with values ranging from 1 to 5, with 1 being the highest confidence and 5 being the lowest confidence. This system is discussed in paragraph 4.e.(6)(b)3 and Table 4.5 of this chapter.

z. Upper Tolerance Limit (UTL). An upper confidence limit of a point estimate of an exposure profile. It is a limit below which can be asserted, with a specified level of confidence, that a specified fraction of exposures will lie. For example, for a given exposure distribution, the value can be calculated below which we are 95% confident that 95% of exposures will lie. This value is sometimes called $UTL_{95\%,95\%}$.

3. Summary

The following is a summary of the exposure assessment strategy outlined in this chapter, which is adapted from Reference 4-1. Since this summary is very brief and the subject is complex, the industrial hygienist should read the full discussion in this chapter as well as Reference 4-1.

a. Identify, based on existing information, scientific references, and qualitative (e.g., professional judgment), semi-quantitative (e.g., screening samples, Bayesian Decision Analysis, limited (less than 6) IH sample data), or quantitative (e.g., statistical analysis of usually at least six IH samples) data, SEGs for the various shops, processes, and hazards present in the workplace.

b. Where quantitative assessment is needed, develop a best estimate of the SEG exposure profile 95^{th} percentile exposure point estimate and the uncertainty associated with that estimate. If sufficient and satisfactory data are available, calculate the $UTL_{95\%,\ 95\%}$ for the exposure profile.

c. Identify the appropriate OELs for each hazard. For SOH standards, assume that there is a high degree of certainty that the SOH standard is correctly set, therefore, adequately protective (i.e., low uncertainty and a small confidence interval). However, the industrial hygienist should consider whether recent scientific evidence increases the uncertainty

around a SOH standard and compensate appropriately in the exposure assessment. One indicator of uncertainty is if more recent OELs are lower than the existing SOH standard.

d. Where the SEG employee exposure assessment is classified as acceptable, no routine exposure monitoring is generally required. However, some hazards require at least initial monitoring by substance specific regulation such as those found in Reference 4-2, and some SEGs may benefit from occasional exposure monitoring to validate the assessment. Additional monitoring may be required if administrative, work practice, or engineering controls are modified. Also, at least qualitative reassessment is needed when circumstances affecting exposure change or during the periodic IH survey.

e. Where SEG employee exposure assessment is classified as uncertain (or with more data acceptable with some level of uncertainty), additional exposure monitoring/information gathering is needed for further estimation of SEG employee exposure. Also, some hazards require particular periodic monitoring by substance specific regulations such as those found in Reference 4-2. Additionally, in some situations, short term/interim controls may be indicated.

f. Where SEG employee exposure assessment is classified as unacceptable, exposures need to be controlled. Routine exposure monitoring/further information gathering is generally no longer required. However, some SEGs may require additional exposure monitoring, especially where particular periodic monitoring is required by substance specific regulation such as those found in Reference 4-2, where monitoring is needed to validate respirator protection factor selection; or if administrative, work practice, or engineering controls are implemented/modified.

g. The additional data collected by exposure monitoring should be used to refine and revise the exposure assessment, and reclassify, if necessary, the SEG employee exposure as acceptable, uncertain, or unacceptable. Some SEGs will continue to have uncertain exposures and should be scheduled for at least annual exposure monitoring. Also, some hazards require particular periodic monitoring by substance specific regulations such as those found in Reference 4-2.

h. Even those SEGs with acceptable exposures require at least a qualitative reevaluation be conducted at least at the frequency stated in Reference 4-6. Also, there will be quantitative data from periodic validation of acceptable exposure assessments or exposure monitoring of uncertain or unacceptable SEGs. Additionally, any changes in the OEL, the SEG, the workplace, or the work force that may affect exposures should be evaluated before or at the time the change occurs; otherwise, any changes to the shop, processes, SEGs, controls, etc. should be noted at the time of the periodic IH survey. Information or exposure monitoring data from any qualitative or quantitative reevaluations should be fed back into the exposure assessment process at the basic characterization step and all the elements of the exposure assessment should be updated.

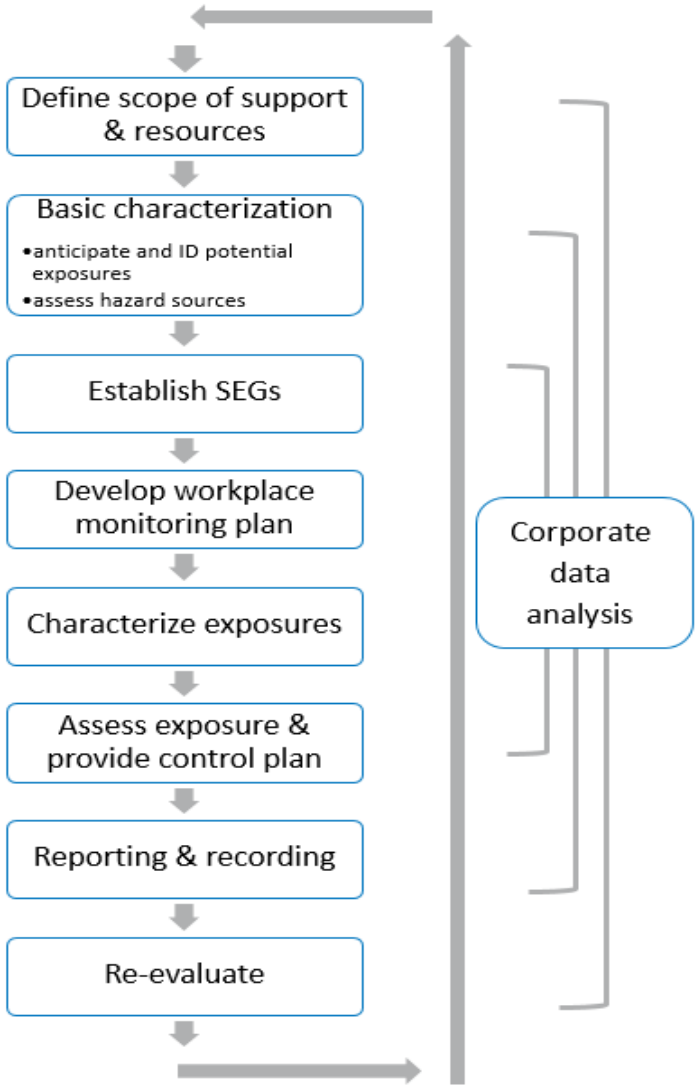
4. Exposure Assessment Strategy

a. The exposure assessment strategy of Reference 4-1 represents a movement away from the traditional compliance assessment strategy toward a strategy that determines whether exposures are obviously acceptable, are obviously unacceptable, or for which there is insufficient information to make such a determination (i.e., uncertain exposures). The benefit is that information about the full exposure distribution is developed instead of just the upper extreme exposures and that exposure monitoring efforts can be focused where it is most needed (i.e., the uncertain exposures). This strategy promises to provide quality information with a minimum number of samples.

b. Reference 4-6 lists the five major steps of a functional occupational exposure assessment program. These are:
   (1) Basic Characterization.
   (2) Exposure Assessment. Includes defining SEGs; defining exposure profiles for each SEG using qualitative, semi-quantitative, or quantitative methods; judging acceptability of each exposure profile; setting priorities for further information gathering; recommending controls; and the setting of priorities for instituting controls.
   (3) Further Information Gathering. Includes obtaining additional qualitative or semi-quantitative data, exposure monitoring, or quantitative data, and performing additional exposure assessment and decision making. It is performed as needed and typically is a follow-on to qualitative or semi-quantitative assessments, or done to provide additional monitoring for quantitative assessments to further define "Uncertain" exposure characterizations. It typically includes a sampling strategy to collect at least 6 samples to aid in and refine quantitative exposure assessment, data interpretation, decision making, and recommending controls.
   (4) Communication and Documentation. Includes reports and records.
   (5) Reassessment.

c. DoD IH Exposure Assessment Model (Figure 4.1). From Reference 4-7, the DoD IH Working Group, chartered under the DoD Safety and Occupational Health Committee and Defense Environmental Security Council, was requested by the DOEHRS Project Management Office to develop a process model for DoD IH. The model was needed to guide development of the DOEHRS-IH module by providing a description of the process that DOEHRS-IH supports.

Figure 4.1 – DoD IH Exposure Assessment Process



d. Reference 4-1 should be used as the basic reference for exposure assessment.
   (1) Table 4.1 shows the steps in the Reference 4-7 DoD IH exposure assessment process, as well as the corresponding five major steps of a functional occupational exposure assessment program from Reference 4-6, and the associated chapters in Reference 4-1. The industrial hygienist is expected to consult Reference 4-1 for a detailed explanation of the exposure assessment process and for any additional exposure assessment strategies.
   (2) The discussion in this chapter will generally follow the more detailed steps of the DoD IH Exposure Assessment Process.

Table 4.1 – DoD, Navy, and American Industrial Hygiene Association (AIHA) Exposure Assessment Comparison

DoD IH Exposure Assessment Process Steps	OPNAVINST 5100.23 Series Exposure Assessment Steps	Reference 4-1 Chapters
Define Scope of Support and Resources		
Basic Characterization	Basic Characterization	Chapter 3 - Basic Characterization and Information Gathering
Establish SEGs	Exposure Assessment	Chapter 4 - Establishing Similar Exposure Groups
Develop Workplace Monitoring Plan	Exposure Assessment Further Information Gathering	Chapter 5 -Defining and Judging Exposure Profiles Chapter 7 - Further Information Gathering
Characterize Exposures	Exposure Assessment	Chapter 5 -Defining and Judging Exposure Profiles
Assess Exposures	Exposure Assessment	Chapter 5 -Defining and Judging Exposure Profiles Chapter 8 - Quantitative Exposure Data: Interpretation, Decision Making and Statistical Tools Appendix IV – Descriptive Statistics, Inferential Statistics. And Goodness of Fit
Provide Control Plan	Exposure Assessment	Chapter 5 -Defining and Judging Exposure Profiles Chapter 7 - Further Information Gathering Chapter 23 - Health Hazard Control

DoD IH Exposure Assessment Process Steps	OPNAVINST 5100.23 Series Exposure Assessment Steps	Reference 4-1 Chapters
Reporting and Recording	Communication and Documentation	Chapter 10 - Recordkeeping and Reporting
Reevaluate	Reassessment	Chapter 9 – Reassessment

e. DoD Exposure Assessment Process Elements.

(1) Define Scope of Support and Resources. Successful occupational health programs require professional supervision and oversight by qualified occupational health professionals. The primary sources of support services are hospitals and medical clinics. The occupational health/IH components of those medical activities are responsible for providing complete occupational health support to all commands within their assigned area of responsibility.

(2) Basic Characterization. Basic characterization is accomplished during the walkthrough survey and records reviews. Several items that affect occupational exposures (i.e., workplace, work force, hazards, controls, etc.) need to be fully described and a review of existing data conducted. The objective of basic characterization is to identify combinations of process, personnel and hazards that can be used to define groups of employees with like exposures that are referred to as a SEG.

(a) Workplace. Description of the workplace involves documenting the processes that are performed and inventorying the chemical, physical, and biological agents that are present in those processes. Although production processes are often well characterized, the industrial hygienist should not neglect to characterize the associated maintenance and repair work that often results in significant exposures.

1. Processes may be partially characterized by obtaining copies of process flowcharts or standard operating procedures. However, it is essential that the process be observed in progress to understand fully the potential occupational exposures involved and to verify that the documents are an accurate reflection of the current process. Informal discussions with workers, supervisors, engineers and activity safety professionals are an important part of understanding the workplace.
2. An inventory of chemical, physical and biological hazards should be collected to allow classification according to their potential hazard. All routes of exposure (i.e., inhalation, ingestion, skin absorption) should be considered. As OELs for airborne exposures are reduced, the contribution from dermal exposure for some hazards may become more significant.
3. Facilities information and use should also be captured with respect to impact on potential exposures. Consideration should be given to size and layout of

space, adequacy of ventilation, existing engineering controls, potential for employees to be affected by other nearby processes and hazards within the shop location or from nearby shops.

(b) Work Force. A combination of review of the activity's personnel classification system, worker/supervisor interviews and direct observation is needed to characterize the work force accurately.

1. In describing the work force, it is important that the industrial hygienist recognizes that identical job titles are not reliable predictors of similar exposures. For example, exposures to welders vary greatly depending on the type of welding performed. A breakdown of employees by department or shop may be useful but within a department or shop there is often a variety of processes (e.g., welding, abrasive blasting, grinding) or tasks (e.g., administrative, quality assurance, production, supervision) performed that result in different exposures. Obviously, departments and shops are structured for business management reasons not for occupational exposure considerations. A process-based or a task-based work force classification is often needed to arrive at the best selection of a SEG.
2. Differences in work tasks and tempo between work shifts also should be considered.
3. Administrative and work practice control utilization information utilization should be captured with respect to impact on potential exposures. Personal protective equipment use should be documented.

(c) Hazards. Working from the list of hazards previously developed, the following information, as applicable, should be developed for each: quantity present/used, relevant chemical or physical properties (e.g., vapor pressure, particle size distribution), health effects, and applicable OELs.

1. The applicable OEL for Navy use should be selected based on the policy in Reference 4-6. This policy is summarized under the OEL definition in paragraph 2.q. of this chapter.
2. Care must be taken in determining what the appropriate exposure averaging time is, as this will determine which type of OEL is appropriate (e.g., Ceiling, STEL, 8-hour TWA).

(d) Records Review. To complete the basic characterization, a review of relevant records needs to be performed. The types of records typically considered are safety, industrial hygiene, and health surveys, results of environmental monitoring, results of IH screening or exposure monitoring, results of biological monitoring, personnel injury or illness reports and engineering control assessments.

(3) Establish SEGs. This is a where the information gathered in basic characterization or by initial monitoring is used to define a SEG.

(a) Defining the SEG. A SEG may be defined by either observing the workplace and work force or by separating the work force based on exposure monitoring data. The observational approach is more common, since in many cases there is

insufficient monitoring data available to use that approach. In a mature IH program, current and past exposure monitoring data are used to refine the definition of each SEG as necessary. There can be many ways to define a SEG depending on the particular situation. However, there are six common bases for defining SEGs. For Navy use, the initial definition of a SEG should be a combination of a shop and process. However, keep in mind that SEGs can certainly include one or more shops and one or more processes, depending on the situation. The definition of every SEG also includes one or more hazards. However, each hazard will often be assessed separately.

1. Determining SEGs through observation.
   a. Combination of shop and process. In this scenario, all employees involved in a process are considered equally exposed. This may be because the hazard is evenly dispersed throughout the workroom or all process employees perform all tasks with essentially the same frequency and duration.
   b. Combination of shop, process, and job title. Addition of an employee's job title may help refine a SEG that is not adequately described by only shop and process. However, the types of work tasks performed by employees having the same job title can vary greatly.
   c. Combination of shop, process, job title, and work task. Including a specific work task in the SEG definition, in addition to shop, process, and job title, more precisely defines the SEG. Different work tasks in a process may produce very different exposures to the same hazard (e.g., process of mortar mixing with work tasks of bag dumping of raw materials, mixing, pouring of finished product, clean up).
   d. Combination of shop, process, and work task. Where job titles do not exist (e.g., small employers) or are not distinctive, job title may be eliminated from use in defining a SEG. This often occurs in manufacturing processes where work task alone keeps employees at a location with specific types of exposures.
   e. Work teams. When work teams share responsibilities and flexible duties, the significance of job title and work task in defining a SEG may be blurred. Reasonable adjustments to defining a SEG may be made as follows:
      (1) If there is little to no division of labor or specialization of team members work team could be substituted for job title (i.e., shop, process, work team);
      (2) If there is specialization of work team members, or where work team members rotate through different positions (specialties) but work the entire workday at one position, work team could be substituted for job title and position could be substituted for work task essentially making each position a separate SEG (i.e., shop, process, work team, position);

(3) If work team members rotate through different positions (specialties) during the workday, work team could be substituted for job title, and position may be ignored (i.e., shop, process, work team), unless exposures will be assessed against a Ceiling or STEL OEL. Ceiling or STEL OELs are inherently task related; so in that case, position would be substituted for work task (i.e., shop, process, work team, position).

f. Locations. When work can be performed at multiple locations for a particular shop and process, the difference in location may, in some cases, affect the exposure assessment. In those cases, location can be added to one of the above approaches.

g. Work shifts. When work can be performed on different work shifts for a particular shop and process, the difference in shift may, in some cases, affect the exposure assessment. In those cases, work shift can be added to one of the above approaches.

h. Non-repetitive work. Much of the work performed in the Navy is not production line work, but batch processes, projects, or research and development. People performing this type of work are difficult to categorize into SEGs. Professional judgment needs to be used in establishing SEGs for such work or pursuing alternate exposure assessment strategies. One strategy is to assess compliance with OELs by assessing worst case exposures. Another strategy, particularly for processes/projects that occur rarely or for short term non-reoccurring special projects, is to consider each project as a distinct process and define SEGs for each project. This strategy, though, can lead to a large number of exposure assessments. Such situations are best addressed by IH professionals with substantial experience that provides a strong basis for accurate professional judgment.

2. Determining SEGs by sampling. Although not recommended in many cases due to the high cost in terms of labor and analysis and the difficulty in executing a massive sampling campaign, SEGs may be defined by sampling results. If sampling is to be used, samples should be collected at random and multiple samples collected for each individual to be able to calculate the within-employee and between-employee variability. When sufficient data is available, the rule of thumb is that within a properly defined SEG the 97.5 %ile exposure should be approximately twice the 2.5 %ile exposure. In other words, 95% of the exposures should span a doubling of concentration. As the 97.5 %ile exposure recedes from the OEL, maintaining this exposure spread in a SEG becomes less critical. For example, a spread of a factor of four between the 2.5 %ile and 97.5 %ile exposures is of little consequence if the 97.5 percentile exposure is still less than one tenth of the OEL. This approach can be more accurate than determining SEGs by observation, but a large amount of exposure monitoring data is needed.

3. Determining SEGs by a combination approach. Since one of the primary reasons for defining SEGs is to reduce the sampling requirements, SEG definition is best done by initially defining the SEG by observation and sampling to verify the SEG and to identify critical SEGs. SEGs with a large geometric standard deviation (>3) may indicate misclassification of the SEG (i.e., the initially defined SEG was not really a SEG and had too many dissimilar factors (e.g., job titles, work tasks, locations, work shifts) that affected the exposures, lumped together). In that case, the SEG should be reviewed, and, if appropriate, redefined into two or more separate SEGs. To optimize the benefits of the combination approach but minimize the risk of misclassification, exposure monitoring efforts should be focused on critical SEGs, where some employees with an unacceptable exposure to a hazard might be inadvertently grouped in with employees judged to have acceptable exposures. Critical SEGs are SEGs that have exposure profiles near but below the OEL for a particular hazard. Critical SEGs can be targeted for more extensive exposure monitoring; statistical analysis can be used to check the homogeneity of the SEG formed initially by observation; and the SEG redefined, if necessary.

(4) Develop Workplace Monitoring Plan (Exposure Monitoring Plan). Initial monitoring plans and general considerations for the mechanics of exposure monitoring will be discussed here in this chapter. However, more detailed approaches for refining the monitoring plans, and prioritizing the SEGs for scheduling exposure monitoring will be discussed later in this chapter under the section 4.e.(6) Provide Control Plan.

(a) Initial Monitoring Plans. Often for initial assessments, the exposure monitoring needed is determined by a combination of professional judgement, regulatory requirements for initial monitoring in substance specific regulations such as Reference 4-2, results of any other screening initial monitoring, results of surrogate monitoring or modeling.

(b) Mechanics of Exposure Monitoring.

1. General. Usually, exposure monitoring is performed for three reasons: profiling, compliance and diagnostic. Exposure data may be required to establish an exposure profile for a SEG or to determine if an established exposure profile is still valid. This type of monitoring relies on statistically valid random sampling. Monitoring may be conducted to determine if exposures are in compliance with an OEL. This type of monitoring usually focuses on worst case scenarios. Hazard levels may be measured to provide information used to control the exposure (e.g., identifying hazard "hot spots").

2. The following discussion covers exposure monitoring as it relates to SEG exposure profiles.

a. Basic exposure monitoring considerations. The following factors should be considered when deciding how and when exposure monitoring should be conducted:

(1) Exposure pathway. The industrial hygienist should select a sampling method that is appropriate for the significant exposure pathways (i.e., inhalation, skin absorption, or ingestion).

(2) Sampling duration. It is important that the duration of sampling be an appropriate mirror of the averaging time of the OEL for that hazard (e.g., full-shift sampling for 8-hour TWA-OELs, 15 minute sample duration for STEL-OELs, 30 minute sample duration for EL OELs).

(3) Seasonal variations. If seasonal changes in working conditions (e.g., doors shut in the winter and open in the summer) will affect exposures, sampling should address those differences. Either sampling should cover all seasons or each season's exposure should be documented with consideration as to whether an additional SEG would need to be created.

(4) Differences between work shifts. If exposures are expected to differ between work shifts, either the different shifts should be different SEGs or all shifts should be sampled.

(5) Differences between locations. If exposures are expected to differ between work locations, either the different work locations should be different SEGs or all locations should be sampled.

b. How many samples? The industrial hygienist should collect 6 to 10 samples from randomly selected (ideally) members of a SEG. Six samples is the minimum needed to provide reasonable certainty and more than 10 samples provides only a small amount of increased certainty per extra sample collected.

(1) Random sampling for profiling. The 6 to 10 samples recommended above need to be collected randomly to allow statistically valid inferences to be drawn. Random selection gives the best chance of documenting variability in the population of all exposures. To randomly select the employees to be sampled and the dates and work shift on which they will be sampled the following actions should be followed:

(a) Determine the time period over which sampling will be conducted (e.g., a year, a season, a month). Very long time periods (e.g., a year, several months) delay the interpretation of the data and risk a change in the exposures during the sampling campaign. Very short time periods (e.g., one week) risk not revealing the true variation of exposures.

(b) Randomly choose sampling dates from the time period selected. If the process in question does not occur frequently, it may be necessary to sample every time it occurs until the required number of samples has been collected. The assumption is the exposure distribution is stationary (i.e., exposure variables such as weather, equipment, engineering controls and operator skill do

not change). Although a stationary distribution may not exist for infrequently performed processes, sampling each occurrence is often the only practical strategy due to the small number of employees involved in these processes. If the number of similarly exposed individuals involved in an infrequent process is large enough (i.e., at least six) then sampling all the individuals or a statistically valid random sample of the individuals in the SEG is a good strategy.

(c) If applicable, randomly choose the work shifts to be sampled on each of the sampling dates.

(d) Randomly choose the employees from the SEG that will be sampled on a given work shift on a given workday. This will probably have to be done within a few days of the sampling date since work schedules change frequently.

(e) If STEL or Ceiling samples are being collected, randomly select the high-exposure tasks that occur during the work shift and workday previously chosen for sampling.

c. Exposure monitoring to fulfill regulatory requirements. While constructing a monitoring plan, the industrial hygienist must ensure that samples required to comply with regulatory requirements are collected; for instance those required by substance specific regulations such as those found in Reference 4-2 (e.g., OSHA lead standard). When possible, exposure monitoring should be arranged to allow samples to serve the dual purpose of meeting regulatory requirements and providing random data points for statistical inferences.

(5) Characterize and Assess Exposures. This is where an exposure profile is determined for the SEG, and the exposure for each group is judged to be acceptable, uncertain or unacceptable. Characterizing an exposure profile consists of obtaining the best estimate of the exposure and its variability, as well as judging how good those estimates are. The exposure profile and its uncertainty and the OEL and its uncertainty are compared to make an exposure assessment.

(a) Initially characterizing and estimating the exposure should involve a combination of quantitative and qualitative or semi-quantitative data. Exposure estimates should be conservative to avoid errors that would lead to a conclusion that an exposure is acceptable when, in fact, it is not. Initially, most exposure estimates will be more qualitative or semi-quantitative, because early in the exposure assessment process sufficient exposure monitoring has usually not occurred. Initial estimates may be enough to provide assessments for some SEGs where the exposure profile is very clearly acceptable or obviously unacceptable. Where needed to adequately characterize and assess the exposure profile, additional exposure monitoring data can be collected, and the exposure assessment can be refined by performing statistical analysis.

1. Professional experience and screening data. The industrial hygienist may draw upon their personal knowledge of exposures from the same or similar process with which the industrial hygienist is familiar. The industrial hygienist should consult the scientific literature for published data. A limited number of screening measurements may be made to add to the available data or confirm that the current process appears to correspond to data developed by others.
2. Surrogate data. When more relevant data is not available, exposure data from another hazard with similar physical properties and used in a similar or the same process may be considered. Such data is also sometimes used to estimate the airborne concentration of other chemicals in a mixture when the airborne concentration of only one of the chemicals is known. Exposure data from another process using the same hazard may also be considered. Such data needs to be tempered with good professional judgment.
3. Modeling. Exposures may be estimated based on models that consider the chemical and physical properties of a hazard along with the effect of existing controls and estimated generation and removal rates. When used, model parameters should be selected to arrive at a conservative estimate of exposure. The industrial hygienist should remember that all models are imperfect and need to be used with a critical eye and sound professional judgment. Modeling based on environmental release data from a process can also help estimate exposures.
4. Exposure monitoring data. Initial monitoring data provides a good basis to initially characterize and assess the SEG exposure profile. For a statistical exposure assessment, usually 6 to 10 random samples should be collected for the SEG.

(b) Statistical Exposure Assessments.

1. Sample data set size. As previously mentioned, 6 to 10 samples is the typical target for statistical analysis. All the samples do not need to be collected at the same time; they can be built up over time. Typically 6 samples is the minimum needed to provide reasonable certainty and more than 10 samples provide only a small amount of increased certainty per extra sample collected. However, some SEGs may require more than 10 samples to achieve the needed certainty; however, keep in mind that if the SEG sampling results are extremely variable, the homogeneity of the SEG may need to be checked to see if the SEG needs to be redefined and separated into more than one SEG.
2. Sample averaging time. For statistical analysis to be performed, the data must have the same averaging time (e.g., all 8-hour TWA samples, all STEL samples).
3. Dealing with results below the analytical LOD. These techniques also apply if LOQ is reported instead of LOD.

a. 8-hour TWA sampling data. Navy industrial hygienists should adjust results that are less than the LOD prior to calculating the 8-hour TWA. Results that are less than the LOD are considered censored data. There are techniques to handle such censored data. At times in the past, the use of such techniques has been referred to as censoring. When a less than LOD result has been adjusted using these techniques, the result is no longer expressed as a "less than" value. This adjusted result can then be used in calculating the 8-hour TWA. (The resulting TWA is likewise not expressed as "less than" the calculated value.)

b. STEL and Ceiling value sampling data. Navy industrial hygienists will also commonly encounter STEL and Ceiling value sampling data sets with censored data that need to be adjusted prior to analysis.

c. Techniques for handling censored data. The following actions are recommended for preparing data sets with less than LOD result values for statistical analysis. Remember that once adjusted, the result value no longer carries the "less than" qualifier.

(1) If 50% or more of the results are less than the LOD, the industrial hygienist should adjust the sampling protocol to obtain data that is greater than the LOD, if possible.

(2) For consistency, Navy industrial hygienists should divide less than LOD results by the square root of 2.

(3) Consult Reference 4-1 for further information for the handling and analysis of censored data.

4. Verifying that the sampling data are lognormally distributed. Use the Shapiro Wilk test (sometimes referred to as the W-test) to determine if the sampling data is lognormally distributed. A log probability plot will also check for lognormality.

Note: Air sampling exposure data for a SEG is generally considered to be lognormally distributed. Noise dosimetry exposure data for a SEG as percent dose is lognormally distributed but as dBA is normally distributed. The below discussion on lognormally distributed data would not apply to noise dosimetry dBA data sets.

a. If the data is not lognormal, either the SEG is not correctly defined or the exposure population is not stationary. In that case, the SEG needs to be redefined. This does not mean to discard the data; rather it means regroup the data into two or more SEGs. For example, if the exposure population was not stationary, separate the sampling results into two groups, one for the samples taken before the exposures changed and one for the samples taken after the exposures changed. In that case, if the new data set had too few samples, additional samples would need to be collected and added to the group containing samples after the exposure changed to provide a total sample size of 6 to 10 samples. Once there is

enough sampling data, the statistical analysis would be performed on this new refined data set.

b. If the data is lognormally distributed, continue the statistical analysis.

5. Verifying that the exposure population was stationary. If the population of exposures changed during exposure monitoring, the sample data cannot be interpreted as a whole. Plot the sampling results sequentially as they were taken and look for trends either upward or downward. If a trend is evident, the data should be separated into two or more groups based on noticeable changes in exposure over time. If no trends are apparent, assume the exposure population is stationary and continue the statistical analysis.
6. Determining the descriptive statistics of the data. Calculate the sample median, range, maximum value, minimum value, arithmetic mean (using the MVUE) and standard deviation. From the log transformed statistics, calculate the geometric mean and the GSD.
7. Determining if the SEG is correctly defined.
   a. As discussed above, data that should be lognormally distributed not being lognormally distributed can potentially be an indication that the SEG is not correctly defined.
   b. Additionally, if the variability of the data is large (i.e., GSD >3), this may be an indication that either the SEG is not properly defined or the process is out of control. The industrial hygienist should determine if this is the case and, if so, adjust the definition of the SEG (i.e., regroup the data into two or more SEGs) to decrease the variability, then collect any additional samples as required, and perform statistical analysis on the new refined data sets.
8. Estimating the exposures in the upper tail. Focus on the upper tail of the SEG exposure profile distribution. The upper tail values are used to assess exposures that are compared to 8-hour TWA-OELs, STEL-OELs and Ceiling-OELs, and are what the Navy currently uses for statistical exposure assessments. DOEHRS-IH SEG Assessment can be used to calculate these parameters. Alternatively, there are various statistical programs currently available, some of which are even geared to IH use.
   a. Determine the 95^{th} percentile exposure point estimate.
   b. Determine the $UTL_{95\%,95\%}$.
   c. Determine the exceedance fraction/probability of noncompliance.
   d. Determine the one-sided 95% upper confidence limit ($UCL_{1,95\%)}$ for the exceedance fraction/probability of noncompliance.

(c) Making the SEG Exposure Assessment. By comparing the SEG exposure profile to the OEL and considering the uncertainties around both the exposure profile and OEL, the exposure may be judged and the SEG assigned an exposure assessment of acceptable, unacceptable or uncertain. This requires consideration of how much uncertainty exists around whether the OEL is adequately protective and whether the exposure estimate is accurate. The idea is to determine those

exposures for which there is high, low, or unknown potential for exceeding the OEL which then corresponds to an exposure assessment of unacceptable, acceptable or uncertain risk of exceeding the OEL.

1. Considering the uncertainty around the OEL. Identify the appropriate OELs for each hazard. For SOH standards, assume that there is a high degree of certainty that the SOH standard is correctly set and, therefore, adequately protective (i.e., low uncertainty and a small confidence interval). However, the industrial hygienist should consider whether recent scientific evidence increases the uncertainty around a SOH standard and compensate appropriately in the exposure assessment. One indicator of uncertainty is if more recent OELs are lower than the existing SOH standard.
2. Considering the uncertainty around the exposure estimate. While developing the SEG exposure profile, the industrial hygienist should have developed at least a subjective estimate of the uncertainty around the exposure estimate. The industrial hygienist is reminded that all exposure models are imperfect. Additionally, with statistical analysis the target exposure estimate for the exposure profile is the 95th percentile exposure point estimate, and its uncertainty is described by the 95% confidence upper tolerance limit around the 95th percentile value (i.e., $UTL_{95\%,95\%}$).
3. Judging/Assessing the SEG exposure profile.
    a. Assigning an EER. EERs are useful to characterize the SEG exposure profile. EERs for chemical hazards with Ceiling, STEL and 8-hour TWA-OELs, and for physical hazards (e.g., noise) can be associated to hazards with established SOH standards. EERs should be based on the 95th percentile exposure point estimate and assigned assuming that no personal protective equipment is worn. Exposure measurements for the SEG should meet the requirements for randomness, stationary population and normal or lognormal distribution. Generally, to minimize uncertainty and maximize efficiency, a sample size of 6-10 measurements is usually sufficient. If dermal exposures are expected to be a significant contribution to overall exposure, adjustments to the EER should be made.

        Assuming that SOH standards have a high degree of certainty, exposure assessments may be assigned to the EER for a SEG based on Table 4.2. The exposure effects categories presented in Table 4.2 are those described in DOEHRS-IH. The DOEHRS-IH EER IH Exposure Hypothesis is essentially the same as that presented in Reference 4-1 for Exposure Rating (Exposure Risk Rating), except DOEHRS-IH adds the “Negligible” category and has ratings from 1 to 5, rather than 0 to 4, where 1 indicates the lowest exposure effect and 5 indicates the highest exposure effect. Since Navy industrial hygienists typically use the 95th percentile exposure point estimate, the 95th percentile should be compared to the OEL or 50% of the OEL for the IH Exposure Hypothesis.

Table 4.2 - Exposure Effect Ratings*

Exposure Effect Rating/ Category	IH Exposure Hypothesis*	Exposure Profile	Actions
5/Very High	Expected to be at or above the OEL	Gross **frequent** contact with agents at very high concentrations; Materials have high vapor pressure or dustiness	Control Monitor: – if required by regulation; – to validate respiratory protection; – if control changes occur
4/High	Likely to be an exposure, but between 50% OEL and OEL	**Likely** contact with agent at high concentrations or infrequent contact at very high concentrations; Materials have significant vapor pressure or dustiness	Monitor: – routine – as required by regulation Gather Information Verify Controls Implement Medical Surveillance or Other Programs, as required
3/Moderate	Exposure frequently <50% OEL or generally between 10-50% of OEL	**Occasional** contact with agent at moderate concentrations or infrequent contact at high concentrations; Materials have low vapor pressure or dustiness	Monitor: – routine Gather Information Specific Hazard Communication as required
2/Low	Exposure infrequent, <10% of OEL	**Infrequent** contact with agents	Workplace Procedures and Training General Hazard Communication Monitor: – to validate assessment – if control changes occur

Exposure Effect Rating/ Category	IH Exposure Hypothesis*	Exposure Profile	Actions
1/Negligible	No detectable exposure	Current science cannot determine that there is exposure to agent	General Hazard Communication Monitor: –to validate assessment –if control changes occur

*Use 95th percentile exposure point estimate

Note: There may be special cases where a more restrictive upper point estimate be used based on the hazard of interest (e.g., STELs for highly toxic compounds).

b. Statistical comparison. In making the exposure assessment, the industrial hygienist needs to decide whether and how the confidence intervals around the SEG exposure profile and the OEL do or do not overlap. That overlap, or lack of overlap, determines the exposure assessment. When there is no overlap the exposure is clearly either acceptable or unacceptable depending on whether it is above or below the OEL. When there is overlap, the exposure assessment will be uncertain.

c. Acceptable exposures. Exposures may be considered acceptable where there is no overlap of the SEG exposure profile and the OEL confidence intervals, and the OEL is greater than the 95th percentile exposure point estimate of the exposure profile and the $UTL_{95\%,95\%}$ of the exposure profile, or for a SEG with an EER of 1 or 2, and possibly 3 or 4 with high certainty about the exposure profile and the OEL. Additionally, exposures may be deemed acceptable where determined by other, qualitative, or semi-quantitative assessment methods. In such cases, the industrial hygienist must exercise sound professional judgment after considering the available information and make the exposure assessment with a well-documented rationale.

d. Uncertain exposures. Exposures may be considered uncertain where there is overlap of the SEG exposure profile and OEL confidence intervals, and the 95th percentile exposure point estimate of the exposure profile is less than the OEL but the $UTL_{95\%,95\%}$ is greater than the OEL, or for a SEG with an EER of 3 or 4 with the upper tail of its exposure profile approaching the OEL, or when the available information is unable to predict with certainty whether overexposure will occur.

e. Unacceptable exposures. Exposures may be considered unacceptable where the 95th percentile exposure point estimate of the SEG exposure profile is greater than the OEL, or for a SEG with an EER of 5.

(d) Refining the SEG Exposure Assessment. The industrial hygienist is reminded that statistics are an aid to decision making and that the ultimate decision should be based on a combination of professional judgment and statistics. As additional exposure monitoring is performed the SEG exposure profile is refined and the reassessed.

(6) Provide Control Plan. This section will discuss refining the monitoring plan/further information gathering, prioritizing SEGs for exposure monitoring, and prioritizing SEGs for control of unacceptable or uncertain occupational exposures.

(a) Refining the Monitoring Plan/Further Information Gathering. Once enough exposure monitoring data is collected, statistical analysis can also aid in developing the monitoring plan to focus on where additional monitoring is needed. The EER is useful for refining the monitoring plan to help determine which SEGs require exposure monitoring/further information gathering. The EER exposure categories are presented in Table 4.2 in paragraph 4.e.(5)(c)3.a.

1. Where the SEG employee exposure assessment is classified as acceptable or has an EER of 1 or 2, no routine exposure monitoring is generally required. However, some hazards require at least initial monitoring by substance specific regulation such as Reference 4-2, and some SEGs may benefit from occasional exposure monitoring to validate the assessment and ensure the exposure profile has not changed. Additional monitoring may be required if administrative, work practice, or engineering controls are modified. Also, at least qualitative reassessment is needed when circumstances affecting exposure change or during the periodic IH survey.
2. Where SEG employee exposure assessment is classified as uncertain (or with additional data acceptable with some level of uncertainty) or has an EER of 3 or 4, additional exposure monitoring/information gathering is needed for further estimation of SEG employee exposure. Also, some hazards require particular periodic monitoring by substance specific regulations such as Reference 4-2.
3. Where SEG employee exposure assessment is classified as unacceptable or has an EER of 5, exposures need to be controlled. Routine exposure monitoring/further information gathering is generally no longer required. However, some SEGs may require additional exposure monitoring, especially where particular periodic monitoring is required by substance specific regulation such as Reference 4-2, where monitoring is needed to validate respirator protection factor selection, or if administrative, work practice, or engineering controls are implemented/modified.
4. The industrial hygienist is encouraged to use professional judgment as appropriate to identify additional SEGs for exposure monitoring as dictated by local circumstances rather than be driven solely by the approach described above. Conversely, the industrial hygienist should not feel compelled to expand exposure monitoring beyond those SEGs selected by the approach if professional judgment does not identify additional SEGs.

(b) Prioritizing SEGs for Scheduling Exposure Monitoring/Further Information and Prioritizing SEGs for Instituting Controls of Unacceptable or Uncertain Occupational Exposures.

1. Assigning a HER to a SEG. Since different hazards produce different health effects, it is logical to use the gradation in health effects to help determine priorities for intervention. There are a number of different health effect rating systems, only one of which will be proposed here. The health effects categories presented in Table 4.3 below are those described in DOEHRS-IH. The DOEHRS-IH HER Health Effect is essentially the same as that presented in Reference 4-1 for HER, except DOEHRS-IH has ratings from 1 to 5 rather than 0 to 4. One indicates the least health effect and 5 indicates the greatest health effect.

Table 4.3 - Health Effect Ratings

Health Effect Rating/Category	Health Effects	Health Effects Codes (OSHA)
5/Very High	Acute life-threatening or disabling injury or illness	**Health Hazard:** HE1 - Regulated carcinogens; HE2 – Chronic (cumulative) toxicity - known or suspect human (IARC Group1 & Group 2A, ACGIH A1 & A2) carcinogens, mutagens; HE17 - Chemical asphyxiants, anoxiants; HE11 – Respiratory effects - acute lung damage, edema **Safety:** Death, Loss of facility or asset **Noise:** Immediate hearing loss, impulse noise
4/High	Chronic irreversible health effects of concern	**Health Hazard:** HE3 – Chronic toxicity - long term organ toxicity other than nervous, respiratory, hematologic or reproductive; HE5 – Reproductive hazards - teratogens or other impairment; HE7 – Nervous system disturbances - other than narcosis; HE10 - Respiratory effects (other than irritation) - cumulative lung damage; HE9 - Respiratory effects (other than irritation) – respiratory sensitization – asthma or other **Safety:** Major property damage **Noise:** Noise induced hearing loss, permanent and temporary threshold shifts, will eventually lead to permanent hearing loss

Health Effect Rating/Category	Health Effects	Health Effects Codes (OSHA)
3/Moderate	Severe reversible health effects of concern	**Health Hazard:** HE14 – Irritation of eyes, nose, throat, skin – marked; HE6 - Nervous system disturbances - cholinesterase inhibition; HE12 - Hematologic disturbances – anemias; HE13 - Hematologic disturbances – methemoglobinemia, anemias; HE4 - Acute toxicity - Short-term high risk effects (non-IDLH) **Safety:** Minor property damage
2/Low	Reversible health effects of concern	**Health Hazard:** HE15 – Irritation of eyes, nose, throat, skin – moderate; HE16 – Irritation of eyes, nose, throat, skin – mild; HE8 - Nervous system disturbances - narcosis **Safety:** Minimal threat to personnel, property, first aid, minor supportive medical treatment, but still a violation of a standard.
1/Negligible	Nuisance health effects (Reversible health effects of little concern or no known or suspected adverse health effects)	**Health Hazard:** HE19 - Generally low risk health effects - nuisance particulates, vapors or gases; HE 20 - Generally low risk health effects – odor **Safety:** No violation of a standard.

Note: Navy industrial hygienists need to use professional judgment and available reference material in assigning a Health Effect Rating to a hazard.

2. Determining the HRR for a SEG. HRR is a numerical rating, ranging from 1 to 25, which is obtained by multiplying the HER times the EER. DOEHRS-IH calculates the HRR as an intermediate step in calculating the EAP, but does not display the HRR. Table 4.4 below illustrates the calculations performed by DOEHRS-IH as a matrix.

Table 4.4 – Health Risk Ratings

		Exposure Effect Rating/Category				
		1/Negligible	2/Low	3/Moderate	4/High	5/Very High
Health Effect Rating/Category	5/Very High	5	10	15	20	25
	4/High	4	8	12	16	20
	3/Moderate	3	6	9	12	15
	2/Low	2	4	6	8	10
	1/Negligible	1	2	3	4	5

3. Determining the uncertainty for a SEG. Unlike the previously used rating system, DOEHRS-IH adds an additional Uncertainty Rating matrix that considers confidence in existing controls and exposure characterizations. It is a numerical rating with values ranging from 1 to 5, with 1 being the highest confidence and 5 being the lowest confidence. The matrix and choices can be seen in Table 4.5 below. This differs from Reference 4-1 Uncertainty Rating that ranges only from 0 to 2.

Table 4.5 - Uncertainty Ratings

		Confidence in Hazard and Exposure Characterization		
		Low	Medium	High
Confidence in Existing Controls	Low	5	4	3
	Medium	4	3	2
	High	3	2	1

a. Confidence in hazard and exposure characterization.

(1) Low. The exposure characterization is based solely on a qualitative review of the workplace, and no quantitative data is available for this or similar activities.

(2) Medium. The exposure characterization is based on a detailed administrative and onsite review of activities within the workplace and application of professional judgment, supported by application of objective based engineering principles; results of screening samples or initial sampling results are within acceptable limits, but not totally conclusive; or exposure characterization is based on comparison to assessments of similar characterized DoD or private sector processes (qualitative, semi-quantitative, or quantitative).

(3) High. The exposure characterization is based on sufficient quantitative evaluation or detailed technical reports where environmental factors do not influence exposures, further quantification is not required; or the source of the hazard does not have the potential to generate significant exposures.

b. Confidence in existing controls.

(1) Low. Controls are inadequate to control exposures; or controls are in a poor state of repair, non-operational, or not actively used.

(2) Medium. Controls will control employee exposures to acceptable levels when regularly and properly used (e.g., administrative controls or personal protective equipment).

(3) High. Engineering controls or work practice controls are in place and fully operational, and evaluations have been completed to demonstrate adequate exposure control.

4. Determining the EAP for a SEG. Unlike the previously used rating system, DOEHRS-IH adds the additional step of calculating the EAP from the HRR and Uncertainty Rating. EAP is a numerical rating, ranging from 1 to 125, which is obtained by multiplying the HRR times the Uncertainty Rating, with 1 being the lowest priority for scheduling additional exposure monitoring/information gathering and 125 being the highest priority. This entire process is illustrated in Figure 4.2 below. Figure 4.2 is from Reference 4-8. The DOEHRS-IH EAP is similar to the Reference 4-1 Information Gathering Priority Rating (essentially HRR multiplied by Uncertainty Rating), but due to the range differences the DOEHRS-IH EAP ranges from 1 to 125 and the Reference 4-1 Information Gathering Priority Rating ranges only from 0-32. Table 4.6 illustrates the calculations performed by DOEHRS-IH as a matrix. This table is similar to a prioritization scheme from Reference 4-1 and illustrates a potential plan for prioritizing additional routine exposure monitoring/information gathering that may be needed, or even prioritizing the institution of controls.

Figure 4.2 – Exposure Assessment Priority Process

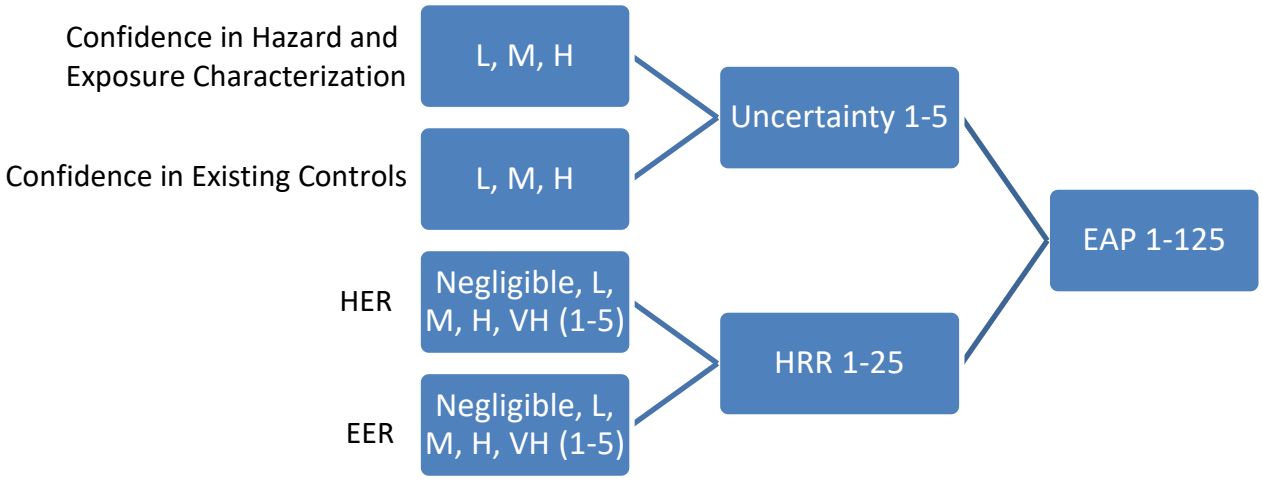


Table 4.6 – Prioritizing Additional Exposure Monitoring/Information Gathering and Instituting Controls for SEGs

Health Risk Rating					
	25	50	75	100	125
	24	48	72	96	120
	23	46	69	92	115
	22	44	66	88	110
	21	42	63	84	105
	20	40	60	80	100
	19	38	57	76	95
	18	36	54	72	90
	17	34	51	68	85
	16	32	48	64	80
	15	30	46	60	75
	14	28	42	56	70
	13	26	39	52	65
	12	24	36	48	60
	11	22	33	44	55
	10	20	30	40	50
	9	18	27	36	45
	8	16	24	32	40
	7	14	21	28	35
	6	12	18	24	30
	5	10	15	20	25
	4	8	12	16	20
	3	6	9	12	15
	2	4	6	8	10
	1	2	3	4	5

Priority for Control

Uncertainty Rating

Priority for Additional Routine Exposure Monitoring/Information Gathering

a. As the Uncertainty Rating increases the priority for needing additional routine exposure monitoring/information gathering increases. As HRR increases (with considering the underlying EER and HER), the priority for instituting controls increases. Sufficient exposure monitoring lowers the Uncertainty Rating and also the EAP.

(1) If the assessment is acceptable and the HRR is low and the Uncertainty Rating is low, there may be little to no need for additional routine exposure monitoring/information gathering.

(2) If the assessment is uncertain, additional routine exposure monitoring/information gathering would generally be needed. Also,

depending on how high the HRR (and considering the underlying EER and HER) and if there was increased Uncertainty Rating, higher priority for short term/interim control may also be indicated.

(3) If the assessment is unacceptable, the exposure needs to be controlled. If the HRR is high and the Uncertainty Rating is low, there may be little to no need for additional routine exposure monitoring/information gathering; however, higher priority for instituting control would be indicated.

(4) The EAP can be a rough guideline to prioritizing any additional routine exposure monitoring/information gathering that may be needed, or even prioritizing instituting controls. However, since based on the HRR, there can be issues in considering the equivalency in HRR given to between SEGs with high EER and low HER and SEGs with low EER with high HER (i.e., a SEG with an EER of 5 (generally unacceptable) and an HER of 2 provides the same HRR of 10 as does a SEG with an EER of 2 (generally acceptable) with an HER of 5). This equivalency issue illustrates that using the EAP for prioritization should be done conservatively, factoring in the exposure assessment, as well as professional knowledge and judgement. Prioritization schemes should NOT displace professional judgment, experience or the evaluation of the particular situation. The industrial hygienist's knowledge is essential in proposing and prioritizing recommendations for additional exposure monitoring/information gathering or instituting controls.

(5) Also, remember, in some cases, initial or periodic exposure monitoring may be required to comply with regulatory requirements, validate the assessment, or validate respirator protection factor selection, and still would be required if administrative, work practice, or engineering controls are implemented/modified.

(c) Actions after additional exposure monitoring/information gathering. After any additional exposure monitoring/information gathering has been completed, the data should be used to refine and revise the exposure assessment.

(d) Actions after controls are implemented. After any new occupational exposure controls are implemented, the SEG exposure assessment should be changed to uncertain and exposure monitoring should be conducted as described in this chapter. This new data should be used to refine and revise the exposure assessment.

(7) Reporting and Recording.

(a) Reports. IH survey reports are provided to the appropriate customers in the manner outlined in Chapter 2 of this document.

(b) Exposure assessments. Exposure assessments need to be well documented by the industrial hygienist and retained in the industrial hygienist's files but the details of the assessment should not be reported to the customer due to the

volume of material involved. Instead, a summary chart/list showing the SEGs and the final exposure assessment category assigned would be appropriate.

(c) DOEHRS-IH. This program provides a recordkeeping system to define SEGs, exposure profiles, and exposure assessments; document exposure monitoring; perform qualitative or quantitative exposure assessments; and document decision making and recommendations.

(8) Reevaluation.

(a) Qualitative reevaluation. Although SEGs with acceptable exposures are not usually candidates for routine exposure monitoring, they require at least a qualitative reevaluation be conducted at least at the frequency stated in Reference 4-6. SEGs with uncertain or unacceptable exposures also would receive periodic reevaluation at least at the frequency stated in Reference 4-6 in addition to any needed exposure monitoring/further information gathering. Information from any reevaluations should be fed back into the exposure assessment process at the basic characterization step and all the elements of the exposure assessment should be updated.

(b) Quantitative reevaluation. Although not required, a program to validate acceptable exposure assessments with exposure monitoring data is recommended for 5% to 10% of these SEGs. Such data collection should not interfere or compete with the more important tasks of exposure monitoring of uncertain exposures or control of unacceptable exposures. Data from monitoring for the reevaluation of acceptable SEGs and from additional monitoring of uncertain or unacceptable SEGs should be fed back into exposure assessment process at the basic characterization step and all the elements of the exposure assessment should be updated.

(c) Changes. Any changes in the OEL, the workplace or the work force that may affect exposures should be evaluated before or at the time the change occurs. Otherwise, any changes to the shop, processes, SEGs, controls, etc. should be noted at the time of the periodic IH survey. Information or exposure monitoring data from the reevaluation should be fed back into the exposure assessment process at the basic characterization step and all the elements of the exposure assessment should be updated.

5. References

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4-5. ACGIH. *TLVs® and BEIs, Threshold Limit Values for Chemical Substances and Physical Agents*. Cincinnati, OH: American Industrial Hygiene Association. Latest edition.

4-6. OPNAVINST 5100.23 Series

4-7. DoD Industrial Hygiene Working Group Report 2000-1, "*DoD Industrial Hygiene Exposure Assessment Model*," 2000.

4-8. DOEHRS-IH Student Guide Chapter 19.