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The Evaluation, Collection, and Management of Exposure Assessment Data

Robert Adams, MS, CIH, CSP
ENVIRON International Corp.
Princeton, NJ

Michael Holton, MS, CIH, CSP
ENVIRON International Corp.
Princeton, NJ

Introduction

Exposure assessment is an integral part of health and safety programs. Exposure assessment drives decisions about investments in control technology, personal protective equipment usage, training, work practices, and hazard communication. Too often, the performance of an exposure assessment is performed only to meet the requirements of an OSHA standard, and, in some cases, only limited sampling is performed for the purposes of meeting minimum requirements. In other cases, sampling is performed that is unnecessary. The exposure assessment process does not start or end with the collection of samples; sampling is only a small part of the exposure assessment process. There are many questions that must be understood before engaging in any exposure-sampling program.

- **Why -** Are you looking to evaluate regulatory compliance, to perform a comprehensive assessment, or some other goal
- **What -**What stressors are present, which do you need to sample for;
- **When** - What shift(s) do you need to sample do you need to collect short term samples or full shift samples, are exposures expected to remain constant throughout the year or vary;
- **Where** - Are exposures limited to specific areas, are area or source samples important to answering your questions;
- **How** - What methods should be used for sampling, are there compounds that interfere with specific analytical techniques, Will direct reading instruments be useful to your assessment; and
- **Who** - What workers or job titles should be sampled; How many workers of a given position need to be sampled?

By answering these questions and developing an exposure assessment plan before collecting samples, you improve the likelihood that you will collect samples in an efficient manner and be able to achieve the goals of you exposure assessment.

The first step to developing a robust exposure assessment program is to recognize that exposure assessment is not a singular event or activity, but a process. Exhibit 1 demonstrates the essential elements of the exposure assessment process and their relationship to one another. The following sections will detail the characteristics and considerations of each of these elements.

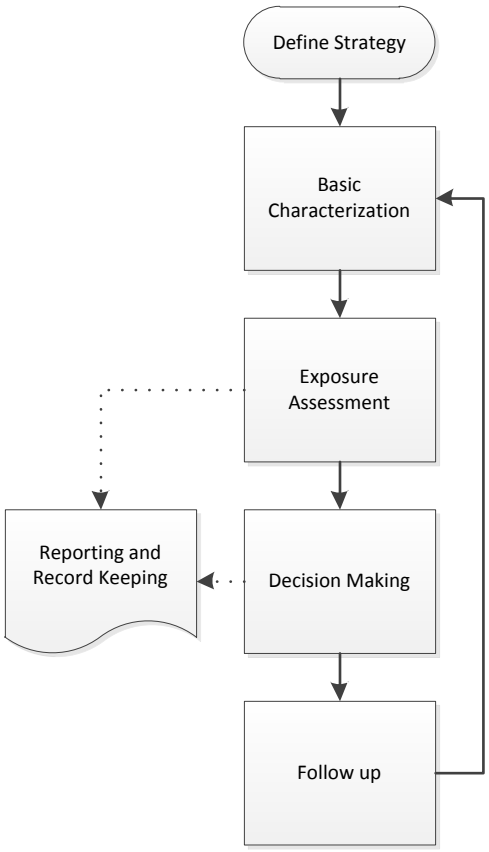

Exhibit 1: General overview of the exposure assessment process

Defining Your Exposure Assessment Strategy

The first question you need to answer before developing an exposure assessment program is "why are you doing the assessment?" Whether you are trying to evaluate overall risk, regulatory compliance, or adherence to voluntary standards will dictate what type of exposure assessment strategy you will employ. The American Industrial Hygiene Association Strategy for Assessing and Managing Occupational Exposures describes two general exposure assessment strategies, compliance strategy and comprehensive strategy (Ignacio and Bullock 2006).

Compliance strategy is the traditional approach to exposure assessment and is aimed at determining if exposures are greater than an established occupational exposure limit. This strategy involves the collection of samples from either worst-case exposures or a representative

group of workers to evaluate exposures relative to the OEL. The primary advantage of this strategy is that it can be performed at lower cost while maintaining regulatory compliance. The NIOSH Occupational Exposure Sampling Strategy is an example of a compliance strategy. (NIOSH 1977)

Comprehensive strategy is a more robust approach that looks to evaluate, and where necessary control, exposure to all stressors, including those without any established Occupational Exposure Limits (OEL). This approach provides greater insight into day-to-day variations in exposure and is more conducive to assessing present day and future health risks. This additional data may come at an increased cost making it undesirable to some businesses.

Regardless of the strategy chosen, a decision must be made about which OELs will be used when evaluating exposures. If a comprehensive strategy is chosen, decisions must be made about the approach for contaminants lacking an OEL. The following are characteristics of some of the commonly relied upon OELs.

- **OSHA PELs** - The PELs are the regulatory enforceable levels set by OSHA. When considering the PEL as your OEL, it is important to note that the majority of PELs are based on data that is over 40 years ago (1968 TLVs). (AIHA 2002)
- **ACGIH TLVs** - The TLVs are airborne exposure levels that represent conditions under which it is believed that *nearly all* workers may be exposed, day after day, over a working lifetime, without adverse health effects. The TLVs are updated annually. (ACGIH 2012)
- **NIOSH RELs** - The RELs are developed by NIOSH to prevent and reduce workers risk of occupational cancer and other adverse health effects. RELs are intended to limit the concentration of the potential hazard in the workplace air to protect worker health. (http://www.cdc.gov/niosh/topics/cancer/policy.html#REL)

In situations where no exposure criteria exist, a decision must be made on how to assess these exposures. Options include developing an internal or working OEL which may be costly or implementing an alternate strategy such as control banding. Control banding is discussed further in the Decision Making section of this paper.

Following the selection of a strategy for your exposure assessment program, a written program should be developed. This should include not only the information about the goals of the program and the targeted exposure values, but also information pertaining to the methodology that will be used in the basic assessment, decision making, follow up, and record keeping, which are discussed in the following sections of this paper.

Basic Characterization and Information Gathering

Basic characterization is intended to accomplish the following:

- anticipate and identify potential exposures; and
- assess hazard sources

The objective of basic characterization is to identify combinations of process, personnel, and stressors that can be used to define groups of workers with comparable exposures that are

referred to as a Similar Exposure Group (SEG). Typically, information about the workplace, work force, stressors, and controls is gathered from a visual walkthrough survey and reviews of available records. Questions to be answered qualitatively as part of the basic characterization process include:

- what are the chemical, physical, biological agents (stressors);
- what are the potential health effects that would be expected from overexposure;
- do the agents have OELs;
- how would the workforce be exposed to these agents;
- what are the sources of exposure;
- what are the work practices, processes or tasks where exposure could occur;
- have controls been put into place;
- has prior exposure information been collected; and
- how has the process changed since the prior assessments were completed?

First, the workplace must be fully described. This involves documenting the processes and/or operations that are performed. Processes and operations may be partially characterized by obtaining copies of process flowcharts or standard operating procedures. It is essential that the process or operation be observed in progress to fully understand the potential occupational exposures involved and to verify that the documents accurately reflect the current situation. Informal discussions with workers, supervisors, engineers, and safety personnel are also an important part of understanding the workplace. Exposure controls that may be in-place (i.e., exhaust ventilation, work practices, protective equipment) must also be identified at this stage. Although production processes and operations are often well characterized, it is essential to also characterize associated maintenance and repair work that might result in potential exposures.

Next, an inventory of chemical, physical, and biological stressors is collected to allow classification according to their potential hazard. Each route of exposure (i.e., inhalation, ingestion, skin absorption) must be evaluated. A site's existing Safety Data Sheet inventory should provide the majority of information necessary. It will also be necessary to assess whether there are any process off-gases, byproducts or intermediates, waste products, or products of decomposition to fully characterize the stressors that might be present in the work place. Again, it is also important to identify materials that are not used routinely, such as cleaning and maintenance chemicals. Physical hazards, such as lasers, ionizing and non-ionizing radiation, hot environments, and noise must also be evaluated. Biological hazards include potential pathogenic organisms and should be assessed if their presence is anticipated in the work environment.

Working from the inventory, the following information should be developed for each potential stressor, as applicable:

- quantity and form of the material;
- relevant physical properties (e.g., vapor pressure, solubility, particle size distribution);
- known or suspected health effects; and
- applicable OELs and appropriate exposure averaging time (e.g., Ceiling, STEL, 8-hour TWA).

The work force is described through reviews of the job titles, job descriptions, or other documents of personnel activity, worker/supervisor interviews, and direct observations of the work tasks being performed. In describing the work force, it is important to recognize that similar job titles are not necessarily reliable predictors of similar exposures. For example, exposures to welders vary greatly depending on the type of welding. A break-down of workers by department or shop may be useful but within a department or shop there are often a variety of processes (e.g., welding, abrasive blasting, grinding) or tasks (e.g., administrative, quality assurance, production, supervision) performed that can result in different exposures. Further, intervariability between workers of the same job duties can be pronounced due to differences in work practices. A process-based or a task-based work force classification may be needed to arrive at the best selection for the SEG. Also, differences in work frequency and duration may occur on different work shifts and must be evaluated. A chemical mixer operator on the first shift may have substantially different exposures than the chemical mixer operator on the second shift.

Finally, a review of relevant records must be performed. Most businesses have a variety of health and safety records including:

- safety and health surveys or audits;
- prior results of environmental monitoring;
- results of industrial hygiene monitoring;
- results of biological monitoring;
- personnel injury or illness reports (OSHA logs); and
- engineering control assessments.

Exposure Assessment

The exposure assessment activity is the portion of the exposure assessment program where the information collected during the basic characterization stage is applied to the SEGs developed to prioritize or quantify exposures. The data created during this activity is then compared against the decision-making criteria discussed in the next section.

Exposure assessment is typically a tiered process. Even where a comprehensive strategy is employed, it is often not necessary or desirable to perform personal monitoring for every possible stressor. By using a tiered approach exposures judged to be minor or trivial can be excluded from extensive exposure monitoring and interim controls can be implemented where exposures are likely to exceed the OEL. Various methods to categorize exposures and determine what qualifies as an acceptable exposure exist; these will be discussed in greater detail in the Decision Making section.

The initial assessment may rely upon a variety of data including:

- **Existing personal monitoring data** - It is possible that personal air monitoring for the contaminant of interest has been performed. This data used in conjunction with information about changes in work practices or exposure controls discovered during the basic characterization stages can be useful in estimating likely ranges of exposure.
- **Screening measurements** - If direct reading instruments are available for the contaminant, it is possible to perform some screening measurements to characterize exposures. Care should

be taken to understand the limitations of any direct reading instruments used when evaluating exposures. For example some direct reading dust monitors are calibrated to a particle with a specific gravity of 1.2, if you are evaluating exposures to lead, which has a specific gravity greater than 11, this would underestimate exposure.

- **Modeling** - Given appropriate knowledge of the process, materials, work practices, and controls, it is possible to use a mathematical model to estimate exposures. (Keil et al. 2009)
- **Analogous materials** - Use of existing data on related materials can be useful in estimating the range of potential exposures. For example, historical dust measurements have been used to estimate asbestos exposures. (Consensus Report 1997). Again, caution must be taken to ensure that the data is relatable.

These estimates formed during the first tier are conservative to minimize potential errors that would lead to a conclusion that an exposure is acceptable when, in fact, it is not. In some situations, the initial assessment may provide sufficient data; however, the collection of personal exposure samples will often be required. Some OSHA chemical specific standards allow for the use of objective data (the type of information used in the initial assessment), but the majority requires the collection of personal samples (see Table 1.) When collecting personal samples, it is important to choose the appropriate methodology that can detect the contaminants in the range desired and will perform adequately in the sampling environment.

Substance	**Standard**	**Allows for use of Objective Data**
Asbestos	1910.1001	Yes
Vinyl Chloride	1910.1017	No
Inorganic Arsenic	1910.1018	No
Lead	1910.1025	No
Chromium (VI)	1910.1026	Yes
Cadmium	1910.1027	Yes
Benzene	1910.1028	No, except to determine where STEL monitoring is required
Coke Oven Emissions	1910.1029	No
Cotton Dust	1910.1043	No
1,2-dibromo-3-chloropropane	1910.1044	No
Acrylonitrile	1910.1045	Yes
Ethylene Oxide	1910.1047	Yes
Formaldehyde	1910.1048	Yes
Methylenedianiline	1910.1050	Yes
1,3-Butadiene	1910.1051	Yes
Methylene Chloride	1910.1052	Yes

Table 1: Allowance for the use of objective data in OSHA general industry standards.

Decision Making

If a well-planned and executed exposure assessment strategy is followed, interpretation and decision making is usually not difficult. The information collected from the exposure assessment process will be interpreted to make two decisions:

- is the SEG's exposure profile adequately characterized; and
- are the exposures acceptable?

The exposure profile is a summary of the exposures of an SEG and consists of obtaining the best exposure estimate(s) and then categorizing that estimate by assigning an exposure rating. Estimating the exposure involves a combination of quantitative and qualitative information.

In determining if the SEGs exposure profile has been adequately characterized, further assessment is needed to make subsequent decisions and determine further actions to take in response to the exposure profile for any SEG. These include the following:

- **Consider the uncertainty of the assigned OEL-** The initial assumption is that there is a high degree of certainty that the OEL is appropriately set and, therefore, adequately protective (i.e., low uncertainty and a small confidence interval). However, a review of recent scientific evidence should be undertaken to assess whether there is any increase in the uncertainty around an OEL and adjust the exposure assessment.
- **Consider the uncertainty around the exposure estimate-** A subjective estimate of the uncertainty around the exposure estimate should be developed. If using exposure models, recognize that all models are imperfect. When relying on measurement data, consider that all sampling and analytical methods have error associated with the sample collection process and the higher the error, the greater the uncertainty. Small data sets, over limited time frames, also have greater uncertainty than large data sets over longer time periods.

Exposure ratings for chemical stressors are an estimate of the exposure concentration relative to a Ceiling, STEL, and 8-hour TWA OELs. Physical stressors (e.g., noise) can be associated to stressors with established OEL also. The exposure rating categories based on the AIHA exposure assessment strategy are summarized in Table 2 below. Exposure ratings are assigned assuming that no personal protective equipment is worn. For chemical stressors, Table 2 addresses only airborne exposures; if dermal exposures are expected to be a significant contribution to overall exposure, than adjustments to the exposure rating should be made.

Category	Quantitative Exposure Rating	Qualitative Exposure Ratings
4	TWA > 100% OEL	Unacceptable exposures
3	100% OEL > TWA > 50% OEL	Uncertain
2	50% OEL > TWA > 10% OEL	Acceptable, with moderate uncertainty
1	TWA < 10% OEL	Acceptable, little to no uncertainty

Table 2: Exposure Rating Categories Based on an Estimate of the Arithmetic Mean of the Exposure Profile (Ignacio and Bullock 2006)

A different approach is presented in the NIOSH Occupational Exposure Sampling Strategy Manual that incorporates the knowledge about sampling and analytical error into a 95% confidence interval around a sample value. This method involves dividing the sample result by the OEL and constructing a confidence interval around that value. Results whose confidence intervals fall completely below 1 are considered acceptable exposures, confidence intervals completely greater than 1 are considered unacceptable exposure, and confidence intervals including one are considered uncertain. (NIOSH 1977) This is demonstrated in Exhibit 2.

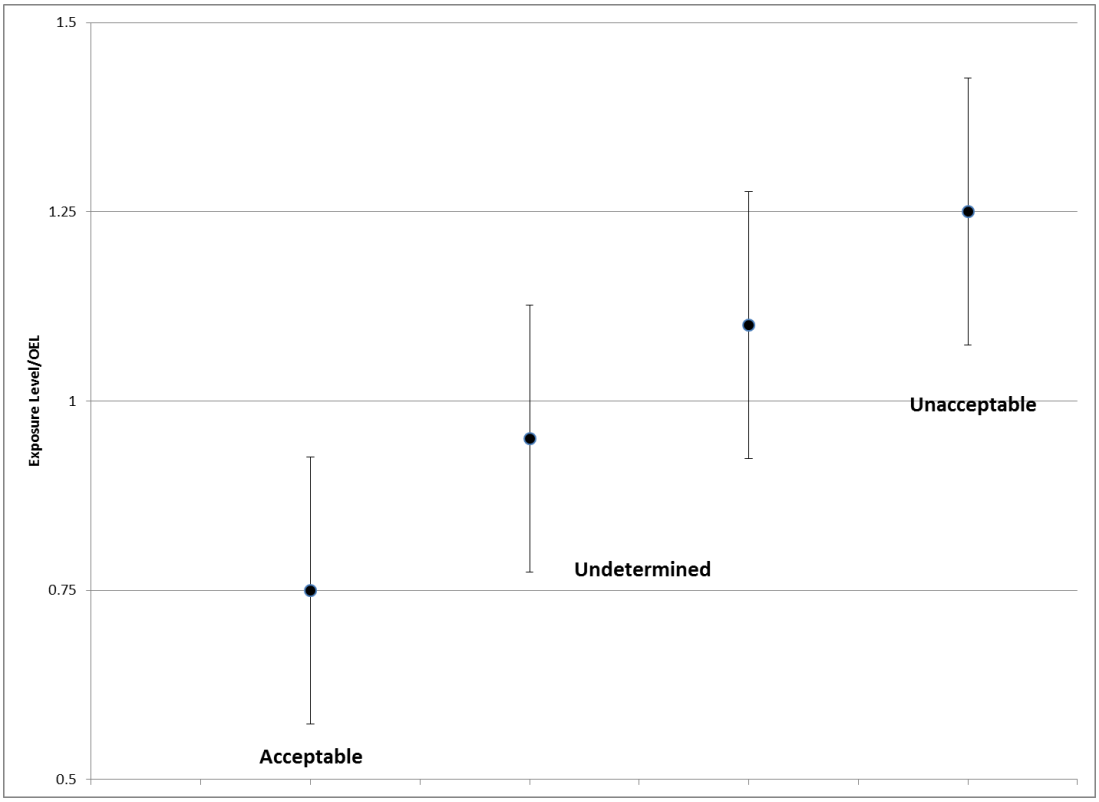

Exhibit 3: Decision making in the NIOSH Strategy

Once the exposure has been assessed, decisions regarding further actions can be made.

Exposure Assessment using Control Banding

Control banding is an exposure assessment technique originally developed for the pharmaceutical industry. It is a way to identify control approaches for working with new or existing chemicals that have no OELs and limited or no toxicity information. With continuing growth in the use of new and novel chemical materials in many industries and emerging technologies (such as nanotechnology), a means is needed to rapidly determine prudent control measures to protect workers while at the same time allowing research and development and production of useful products to proceed.

Control banding is a qualitative strategy for assessing and managing chemical hazards in the workplace. It is based on the concept that there are many chemicals that workers may be exposed to in the workplace but there are a limited number of common approaches to hazard control. It also considers that exposure problems have been encountered and solved before with analogous materials. It relies on information that is generally available from the manufacturers or suppliers of chemical products so that the materials can be grouped into levels or bands based on how much protection would be needed; the better the available information, the more refined the hazard control approach. The process involves taking the assessor through a series of basic information gathering steps, not unlike the basic characterization step previously discussed, to assess the health hazard and the exposure potential. The basic information gathering includes answering the following questions:

- What is known about the toxicity of the product(s); what R-phrases have been identified;
- What is (are) the pathway(s) for exposure (is the product in a fine particulate form or is it a volatile substance);
- What is(are) the work process; how likely is(are) the substance(s) to become airborne (e.g. batch process vs. closed system);
- What is the frequency and duration of exposure; is this a routine or non-routine activity; and
- What is the quantity of the product(s) used?

Once the hazard band is determined, a control measure strategy is suggested. A product with greater health risks and higher exposure potential will have more stringent controls than a product with low health risk that is unlikely to come in contact with or enter the body.

The following is a simple model for control banding:

Band No.	**Hazard Group**	**Control**
1	Skin and/or eye irritant	Use good industrial hygiene practice and general ventilation.
2	Harmful on single exposure	Use local exhaust ventilation.
3	Severely irritating and/or corrosive	Enclose the process.
4	Very toxic on single exposure; reproductive hazard; sensitizer; carcinogen	Seek expert advice.

Exhibit 4: Simple model for control banding from Control Banding: Pharmaceutical Caterpillar to Mainstream IH Butterfly (Sullivan and Malik 2007)

The following is a variation of the above control-banding matrix;

Health Hazard		High	Medium	Low
Exposure Potential	High	HIGH Isolation	MEDIUM Engineering Controls	MEDIUM Engineering Controls
	Medium	HIGH Isolation	MEDIUM Engineering Controls	LOW Dilution Ventilation
	Low	MEDIUM Engineering Controls	MEDIUM Engineering Controls	LOW Dilution Ventilation

Exhibit 4: Variation of model for control banding from Control Banding: Pharmaceutical Caterpillar to Mainstream IH Butterfly (Sullivan and Malik 2007)

Control banding offers a way to qualitatively assess risks and choose relevant control measures to reduce exposures in workplaces. It allows for recommendations to be made for chemicals and products that do not have occupational exposure limits. However, control banding is not without its limitations, which include:

- Must be used in conjunction with the hierarchy of health and safety control, particularly elimination or substitution;
- Not a replacement for experts in occupational safety and health;
- Does not eliminate the need to perform exposure monitoring;
- Not fully validated yet and there is no universally adopted method of control banding;
- Not all types of hazards are covered by any one control banding system (For example, safe handling of certain chemicals with a specific toxic effect may be covered, but flammability and reactivity hazards have not been addressed by the control banding system);
- Some risk in generalizing hazards when using control banding;
- Errors when identifying hazards or an inaccurate estimation of exposure assessment; and
- R-phrases used in Europe depend on the manufacturer or supplier selecting the correct phrase.

Follow Up

Based on the decisions made about the exposure assessment data, some level of follow up will be required. Where exposures are greater than the OEL, controls will need to be implemented. Generally, exposures should be re-evaluated any time that there is a change in process, equipment, or materials which may alter exposures. The AIHA Strategy outlines the following periodic exposure-monitoring program (Ignacio and Bullock 2006):

- Exposure > OEL - Quarterly
- Exposure < OEL, but > 50% of OEL – Semi-annual
- Exposure < 50% of the OEL, but > 205% of the OEL – Annual
- Exposure < 25% of the OEL – Biannual

The NIOSH Strategy recommends sampling at least monthly for exposures greater than the PEL and bimonthly for exposures greater than an action level (NIOSH 1977)

Some OSHA chemical specific standards provide specific frameworks for the timing of exposure monitoring based on previous results.

It is important the exposure assessment programs not sit dormant. At a minimum, an evaluation of the exposure characterization and exposure strategy. If exposures are re-evaluated on a periodic basis, updates to the basic characterization and exposure assessment may be minimal; however, if long periods lapse between assessments, significant effort may be required for re-assessment.

Record Keeping and Reporting

Based on OSHA requirements, exposure records should be retained for 30 years; however, there are some exceptions to this rule detailed in Table 2. Further, if the goals of your exposure assessment program include the use of the data as part of a study of health outcomes then data may need to be retained for longer periods of time based on the latency period associated with the specific health outcome being studied.

Exposure	Standard	Data Retention Period
Noise	1910.95	Two years
Inorganic Arsenic	1910.1018	Longer of: 40 years or duration of employment plus 20 years.
Lead	1910.1025	Longer of: 40 years or duration of employment plus 20 years.
Coke Oven Emissions	1910.1029	Longer of: 40 years or duration of employment plus 20 years.
Cotton Dust	1910.1043	At least 20 years
1,2-dibromo-3-chloropropane	1910.1044	Longer of: 40 years or duration of employment plus 20 years.
Acrylonitrile	1910.1045	Longer of: 40 years or duration of employment plus 20 years.

Table 2: Data retention requirements under OSHA general industry standards

In terms of reporting chemical exposure assessment results to workers, there is generally no OSHA requirement that results be reported to workers, except for the following chemical specific standards that require reporting of exposures within 15 days:

- Asbestos
- Vinyl Chloride
- Inorganic Arsenic
- Lead
- Chromium (VI)
- Cadmium
- Benzene

- Coke Oven Emissions
- Cotton Dost
- 1,2-dibromo-3-chloropropane
- Acrylonitrile
- Ethylene Oxide
- Formaldehyde
- Methylenedianiline
- 1,3-Butadiene
- Methylene Chloride

For noise exposures, employers must inform all employees exposed at or above 85 dBA of the results of the monitoring. There is no timeframe for this reporting within the regulatory language.

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Occupational Safety and Health Administration (OSHA). 29 CFR 1910.1020, *Access to Employee Exposure and Medical Records*

Occupational Safety and Health Administration (OSHA). 29 CFR 1910.1025, *Lead*

Occupational Safety and Health Administration (OSHA). 29 CFR 1910.1026, *Chromium (VI)*

Occupational Safety and Health Administration (OSHA). 29 CFR 1910.1027, *Cadmium*

Occupational Safety and Health Administration (OSHA). 29 CFR 1910.1028, *Benzene*

Occupational Safety and Health Administration (OSHA). 29 CFR 1910.1029, *Coke Oven Emissions*

Occupational Safety and Health Administration (OSHA). 29 CFR 1910.1043, *Cotton Dust*

Occupational Safety and Health Administration (OSHA). 29 CFR 1910.1044, *1,2-dibromo-3-chloropropane*

Occupational Safety and Health Administration (OSHA). 29 CFR 1910.1045, *Acrylonitrile*

Occupational Safety and Health Administration (OSHA). 29 CFR 1910.1047, *Ethylene Oxide*

Occupational Safety and Health Administration (OSHA). 29 CFR 1910.1048, *Formaldehyde*

Occupational Safety and Health Administration (OSHA). 29 CFR 1910.1050, *Methylenedianiline*

Occupational Safety and Health Administration (OSHA). 29 CFR 1910.1051, *1,2-Butadiene*

Occupational Safety and Health Administration (OSHA). 29 CFR 1910.1052, *Methylene Chloride*

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