Exposure Assessment: What is It, and What Does it Mean

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Introduction

Exposure assessment is where theoretical science, medicine, and applied science, merge to define what the possible health effects of a chemical product may be for human beings. For this subject, as for every area of modern life, complexity increases the more we learn.

Occupational health and safety professionals are interested in workplace exposures, but exposure to chemicals happens constantly, everywhere. Our lifestyle choices and often our environment literally bathes us in chemicals. We encounter chemical products at work, at home depending on our choices as consumers, and in the environment depending on everyone else's choices as consumers.

Much of what is done as part of exposure assessment is an approximation. Figuring out exactly, to the smallest degree, which chemicals may have affected any one person enough to harm their health can be complicated even if there's only one chemical, we know what it is, and where to go to measure it. It's an incredibly complex process to pinpoint sources, amounts and how these amounts may change a person's health. The more we have learned about biological mechanisms of action and toxicology, the harder it has become to identify the source of biological effects. What combination of workplace, environment, and lifestyle choices caused the exposures? How do we prove the health effect resulted from any or all of them? Can we separate workplace exposures from non-workplace exposures?

The current state of the EOSH profession includes identifying preventive measures for non-work-related events that can lead to injuries or illnesses. Wellness programs, safety and health awareness training for smoking, driving, biking, boating, and protecting children against chemical stressors, are all part of keeping people healthy and productive. An exposure assessment provides critical evidence to answer the question, "What caused the health effect?"

What is an Exposure Assessment?

To make decisions on the risk to people from any stressor, we need to know the basics. It starts with the material or stressor itself. In industrial hygiene, noise, heat, cold, and light are considered stressors; the predominant concern is airborne, inhalable contaminants. The critical parts of the assessment must define contact between the worker and the chemical, and how much of the material enters the worker's body, or the body-burden. The toxicology of the material, how it is processed by the body, and individual allergies and sensitivities are the biological components that help make exposure assessments deviously complex.

Screening-level assessments allow quick prioritization of exposures for further work; these assessments are based primarily on readily available data, conservative assumptions and simple models.

Advanced assessments focus on higher priority exposures that represent actual environmental conditions and exposures; these assessments require more data and make use of more sophisticated mathematical models or ideally, a well-designed study.

Risk is estimated by integrating a health assessment and an exposure assessment, thus making high-quality exposure assessments essential. Achieving this requires improvements and the integration of different types of methods, measurements, and mathematical models for exposure.

Workers are continuously exposed to a wide variety of chemical substances, biological agents, physical agents, and other stressors encountered both in and out of the workplace. Each stressor has the potential to cause some health effect, whether it is a prescribed pharmaceutical, consumed food, cleaning product, automotive exhaust emission, solvent, ultraviolet radiation, noise, whole-body vibration, or social or psychological stress.

The concentration of the chemical and the extent of the contact are important components of exposure assessment. The results of an exposure assessment are often considered with a hazard assessment of the chemical. A hazard assessment provides an understanding of the potential for the chemical to cause adverse effects to humans and plant and animal life. Together, the exposure assessment and the hazard assessment can be combined into a risk assessment, which reaches conclusions about the likelihood of adverse effects in the exposed population.

Exposures to mixed stressors can produce health consequences that are additive, synergistic, antagonistic, or can potentiate the response expected from individual component exposures. Little information is available to guide occupational hygienists on when to apply the exposure additivity formula, when to consider the effects of multiple exposures as independent, and when synergistic or antagonistic effects may be expected.

Exposure analyses are best when combined with epidemiological or disease studies to obtain solid evidence of an association, or to at least learn about the cause-effect relationship, if there is one. This information can also be applied to the design of more realistic animal toxicological studies, because it is often difficult to transpose an animal study to human beings.

Workers from agriculture, construction, mining and other industries are commonly exposed to combinations of chemical substances, biological or physical agents, and other stressors. Knowledge is limited of the potential health effects of mixed exposures. Additional nonwork-related exposures (such as using alcohol or tobacco, or the use of insect repellents, cosmetics, or other chemicals) and individual susceptibility and metabolic toxicology mentioned above, add to the complexity of exposure and resulting biological responses.

To define environmental concentrations of chemicals, releases to the environment need to be estimated. Chemicals can be released to air, water, or landfill. Release estimates are generated using industrial data, engineering expertise and information on the production process. Manufacturing and processing operations are reviewed to determine potential releases in the work place (e.g., vapors from processing equipment, etc.,) that could result in worker exposure and releases to the environment. Releases from consumer products should also be considered.

Research has shown that interactions from mixed exposures can lead to an increase in severity of the harmful effect. Examples of known or perceived health risks with toxicological endpoints and consequences from mixed exposures include synergistic carcinogenesis of asbestos and smoking, and exposure to noise and the solvent toluene, which results in a higher risk of hearing loss than exposure to either stressor alone. Other examples show more uncertainty. Exposure to carbon monoxide and methylene chloride produces elevated levels of carboxyhemoglobin, reducing the blood’s ability to carry oxygen in the body. The Gulf War syndrome and the mixed-exposure-associated health effects from jet fuel (JP-8) exposures are far from clear.

This lack of clarity stems from the complex nature of the mixtures involved and their related biological consequences. These mixtures not only interact within the human system, they can also undergo chemical transformations in the environment. Examples of this transformation are the conversion of some chlorinated hydrocarbons into toxic phosgene in the presence of ultraviolet light, and the enhanced transport of radionuclides into the lungs when adsorbed by respirable dust. The problem of mixed exposures once again adds to the complexity, given the large number of combinations that occur every day in a variety of workplaces and in our everyday life experiences.

All exposure scenarios cannot be measured for reasons such as limited finances and limited availability of measurement methods. Hence, exposure modeling is necessary. Optimal models are built using a combination of measurement data and theoretical information and are evaluated with measurement data. Modeling becomes even more important with mixtures because of the difficulty (and in some cases the impossibility) of measuring complex mixtures. For example, exposures could be better predicted if a complex exposure model were available based on the chemicals in the environment of interest; the physiochemical properties of the chemicals; the relevant fate, transformation, and distribution characteristics under realistic conditions; and activity patterns of the potentially exposed people. With a scientific basis to estimate the number of people likely to have exposure to other stressors (for example, noise, certain pharmaceuticals), the total exposure would be better understood as input into health models for eventual risk assessment.

Control Banding

Control banding is a system used to assess and manage workplace risks. It is a process that matches a control measure (e.g., ventilation, engineering controls, containment, etc.) to a range or "band" of hazards and exposures (e.g., skin/eye irritation, very toxic, carcinogenic, etc.). The control banding system groups chemicals according to similar physical or chemical characteristics, how the chemical will be handled or processed, and what the anticipated exposure is expected to be. This system then determines a set of useful controls that will prevent harm to workers.

Control banding was originally developed by the pharmaceutical industry as a way to safely work with new chemicals that had little or no toxicity information. These new chemicals were classified into "bands" based on other more-studied materials' toxicity and anticipated safe work practices, taking into consideration exposure assessments. Each band was then aligned with a control scheme.

For this reason, it is commonly associated with chemical exposures but other similar systems are being developed for other workplace hazards. As such, several control banding models or systems have been developed. Control banding is also referred to as a "risk management tool" or "toolbox."

The overall goal of control banding is to help workplaces by providing an "easy to understand" and "easy to apply" approach to controlling hazards. The control banding model is meant to be used by small- and medium-sized workplaces that have limited expertise in workplace health and safety, industrial hygiene or chemical control. This principle is also being examined for its use with chemicals and products that do not have occupational exposure limits (OELs), or for new processes such as nanotechnology.

The introduction to NIOSH's 2009 document on control banding discusses the fact that thousands of new chemicals are produced each year, with little or no knowledge of the effects they may have on living systems. Additionally, the specific concerns of industries, like the pharmaceutical industry, that must be aware of and control minute amounts of very biologically active compounds must be considered.

The traditional method of assessing risk from chemicals is to understand the properties of the chemical, have a way to measure it during the process involving the worker, and determine if the amount the worker receives is capable of causing adverse health effects.

Control banding (CB) is a technique used to guide the assessment and management of workplace risks. It is a generic technique that determines a control measure (for example, dilution ventilation, engineering controls, containment, etc.) based on a range or "band" of hazards (such as skin/eye irritant, very toxic, carcinogenic, etc) and exposures (small, medium, large exposure). It is an approach that is based on two pillars; the fact that there are a limited number of control approaches, and that many problems have been met and solved before. CB uses the solutions that experts have developed previously to control occupational chemical exposures, and suggesting them to other tasks with similar exposure situations. It is an approach that focuses resources on exposure controls and describes how strictly a risk needs to be managed. NIOSH considers CB a potentially useful tool for small businesses.

Control banding must be used in conjunction with health and safety practices such as substitution. Substitution for a less hazardous chemical is still highly recommended to prevent exposure. It is important to note that CB is *not* a replacement for experts in occupational safety and health nor does it eliminate the need to perform exposure monitoring. CB highly recommends the use of professionals to provide recommendations. The fourth band specifically recommends seeking professional assistance for highly hazardous exposures. Furthermore, CB recommends exposure monitoring to follow the CB intervention to ensure the installed controls are working properly.

Control banding methods should be enhanced, and additional modeling methods should be developed and validated to address other needs such as exposure classification, exposure ranking, data interpretation, expert systems, and complex exposure scenarios such as mixtures and non-ambient conditions.

Mathematical Models: Environmental

The EPA Center for Exposure Assessment Modeling (CEAM) was established in 1987 to meet the scientific and technical exposure assessment needs of the United States Environmental Protection Agency (U.S. EPA), as well as state environmental and resource management agencies. CEAM provides proven predictive exposure assessment techniques for aquatic, terrestrial, and multimedia pathways for organic chemicals and metals. The following information is from the Environmental Protection Agency (EPA) Office of Pollution Prevention and Toxics (OPPT) website. It is recommended as the first stop for anyone wishing to get more information on the topic of exposure assessment.

The most accurate way to obtain environmental concentrations and human exposures is usually to conduct a well-designed exposure monitoring study. Elements of a well-designed exposure monitoring study include: establishing quality assurance objectives that will allow exposure assessors to make estimates of average and high-end exposures with a known level of reliability; where possible, using sampling and analytical chemistry methods that have been found acceptable by an independent authoritative body (e.g. ASTM, NIOSH, etc); and ensuring that quality control procedures have been employed and documented.

Groundwater models: These models quantify the movement of subsurface water and provide inputs to subsurface contaminant transport models. Simulation provides insight into groundwater and contaminant behavior and quantitative assessments for environmental decision making.

Surface water models: By modeling contaminant movement and concentration in lakes, streams, estuaries, and marine environments, researchers can better understand how exposure to contaminants affects aquatic environments.

Food chain models: Contaminated aquatic and terrestrial environments typically result in the bioaccumulation of chemicals within all trophic levels of an ecosystem. Software models provide tools for tracking the movement of contaminants through food chains and for estimating chemical impacts on exposed biota.

Multimedia models: Contaminants may travel through the atmosphere, soil, surface water, and the organisms that inhabit these media. The multimedia approach to exposure modeling quantifies the impacts of contaminants as they travel through more than one of these environments.

The screening level tools often make simplifying assumptions, which are protective by design (for example, assuming that people live near chemical discharge locations). Higher tier tools are more complex and allow for more realistic exposure assessments, such as using census data and a measure of the distance between the location of the chemical release and the populations living nearby. Daily activities include the amount of time people spend at home as well as the amount of air they breathe and the amount of water they drink. For workers, daily activities include the amount of time they spend handling the chemical during the day. The amount of chemical that an individual breathes, comes into contact via the skin, or drinks via water, is the final product of an exposure assessment. Often, a report describing the exposure assessment is prepared. Depending on the complexity of the assessment, the report can be a few pages or it can be quite lengthy.

Mathematical Models: Workplace

The American Industrial Hygiene Association (AIHA) Press published a document on mathematical modeling in 2000, edited by Dr. Charles Keil, with an outstanding preface written by Dr. John Mulhausen. In this preface, Dr. Mulhausen discusses how available information is used to assess exposures and classify them as acceptable, unacceptable, or uncertain.

He goes on to say that mathematical modeling has a special advantage over other exposure estimating techniques, in that it can be used to estimate exposures in the absence of the physical presence of the process or operation. Mathematical models can then be used as a means for prospectively assessing exposures for new operations not yet installed. This is great for planning needed control measures, and estimating costs.

Some of the different types of mathematical models that can be used and are discussed in this manual include determining mixing of contaminants and concentrations for indoor air systems. This would help for projects like addressing “sick building syndrome” and other indoor air quality questions. There are generation rate models for filling drums; a saturation vapor pressure model for how long it will take a spilled chemical vapor to fill up a space; and the tried-and-true box model for determining a concentration of a chemical in a room with air moving in and out at a certain rate.

Other interesting mathematical models include the two-zone model, which is designed to estimate exposures to workers close-in to the source of the chemical, and then calculate what other workers in the same room but distant from the source might receive as an exposure. Dermal exposure monitoring is used to estimate skin exposure and penetration, and the usefulness of a model like this is obvious. Skin reactions and dermatitis are the most common of occupational injuries, and skin exposures can greatly add to the worker's body burden for a variety of toxic substances. Skin exposures from powders and liquids, and how different materials interact and transport across the layers of the skin is a fascinating specialty area for many scientists and health professionals.

<u>Retrospective Exposure Assessment</u>

Retrospective exposure assessment applies all of the above mentioned ideas, and uses mathematical models to guess what a worker's past exposures may have been. Exposures for past work are estimated, using measurements collected on similar jobs or processes. Even though the worker was not monitored or observed when the work was done, an estimate of the range of exposures can be done to assist in deciding if the total estimated exposure could have contributed to an observed disease or health effect. This is commonly done with asbestos, because of the large body of information collected on various jobs, such as transite removal, brake work, and so on. Much research has been gathered about what levels of asbestos must be inhaled to cause different disease states in the human body.

This type of past-history study can be done with other stressors, such as pesticide, lead, or dust. If total estimated exposure is below levels considered significant for health effects, it can be argued that the past history was not a likely factor in the health result. If the past exposures are estimated to be high, even without data collected on that worker at the time they performed the work, it might be difficult to argue that observable health effects did not result from these past workplace exposures.

Retrospective exposure assessment is a field in its own right, and also continues to develop. Mathematical models, like the Monte Carlo Model, have been used that generate a certain number of randomly computer-generated exposures, based on all available information of duration, size of particle, air currents, and whatever other variables can be plugged into the model. Using these is an art in itself and is currently presented at a variety of scientific conferences.

What Does an Exposure Assessment Mean?

This is a question for policy makers, for government and public health officials, and business leaders. Decision makers need the right information so they can design and carry out public health policy for the general environment, consumer product and food and drug safety, and the protection of workers.

Problems can be caused by different interpretations of an exposure assessment. One of the more common is the insistence of an answer to the question "is it safe?" The uncertainty discussed by Dr. Mulhausen in his essay is the reason that the person asking such a question, cannot be given a "bright line" (this is safe, that is not) because of all the different reasons why the exposure estimates may vary across a wide range.

A common mistake is to make a crucial judgment on limited or no data. This may work for very low exposures, for operations or work that is known, and with adequate protective measures in place. This is the strong argument for control banding. However, if an exposure assessment estimate will be high enough to potentially cause a health effect, deciding what to do will depend on the uncertainty of the model being used; the expense associated with various control options; the expense of monitoring; and the toxicity of the chemical.

In the majority of cases studying industrial processes, it is expensive to measure, and expensive to control. Collecting more data may help to improve methods of control, but more than likely personal protective equipment (PPE) is used to protect workers, especially in cases where the stressor or chemical is toxic. One must beware of using the low end of exposure assessments to justify not funding controls; or conversely arguing that health effects are a direct result of the higher end of the estimated exposure.

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