Avoiding Common Mistakes in Screening Level Risk Assessments

An Online Continuing Education Course for Engineers

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Introduction to Screening Level Risk Assessment

Defining Risk and the Component Parts of Risk Assessment

For purposes of conducting scientific assessments, risk is commonly defined as: the probability that exposure to a hazard will lead to negative consequence (i.e. risk). This definition can be represented in a more mathematical format as:

Hazard * Exposure = Risk (or probability of negative consequence)

Risk is therefore assessed by comparing the level of hazard associated with a chemical or substance to the level of exposure. This can be done quantitatively if there is sufficient data on both the hazard and the exposure, or it can be done in more qualitative forms. The equation can also be rearranged such that an exposure concentration is determined that protects against a certain prescribed level of risk.

Exposure = Risk / Hazard

This revised mathematical format is the basis for developing risk-based concentrations of chemicals in environmental media (i.e. soil, air, sediment, or water). As the above equation indicates, this risk-based concentration is based on protecting against a certain level of risk and upon a numeric expression of the hazard (i.e. toxicity). A more complete understanding of the risk assessment process is obtained by describing each of these component parts of the definition of risk.

Hazard

Hazard refers to the source of the risk. In human health and environmental risk assessment this is typically a chemical but may include other materials such as asbestos or materials that are essentially collections of chemicals like gasoline. A characterization of the hazard posed by chemicals and hazardous materials is provided by toxicological (generally laboratory studies on animals or tissues) or epidemiological (studies on cases of human exposure) studies. These studies provide the necessary understanding of the relationship between doses (how much is taken into the body by various routes of exposure) and toxicity.

Exposure

Exposure refers to the degree to which an organism may come into contact with the hazardous agent. This requires an understanding of how an area is currently used by people or may be used by people in the future. Typical questions involve how often the site is used; whether the site is used by younger or older people or others who are often considered more susceptible to toxic effects; and the kinds of activities that are or might be performed. Activities that generate a lot of dust, for example, are recognized to increase the potential for inhalation or incidental ingestion of chemicals in the disturbed soil.

The exposure assessment then also considers how chemicals may move in the environment in ways that can increase exposure. Typical questions involve consideration of things like how volatile the chemical is, how windy is the site, how much vegetative cover is provided to prevent wind-blown dust, rainfall levels and its effects on storm water runoff quality or potential for carrying chemicals down into groundwater, and so on. The intent is to gain an understanding of the potential for exposure.

Risk-based screening level standards and criteria defining safe concentrations of chemicals in the environment employ a host of explicit and implicit assumptions about exposure. Being aware of what these exposure assumptions are and whether they properly reflect a specific application is important for avoiding mistakes in the application of risk-based standards and criteria.

Risk

Risk refers to the potential for a negative consequence. This can be expressed as a probability or in more absolute terms. In human health risk assessment, risks for chemicals that may cause cancer are expressed in probabilistic terms. Laws and regulations governing EPA generally seek to take action when risks are calculated to exceed the range of 1×10^{-4} to 1×10^{-6} (that is one in one hundred thousand to one in one million). Under this approach, risks for toxic effects persist with exposure to chemicals at levels below established standards or criteria establishing "safe" concentrations of chemicals in the environment.

Conversely, human health risk for non-carcinogenic chemicals and all risks to all ecological organisms are assessed in non-probabilistic terms. Therefore, it is possible to define standards below which exposure to non-carcinogenic chemicals are not expected to cause an adverse toxic effect. This "not expected to" aspect leaves a tie-in to probability, in that we can never be sure that the exposed individual will not be more sensitive than expected or that new studies will identify some toxic endpoint at a lower level of exposure than previously known. However, this kind of probability cannot be mathematically defined, and uncertainty factors are often applied in developing screening level standards to manage these uncertainties.

The Context and Role of Screening Level Risk Assessments

The term "screening-level" refers to the relatively simple, yet health protective approach used to assess risk. A definition specific for ecological risk assessments provided by EPA (2001, p. 1) provides an example of the context and role for screening level risk assessments:

"Screening-Level Ecological Risk Assessments (SLERAs) are conservative assessments in that they provide a high level of confidence in determining a low probability of adverse risk, and they incorporate uncertainty in a precautionary manner. It must be stressed that SLERAs are not designed nor intended to provide definitive estimates of actual risk, generate cleanup goals and, in general, are not based upon site-specific assumptions."

While practices can vary, generally speaking screening level risk assessments are used to determine if further assessment or actions are needed to reduce risk. As shown in Figure 1, when concentrations of chemicals in the environment are shown to be below screening levels, then little to no risk is expected from exposure and additional assessments or actions to reduce risk are needed. When screening levels are exceeded, additional assessment, such as more detailed assessments that carefully consider site-specific needs and/or response actions, may be needed.

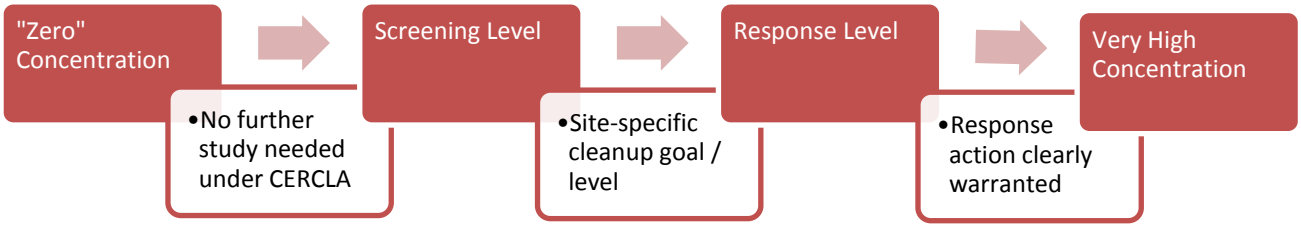

Figure 1. Conceptual Framework for Risk Assessment and Risk Management.

Screening level standards and criteria are based on conservative (i.e. health protective) assumptions of exposure that consider a broad range of potential activities. Conversely, a site specific assessment uses increased levels of knowledge about site use and other variables that can control exposure to determine a concentration that is protective within the specific application. Generally, as more information about the site is known and applied to assess risk, the higher the response level (also called cleanup level) becomes.

Generally speaking, errors can creep into screening level risk assessment when the toxicity studies used to assess hazard are not applicable to the site and when exposure assumptions are not consistent with site conditions. In some cases, simple modifications to the numerical assumptions used to determine the screening level value can be performed within the scope of a screening level risk assessment, thus avoiding the more costly for assessing and presenting a site-specific risk assessment. Moreover, an adequate understanding of risk assessment assumptions

can be used to knowledgeably determine when to commit to action without the need for the cost and possible schedule delays associate with doing a site-specific risk assessment.

Methodology for Conducting Screening Level Risk Assessments

In its simplest form, a screening level assessment is performed by simply comparing a measured concentration of a substance in soil, sediment, water, or air to a risk-based standard. These risk-based standards generally apply a high degree of conservatism in their derivation to ensure that they apply to a wide range of potential applications, and to serve as a low-cost starting point in assessing risk. The EPA and many states maintain web sites that provide the screening-level standards (see Appendix A). Generally, if you look for the footnotes or guidance documents that are integral to or supporting the tables of standards or criteria, the assumptions used to establish the standards can be identified.

It is generally a good idea to become familiar with these assumptions and consider their relevance to your project site. Whenever you see a summary table that uses screening level data but does not have footnotes or other explanations of the basis of the standards, you might anticipate that it was made by someone who is prone to the types of errors that are presented in this course.

Most people generally consider modest modifications to the assumptions supporting a published standard and subsequent comparison to a concentration in the environment to still be consistent with the scope of a screening level risk assessment. At some point in this process of applying more modifications, it becomes necessary to assess and present risk in the more thorough and rigorous format of a site-specific risk assessment. Methodologies for conducting site-specific risk assessment are beyond the intended scope of this course, but can be investigated at the website of the EPA.

Common Errors in Hazard Assessment

This part of the course focuses on what you need to know about the scientific studies that support the development of a health-based, screening level standard. Making overly broad or under-informed judgments about the types of adverse impacts and levels of certainty that a screening level value applies can lead to misapplication of the results. Estimates of risk may therefore be over or under determined and opportunities to revise the screening level values to more accurately reflect exposure conditions and applications may be missed.

Understanding the Exposure Assumptions

There is a tendency to want to apply the first standard presented or uncovered, which is generally a value provided in some form of guidance by a regulatory agency. This can be quite dangerous, however. Don’t use or necessarily accept as unchangeable the first number you see. Guidance values are just that, guidance, not regulation. Even where standards are set in regulation, such as water quality criteria in most states, there are provisions in regulation that allow for site specific

adjustments to be made. Often times these adjustments can be made while keeping within the overall level of complexity involved in risk screening assessment. There are several broad categories of standards that should be recognized and evaluated separately to consider where such adjustments are necessary and appropriate.

Duration of Exposure

Toxicity is dependent upon the amount of chemical or substance that one is exposed to over a given period of time. Generally speaking, an individual (meaning a person or an organism) can withstand relatively high concentrations for a short period of time, but lower concentrations may cause adverse effects when exposed over a longer period of time. There are variations of what constitutes a shorter or longer period of exposure depending on the situation; however, three general categories are g

Acute:

Definitions vary from ir gs and substances to days or weeks for humar ent.

Sub-chronic:

This category is less frequ available to support these assessments. Duratic 89) defines sub-chronic exposure as follow

> "An estimate (with e or greater) of a daily exposure leve populations, that is likely to be without ortion of a lifetime (as a Superf "

Chronic:

Definitions of chronic address daily levels of exposure over many years. EPA (1989) defines chronic exposure as follows:

> "An estimate (with uncertainty spanning perhaps an order of magnitude or greater) of a daily exposure level for the human population, including sensitive subpopulations, that is likely to be without an appreciable risk of deleterious effects during a lifetime. Chronic RfDs (reference doses) are specifically developed to be protective for long-term exposure to a compound (as a Superfund program guideline, seven years to lifetime)."

Care should be taken to ensure that standards are obtained to separately assess different durations of exposure.

Type of Toxic Effect and Target Levels of Risk Protection

When assessing risk for chronic exposures, assessments often distinguish between carcinogenic and non-carcinogenic substances. The prevailing theory of toxicity for carcinogenic chemicals