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Revision Memo

12/01 This is a new Design Practice. As more information and field experience become available, this document will be updated.

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SCOPE

This Design Practice provides guidance for the effective use of human health risk assessment as a valuable decision-making tool that should be an integral part of developing and supporting risk management alternatives for site remediation projects. The human health risk assessment process is briefly discussed along with how risk assessment methods can be used on site remediation projects. In addition, guiding principles for conducting and reviewing risk assessments are provided.

REFERENCES

DESIGN PRACTICE

DP XX-B Guidelines and Considerations for Site Remediation

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DEFINITIONS

Absorption - The movement of a chemical into the blood stream after its entrance into the body through the skin, lungs, or gastrointestinal tract.

Acute - Related to a single large exposure over a single or short period of time.

Carcinogen - A chemical that causes cancer in a living organism.

Central Tendency - The mean (average) or the median (midpoint) of a range of relevant risk estimates for a particular situation, exposure or chemical hazard.

Chronic - Repeated exposure to a chemical over a long period of time.

Dermal - Related to the skin.

Distribution - Movement of a substance from site of entry to other parts of the body.

Dose - A measure of exposure usually expressed as mass of chemical per unit of body weight.

Dose-response - A relationship between the dose administered to a group of organisms and the magnitude or incidence of the biological effect (response).

Effect - The physiological response caused by exposure to a chemical.

Epidemiology - The study of the distribution and causes of diseases and injuries in human populations.

Excretion - Removal of a substance or its metabolites from the body in urine, feces, or expired air.

Exposure - Receiving a dose of a substance; contact with a chemical substance.

Extrapolation - Making inferences about the unknown by projecting or extending known information.

Hazard - A source of possible damage or injury. For chemicals, the inherent adverse effect that a chemical poses.

Ingestion - Intake of a substance through the mouth.

Inhalation - Intake of a substance through the lungs.

Preliminary Remediation Goals (PRGs)- PRGs are conservative chemical concentrations in specific media (i.e., soil, air) used by risk managers for screening purposes.

Qualitative - Description of an occurrence or value in non-numeric terms.

Quantitative - Describing an amount or value in numeric terms.

Response - The reaction of the body to a chemical substance.

Risk - The probability of a specific outcome, generally adverse, given a particular set of conditions.

Risk Assessment - The determination of the potential toxic effects due to chemical exposure in a particular situation. It involves use of both a toxicity assessment and an exposure assessment.

Risk Management - The process of analyzing, selecting, implementing, and evaluation actions to reduce risk.

Subchronic - Occurring after a limited period of time, generally about one-tenth of the lifetime of the exposed subjects.

Systemic - Within the body; that is, not localized at the point of contact. Thus, for example, skin irritation caused by contact with a chemical is not a systemic effect, but liver damage due to absorption of the chemical through the skin is.

Threshold - The level exposure above which adverse health effect is thought to occur, and below which no adverse effect is thought to occur.

Toxicity - The adverse effects of a chemical on a living organism.

Toxicology - The study of the adverse effects of chemicals on living organisms.

Uncertainty Factor - Factor used to provide a margin of safety when extrapolating from animal testing results to humans.

Variability - A population's natural heterogeneity or diversity, particularly that which contributes to differences in exposure levels or in susceptibility to the effects of chemical exposures.

INTRODUCTION

Risk assessment is a valuable decision-making tool for an integrated site remediation strategy (**Figure 1**). As part of site remediation projects, risk assessment can be used in many capacities and at several levels, depending on site-specific requirements, site complexities, risk management objectives and regulatory needs. Although there has been a traditional separation between risk assessment and risk management from a regulatory perspective, it is becoming increasingly common to integrate risk assessment and risk management to ensure the most cost-effective approach to reducing the potential risks at contaminated sites. From a project manager's standpoint, it is important to understand how the risk assessment is integrated into the risk management process so that ExxonMobil projects are completed in a cost-effective manner using sound science consistent with laws, regulations, policies and guidance of environmental agencies. To support the use of risk assessment, several guiding principles are defined.

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INTRODUCTION (Cont)

Risk assessment can effectively support site remediation activities in several ways, such as:

- Identifying areas that require remedial action;
- Prioritizing areas requiring remedial action;
- Supporting no action alternatives;
- Developing cleanup goals;
- Selecting risk management alternatives; and
- Evaluating remedial technologies.

Based on the site-specific conditions and the goals and objectives of the remedial strategy, the risk assessment can be conducted at several levels. The risk assessment should be conducted with open dialogue between the risk assessors, risk managers and regulators. The interactions between these groups should occur early in the process to ensure that all parties concur with the goals and objectives of the risk assessment and throughout the process to ensure that the risk assessment supports the decision-making process as it changes based on new information.

Typically, the risk assessment is conducted using a tiered approach where the initial tier requires the least amount of site-specific data but which relies strongly on conservative assumptions that may substantially overestimate the potential for significant risk to human health. Based on the results of the initial evaluation (Tier 1), either no significant risk is predicted or additional evaluation is warranted. By integrating the risk assessment with risk management decision-making, the additional evaluation can include additional site investigation, more detailed risk assessment (Tier 2 or 3) or implementation of a risk management alternative.

The three general levels of a risk assessment are:

- **Tier 1 - Screening Evaluation.** A screening-level evaluation can be conducted using limited data sets and generic screening criteria such as Risk-Based Concentrations (RBCs) or chemical-specific Preliminary Remediation Goals (PRGs). For a screening level evaluation, chemical concentrations, typically average and maximum concentrations, for each constituent in each environmental medium are compared to the screening criteria. If all concentrations are lower than the RBCs or PRGs, no significant risk to human health is predicted and no additional remedial action is required (unless other, non-risk-based regulatory requirements are drivers for remedial action). For sites that have constituent concentrations that exceed the screening criteria, a decision is required on the most appropriate and cost-effective approach for further evaluation of those constituents of potential concern or for implementing a remedial alternative that will minimize any potential risks to human health.
- **Tier 2 - Limited Quantitative Risk Evaluation.** For those constituents with concentrations exceeding screening levels, additional site data can be collected to support a more detailed risk assessment. These data may include additional concentration data for specific environmental media, limited exposure assessment to consider more realistic (e.g., less conservative) exposure pathways and doses (e.g., considerations of current and likely future land uses), limited modeling to better estimate current and future exposure point concentrations, or a combination of these data needs. The results from the Tier 2 evaluation can be used to support no further action, to develop cleanup goals, to focus additional data collection and detailed risk assessment or to support risk management alternatives that will minimize the potential for significant risks to human health.
- **Tier 3 - Detailed Quantitative Risk Assessment.** Within the scope of Tier 3, the level of detail used to complete the risk assessment should be commensurate with the complexities of the site, as well as economic and regulatory considerations. The quantitative risk assessment can include sophisticated statistical data analysis, complex multi-compartment fate and transport modeling, rigorous exposure modeling and assessment and state-of-the-science toxicological evaluation of chemicals of concern. In addition, Tier 3 can consider probabilistic risk assessment techniques such as Monte Carlo analysis. The cost of completing a detailed risk assessment can vary substantially. In addition, the level of public and regulatory scrutiny increases, increasing the need for clarity and transparency so that the technically sound and scientifically-defensible inputs and results are not readily disputed.

RISK ASSESSMENT PROCESS

A risk assessment is composed of four distinct steps (**Figure 2**). These steps are:

- Hazard Identification/Data collection and evaluation
- Exposure assessment
- Toxicity assessment
- Risk characterization

Each of these steps is discussed in more detail below.