Association of State and Territorial
ASTSWMO
Solid Waste Management Officials

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FACT SHEET
Overview of the Human Health Risk Assessment Process in Environmental Cleanup Programs at Federal Facilities

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Due to site-specific issues and contaminants at each facility, ASTSWMO does not endorse conducting these activities at all federal facilities.

This Fact Sheet has been developed as a resource for State and Territorial federal facility risk managers and project managers who communicate risk information to the public. It is written to provide information that can be used to help increase an understanding of risk assessment and key factors helpful in communicating risk. This Fact Sheet is based on information gathered by the Association of State and Territorial Solid Waste Management Officials (ASTSWMO) Community Involvement Focus Group.

What is Risk Assessment?

A risk assessment is a mathematical model used to evaluate the relationship between potential contaminants, the toxicity or potential health effects related to the contaminants, how people or animals may come into contact with these contaminants and what effect these contaminants could have on those who come in contact with them.

At federal facilities, remediation of contaminated sites is mandated by Section 120 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). Many States and Territories utilize CERCLA to achieve this statutory mandate, while others rely on the Resource Conservation and Recovery Act (RCRA), or other State-specific authorities. The risk assessment is one part in a process where site specific data is evaluated in the context of current and foreseeable site use. Both human health and ecological risk assessments are conducted to provide risk managers with information to assist with remedial decisions. In addition, many States conduct their own risk assessments and develop their own standards, which may be more conservative than federal levels.

A human health risk assessment studies health effects from exposure to a contaminant to help define:

- Is there a risk?
- Who is at risk?
- How great is the risk?
- What is the source of the risk?
- What is present at a site?
- What must be cleaned up?
- What can be left on site?
- What is the future land use?
- What must be done in the short-term?
- What must be done in the long-term?
- What is the additional incremental risk added to our lives?
- How extensive is the contamination now?
- Could the situation deteriorate in the future?

Defining Risk Assessment Terms

The goal of risk assessment is to support the decision making process and to help answer the question, "How clean is clean?" for a particular site. Project managers and risk assessors gather site specific data, identify contaminants of potential concern and levels detected, and then proceed to calculate risks posed by a chemical based on established standards. Sources of information used in risk assessment include:

- Integrated Risk Information Systems (IRIS).
- EPA's Provisional Peer Reviewed Toxicity Values.
- Other toxicity values.

In the absence of standardized cleanup levels, formulas have been developed to help professionals determine acceptable levels of risk at a site commensurate with the property's intended use.

The results of a risk assessment are presented as probabilities. The results reflect the chance that a person or organism (e.g. receptor) could develop a health effect based on contact with the contaminants identified at the site under investigation. Results are discussed in terms of the likelihood of developing a health effect above and beyond the chance from everyday life.

Did you know?

Cancer and adverse health effects happen in life, independent of chemical contamination found at a cleanup site. The American Cancer Society (2008) reports the lifetime probability of developing some form of cancer is 1 in 2, or 44.94 percent for males and 1 in 3, or 37.52 percent for females.

http://www.cancer.org/downloads/PRO/08_Lifetime%20Probability_2002-2004.pdf

Risk assessment uses terminology to discuss the various parts of the model, the process and the results. A definition for these terms and others can be found in U.S. EPA's Risk Assessment Guidance for Superfund (Parts A-E) (http://www.epa.gov/oswer/riskassessment/risk_superfund.htm). In presenting risk assessment information, it is important to explain the following terms:

- **Contaminants of Potential Concern (COPCs)**– contaminants or chemicals that have been identified as chemicals that could cause health effects to receptors, depending on the amount of the chemical present, the toxicity of the chemical, and how the chemical is contacted.
- **Receptors** – generic name for a collective group of people, plants, or animals that are evaluated in the risk assessment model. Receptors represent the people, plants or animals that can contact the contamination.
- **Receptor assumptions** – the actual input values that are used in the risk assessment model to represent the different ways that receptors can contact contamination.
- **Slope Factors** – a number used in the risk assessment model to reflect the toxicity of a cancer causing contaminant
- **Reference dose** – a number used in the risk assessment model to reflect the level or threshold associated with contaminant and a non-cancer health effect.
- **Risk characterization** – refers to the results of a risk assessment model. Results are often discussed in terms of cancer risks and non-cancer risks. Cancer risks are discussed in terms of the additional chance of developing cancer above and beyond the chance of developing cancer from just living in everyday life. Non-cancer risks refer to the chance of developing some adverse health effect, such as a rash or something other than developing cancer.

Steps in the Risk Assessment

In preparing to conduct a risk assessment, a Conceptual Site Model (CSM) is helpful in identifying the source, pathways and receptors. It is important to explain to the community the CSM and what each of the steps of the risk assessment involves, when developing a strategy to present results. There are four main steps in the risk assessment:

1. Hazard Identification.
2. Exposure Assessment.
3. Toxicity Assessment.
4. Risk Characterization.

1. Hazard Indentification

The Hazard Identification step is the process of collecting data by taking samples of environment media such as soil, water, and air, and comparing the levels to various effect thresholds and background levels, if available. Hazard identification will generate a list of COPCs, which help managers focus further investigative efforts on specific contaminants. For example, iron and other essential nutrients are often present at a site, but not at levels that exceed the recommended daily allowance for humans. Therefore, it is not in the best interest of the community to use limited funds to investigate some COPCs further. In contrast, it is wise to spend cleanup funds investigating those contaminants that are truly problematic at a given site.

2. The Exposure Assessment

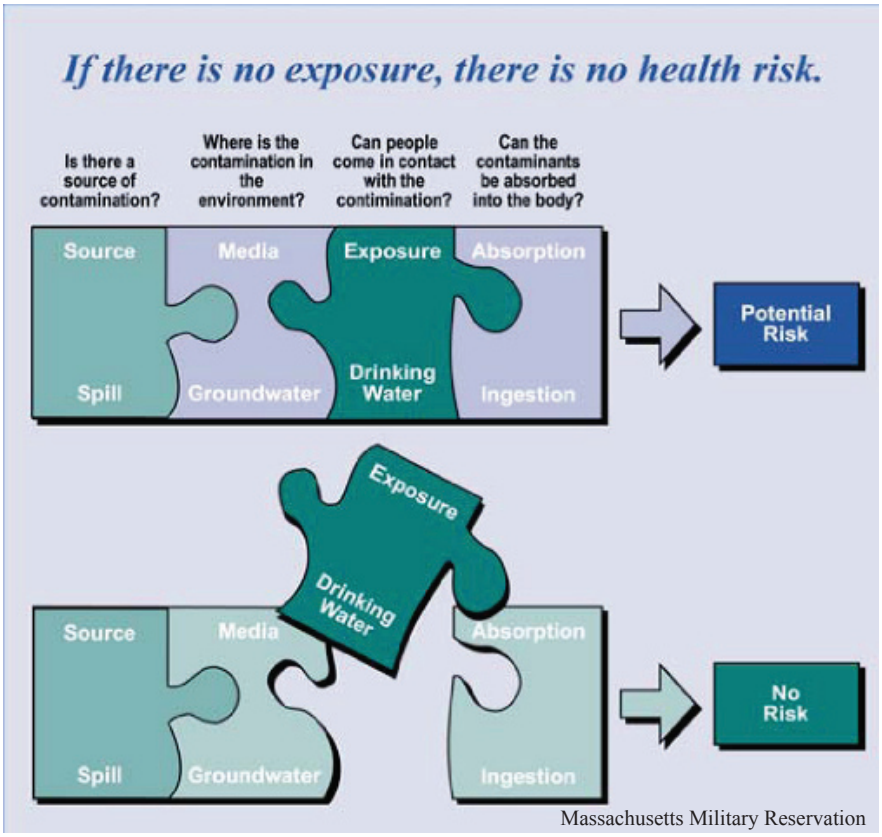
The Exposure Assessment step is the process of identifying how people or organisms may come in contact with these contaminants and how much and how long the exposure is/was. It is important to explain to the public that they must come in contact with the contaminants in order to be exposed.

The key message is: No Exposure = No Risk.

The presence of contaminants alone does not constitute an exposure. The amount of risk depends on the duration of the exposure, the toxicity of the contaminant, the concentration detected, and various personal and site specific factors. Background concentrations are analyzed also. There must be a pathway for the contaminant to travel from the source to the receptor.

Exposure pathways include:

- Breathing (inhalation).
- Eating/Drinking (ingestion).
- Touching (dermal contact).



Massachusetts Military Reservation

3. Toxicity Assessment

The Toxicity Assessment step involves determining what health-related problems the contaminants identified can produce and whether the contaminants cause cancer or other non-cancer effect, such as a rash. It is important to explain to the public the uncertainties associated with toxicity information because most of this information is based on animal studies and the effects of those studies are extrapolated to effects in humans. There is very little research actually done on humans, which is why uncertainties with the risk assessment should not be overlooked but rather discussed with the public. Due to these uncertainties, the risk assessment model has many levels of conservatism built in to ensure the results are not underestimated.

Some factors used to help determine the type and severity of health effects include:

- Characteristics and toxicity of a chemical.
- Age of receptor.
- Sex.
- Medical history.
- Genetics.
- Life style.
- Sensitive receptor group.

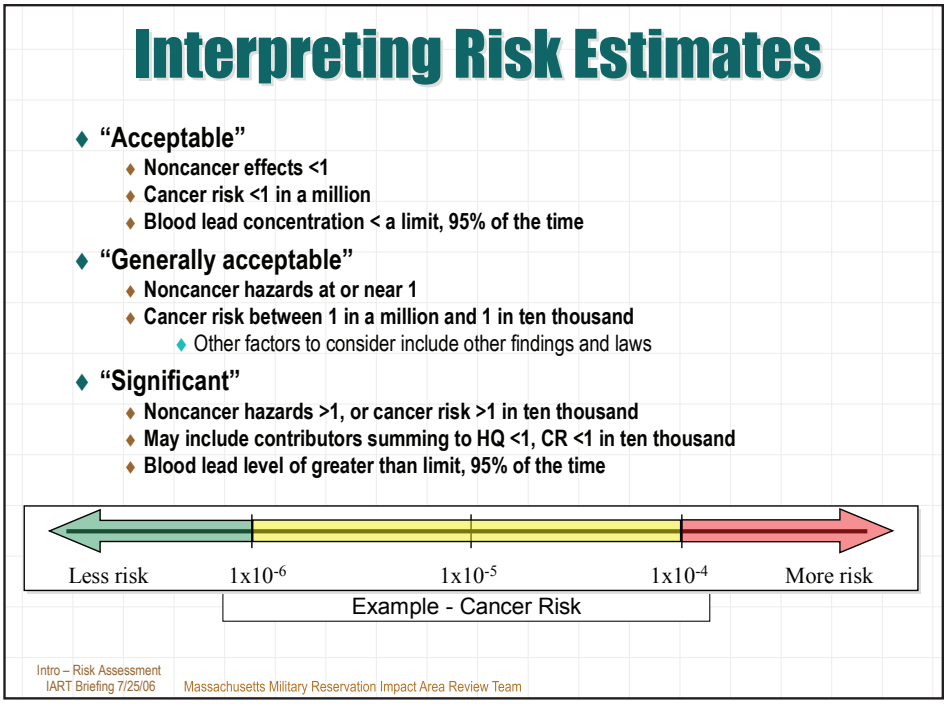
4. Risk Characterization

The Risk Characterization step is the process of putting all four steps together to identify which COPCs are actually problematic and need to be addressed by taking some type of remedial action. The term for the group of contaminants analyzed further is Contaminants of Concern, or COCs.

Results of Risk Assessment

The results of the risk assessment are used by risk managers to help make decisions about site cleanups and determine what course of action is appropriate. Some of the remedial action options include: removal of contamination, treatment of contamination, or possibly containment and monitoring. Other options may include No Further Action, long-term monitoring, or the placement of institutional or engineering controls.

Information gathered in each of the four steps attempt to interpret risk estimates, based on probabilities. The risk assessment does not determine who will get cancer or a rash nor does it explain cancers or health effects that one may already have.



Risk Assessment versus Risk Management

Risk assessment and risk management are different. Risk assessment is the process of identifying contaminants that may pose a problem based on their toxic effects to health and the environment. The results of the risk assessment are used by risk managers to help make remedial decisions on a site. Risk management is the process of how to best manage the problems posed by COCs as potentially causing an adverse effect to human health and environmental organisms. In addition, risk management considers other factors such as background levels, costs and the CERCLA nine criteria.

It is important to keep risk assessment separate from risk management even though it may seem these overlap. Risk management has flexibility to use other tools and information, in addition to the risk assessment, to make remedial decisions and determine the appropriate course of action at a site. Whereas, risk assessment is just one tool in the tool box used to investigate a site.

Conclusion

There are many tools used to investigate a site to determine the appropriate course of action. Risk assessment is used to help risk managers with decision making, but also can be used in other ways. For instance, the risk assessment model can be used to establish cleanup standards based on site specific information. The risk assessment model can be used after a cleanup or remedial action is taken to determine if there are any residual risks remaining at a site. In using risk assessment as a tool, it is important to note that risk information addresses a specific point in time. Cleanup may be an iterative process and risk assumptions must be evaluated when site use, exposure pathways or regulatory standards change. The risk assessment model, as discussed in this paper, is only one way that this tool can be used during an environmental investigation. All information (e.g. sampling data, historical information, risk assessment models, etc.) generated during a site investigation is used by risk managers to make remedial decisions on a site.

For More Information

Contact the Federal Facility Community Involvement Focus Group on the Web at
http://astswmo.org/programs_federalfacilities.htm

"The mission of the Community Involvement Focus Group is to identify issues and to encourage improved partnerships between States, Communities and Federal agencies."

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