

Risk-Based Decision Making for Site Cleanup

The Oklahoma Department of Environmental Quality (DEQ) has adopted a risk based decision making process to provide a framework for determining cleanup requirements at contaminated sites. This process ensures that DEQ's cleanup decisions are protective of human health and the environment.

Risk based decision making is a tool that ensures contaminated properties are adequately addressed. DEQ uses risk based decision making to oversee remediation of contaminated properties and ensure that cleanups are protective, all Applicable or Relevant and Appropriate Requirements (ARARs) are evaluated, and cleanup is accomplished in a practical and effective manner. Risk based decision making allows properties to be returned to productive reuse.

DEQ uses risk based decision making for cleanups conducted under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), Resource Conservation and Recovery Act (RCRA), Oklahoma Voluntary Clean-Up Program (VCP), and the Oklahoma Brownfields Voluntary Redevelopment Act. DEQ is committed to the application of consistent decision making to determine the level of cleanup that needs to occur at a site.

What is Risk Based Decision Making?

Risk based decision making involves evaluating actual and potential risks posed by a contaminated site in order to make responsible and practical decisions to mitigate those risks. The process includes identifying hazards, assessing exposure, assessing toxicity, characterizing the risk, and making an informed decision. Risk based decision making cannot be fully utilized without adequate site characterization. Adequate site characterization includes sampling an adequate list of analytes to effectively determine

the nature and extent of contamination. The DEQ typically requires minimum analysis for volatile organic compounds (VOCs), semi-volatile organic compounds (SVOCs), metals and total petroleum hydrocarbons (TPH) to adequately characterize a contaminated site and determine the chemicals of concern. Additional analyses may be required if the history of the site suggests other chemicals may be present.

Risk based decision making is not appropriate when immediate risks are recognized (i.e spills) or waste is present. Immediate risks and observable waste should be addressed by prompt actions that protect human health and the environment.

General Requirements for Risk Decisions

Information about the property is needed to make informed decisions about the environmental risks to the community and future occupants. In general, the following must be evaluated:

I. Data Quality Objectives (DQOs):

- a. DQOs are quantitative or qualitative statements developed in the planning stage to define the goals of data collection. DQOs guide the project and ensure the data collected is usable, sufficient, and exhibits the quality necessary to make cleanup decisions. DQOs are established in the Quality Assurance Project Plan or Work Plan for the site.
- b. The DEQ requires that data be suitable to perform an evaluation of risk. DEQ will consider, but will not always accept, data that is collected outside its oversight. If data is more than two years old, further sampling and analysis may be required.

2. Identify All Contaminants of Concern (COC):

- a. COCs are determined from the data generated during the site characterization.
- b. Chemicals identified on the property above the analytical method's detection limit should be compared to ecological and human health screening levels (See page 6),
- c. Initial COCs are the contaminants on site above their respective screening level.

3. Compile a Site Conceptual Model Including:

- a. Maps showing the geographic and physical characteristics of the site, adjacent property uses, creeks, ponds, and other ecological habitat,
- b. Delineation of contamination (lateral and vertical extent),
- c. The hydrogeology of the site,
- d. Potential current and future receptors, exposure pathways, and exposure scenarios – both human and ecological receptors must be considered,
- e. The future use of the affected property (residential, commercial or industrial)
- f. Current and future use of ground water and surface water both on and off site.

4. Applicable or Relevant and Appropriate Requirements (ARARs)

- a. Identify applicable state and federal laws and regulations,
- b. Identify and consider relevant and appropriate state and federal standards, policies and guidance.

5. Use of Institutional and Engineering Controls

- a. Unless the cleanup is performed to achieve “unrestricted residential use,” engineering controls (ECs) and institutional controls (ICs) must be in place to protect the cleanup and ensure that land use does not change over time.
- b. Controlling the site through the use of ICs and ECs can be proposed as a part of remediation; however, evidence of their long term effectiveness or a plan to monitor their effectiveness may be required.
- c. When cleanup of contaminated property to

risk based levels is performed under a permit, order, or remediation plan approved by the DEQ, the DEQ is required to file a recordable notice of remediation/deed notice in the land records of the county in which the property is located (27A O.S. § 2-7-123(C)). Land use restrictions run with the land, must be considered as permanent, and will limit the future use of the property. If the property is cleaned up to “unrestricted residential use,” a deed notice is not required.

6. Consideration of the Community's Needs and Preferences

- a. Affected property owners and community members should be involved in the risk based decision making process. Public comment, advice, and concerns should be considered in the planning and implementation of remediation goals.
- b. Community development patterns and pressures should be contemplated in the risk evaluation.
- c. Some DEQ programs require specific public comment periods.

7. Risk Management

- a. Risk evaluation is used to establish environmental risks at a site and provide cleanup goals that are protective of human health and the environment.
- b. Risk management decisions will also consider factors such as practicality, avoidance or creation of additional risk, ICs and ARARs.

DEQ's Risk Evaluation Process

Participants in consultation with DEQ must determine “how clean is clean?” The decision is driven by what the future use of the property will be, whether contamination is migrating off site, and how well the participant can control the use of the property in the future. Calculating cleanup levels is only a portion of managing the risk sites pose to human health and the environment.

Adequate Site Characterization - Except for removal actions in immediate response to spills or other immediate dangers, site characterization

must be performed prior to remediation. Immediate risk(s) can sometimes be evaluated with very limited information; however, the nature and extent of contamination must be known before all aspects of long term risk can be fully evaluated.

Existing site data should be reviewed by participants and DEQ to determine what additional information is necessary. All sampling and analytical work must be performed using a DEQ-approved Site Characterization Work Plan or a Sampling and Analysis Plan (SAP) and Quality Assurance Project Plan (QAPP) (plan requirements are program dependent). Participants should determine whether they will clean up to screening levels, calculate conservative default cleanup levels, or conduct a formal risk assessment of the site. The decision to conduct a formal risk assessment will affect the sampling design, so it is important to determine the risk calculation mechanism early in the process. DEQ will determine when the site has been adequately characterized.

Determining Risk Based Cleanup Levels - In consultation with DEQ, participants may choose to clean up their properties to EPA Regional screening levels (suitable for the proposed use of the property); site specific, conservative cleanup levels calculated using default inputs; or site specific cleanup levels determined through risk assessment. This tiered approach provides numerical cleanup goals for the site; however, non-numerical criteria such as rules and statutes will also be considered in the decision making process. Risk evaluations must consider all potential receptors and exposure pathways in the risk analysis.

Screening Levels - Human health and ecological screening levels were not developed to be site cleanup levels; however, cleanup to screening levels is allowable, is generally accepted to be protective of human health and the environment, and can shorten the project's planning and review time line. DEQ will generally use the most conservative level for screening purposes. If a chemical does not have a published screening level, a site specific screening level may be established and/or approved by the DEQ when adequate information is available. Comparison of site data to screening levels can provide a basis for

a determination that no cleanup action is warranted if site contaminants are below screening levels.

Calculated Default Cleanup Levels - DEQ allows site specific cleanup levels to be calculated using EPA's Risk Assessment Guidance for Superfund (RAGS) default exposure inputs and site specific data. This provides conservative cleanup goals and can be completed quickly. DEQ can provide assistance with this process. These calculated cleanup levels are conservative and protective.

Written approval from DEQ is required throughout the risk assessment process, including:

- Any deviation from RAGS
- The Risk Assessment Work Plan
- Any deviation from DEQ or EPA default input values
- Toxicity factors
- Exposure scenarios

Risk Assessment - A formal risk assessment can be an expensive, lengthy and detailed process requiring an extensive amount of information. All data and information used for the assessment must meet high standards of quality assurance and control and must be appropriate to the parameters being measured. DEQ requires that the methodologies and organization described in EPA's Risk Assessment Guidance for Superfund (RAGS) <http://www.epa.gov/oswer/riskassessment/ragsa/index.htm> be followed.

Prior to developing cleanup levels through a formal risk assessment, consultation with the DEQ's site project manager and risk assessment team and submittal of a risk assessment work plan is required. All potential exposure pathways must be examined. If an exposure pathway is deemed incomplete, specific evidence must be provided to justify that conclusion and all characteristics of the contaminant must be examined.

Preliminary cleanup levels should be developed early in the project and be used to guide site activities. Site specific cleanup levels should be calculated for protection of ground water or surface water resources as well as protection of receptors from

ingestion, inhalation, and dermal exposure. The preliminary levels can be refined as more information becomes available.

Numerous exposure scenarios are included in risk assessments. The exposure scenario selected for the development of the remedial goals must be fully justified and approved by DEQ in writing. Both cancer and non-cancer endpoints must be evaluated, with the most conservative level determining the cleanup goal. By policy, DEQ uses an excess cancer risk level of 10^{-5} , unless this number exceeds the appropriate non-cancer endpoint, is not protective of ground water, or leaves contamination in place that is characteristic or listed hazardous waste. The 10^{-5} level is intended for individual constituents and does not consider the additive effects of various chemicals. Sites involving multiple contaminants must consider the additive effects of those contaminants. DEQ will consider site specific information in determining risk and under some circumstances may require a calculation of a lower (10^{-6}) excess cancer risks. For example, off-site risk may be required to be lower than on-site risk.

Please note that screening levels or cleanup levels apply to contaminated media such as soil or water. If an obvious waste or waste source is found, or is known to exist from historical records, this source and waste material should be removed, treated, or mitigated.

If the risk assessment is based on ground water modeling or if ground water contamination remains after the cleanup, provisions must be made for long-term ground and/or surface water monitoring to demonstrate that the models are accurate and to verify that contamination is still defined and controlled. Long-term groundwater monitoring may also be required if waste or a significant source of contamination is left in place but groundwater contamination has not yet been detected. Such monitoring is expected to continue until the ground water remedial goals have been reached. Financial assurance may be required to ensure that monitoring and maintenance of the site is performed.

Acceptable Risk Assessment Input Values

DEQ, by policy, uses the following input values for risk assessments performed under its authority. Any deviation from these values must be discussed and approved, in writing, by DEQ.

Table 1: DEQ State Specific Risk Calculation Input Parameters*

Scenario	Input	Value
Construction worker	Exposure Frequency	90 days/year
Construction worker	Exposure Duration	1 year
Construction worker	Soil Ingestion	200 mg/day
Outdoor worker	Exposure Frequency	240 days/year
Outdoor worker	Exposure Duration	25 years
Outdoor worker	Soil Ingestion	100 mg/day
Adult subsistence farmer	Exposure Frequency	350 days/year
Adult subsistence fisherman	Exposure Frequency	Site specific
Adult subsistence fisherman	Fish Tissue Ingestion	Site specific
Recreational user	Exposure Frequency	Site specific
Adolescent trespasser	Exposure Frequency	52 days/year
Adolescent trespasser	Exposure Duration	6 years
Adolescent trespasser	Body Weight	52 kg

* Note that all EPA standard default input parameters apply in addition to Oklahoma specific input parameters. Additionally, any deviation from EPA or State input parameters will require calculation methodologies and written approval from DEQ.

Risk assessments provide useful information in decision making, but a risk assessment should not be considered to supersede or negate ARARs. The risk assessment report should be a stand-alone document and serve as a risk communication tool to be used by a community for information and as the basis for its involvement in the cleanup decision making process. Any statement regarding risks must be supported by complete calculations, documentation, and references.

Any risk assessment submitted and approved by DEQ remains valid for five years after the approval date. If the cleanup does not occur within five years, the DEQ will require revised risk assessment calculations and a review of remedial goals. If new guidance is introduced, reference dose(s) or

slope factor(s) change, or other significant input parameters change within the five year window, DEQ will require a revised risk assessment. The use of a risk based approach to site cleanup may result in some contamination being left on or beneath a site. Any remediation of a site to less than “unrestricted residential use” will require the placement of a deed notice in the county land records (27A O.S. 2-7-123). Land use restrictions run with the land, must be considered as permanent, and will limit the future use of the property. Long-term maintenance of engineering controls, such as fencing or disposal cell caps, must be part of the cleanup plan. Long-term, periodic monitoring of ground water and surface water may also be required.

Helpful Resources

The Integrated Risk Information System (IRIS) is utilized to obtain toxicity information regarding chemicals of potential concern. The DEQ Risk Team should be consulted when chemicals do not have a published toxicity factor <http://www.epa.gov/IRIS/>.

Chemicals of potential concern for all routes of exposure for human health and ecological risk are identified by comparing the contaminants in all media (ground water, surface water, soil, soil vapor, indoor air (as appropriate), sediment, etc.) to, at a minimum, the following:

1. For Human Health; soils, surface water, indoor air, and ground water protection:

- a. Background levels specific to the locale, which should consist of actual sample data or published, peer reviewed levels.
- b. The EPA Regional Screening Levels (RSL) - http://www.epa.gov/reg3hwmd/risk/human/rb-concentration_table/Generic_Tables/index.htm.

2. For Ecological Risk; all media

- a. The EPA Ecological Soils Screening Level (ECO SSLs) guidance document - <http://www.epa.gov/ecotox/ecossl/index.html>.
- b. The Oak Ridge National Laboratory (ORNL) toxicity benchmarks - <http://www.ornl.gov/sci/ees/bsd/>.
- c. The National Oceanographic & Atmospheric Administration (NOAA) Screening Quick Reference Tables (SQuiRTs) - <http://response.restoration.noaa.gov/cpr/sediment/squirt/squirt.html>.

3. Other Useful References

- a. EPA's website for risk related issues - <http://www.epa.gov/risk/>.
- b. ATSDR Toxic Substances Portal - <http://www.atsdr.cdc.gov/toxfaqs/index.asp>.
- c. Interstate Technology & Regulatory Council (ITRC), Risk Assessment Resources - <http://www.itrcweb.org/guidancedocument.asp?TID=44>.
- d. US Fish & Wildlife Service – Regional/State Threatened & Endangered Species Information - <http://www.fws.gov/southwest/>.
- e. Cleanuplevels.com provides numerous links to EPA's regional, ecological, medium-specific screening levels, soil screening guidance, RAGS, Federal Drinking Water Standards, state levels, international guidance/values, etc. - <http://cleanuplevels.com/>.
- f. The Oklahoma Water Resources Board promulgates Water Quality Standards for the state - http://www.owrb.ok.gov/util/rules/pdf_rul/RulesCurrent2011/Ch45-Current2011.pdf.

DEQ's statutory authority includes but is not limited to 27A O.S. § 2-6-105(A). "It shall be unlawful for any person to cause pollution of any waters of the state or to place or cause to be placed any wastes in a location where they are likely to cause pollution of any air, land or waters of the state. Any such action is hereby declared to be a public nuisance." Also 27A O.S. § 2-6-105(B) "If the Executive Director finds that any of the air, land or waters of the state have been, or are being, polluted, the Executive Director shall make an order requiring such pollution to cease within a reasonable time, or requiring such manner of treatment or of disposition of the sewage or other polluting material as may in his judgment be necessary to prevent further pollution. It shall be the duty of the person to whom such order is directed to fully comply with the order of the Executive Director."

Pros and Cons of the Risk Based Decision Tiers

Although a risk assessment can be performed on any site, not all sites need a formal risk assessment. DEQ allows a tiered approach for developing cleanup levels

for a site. Participants should consider their goals for the site, remediation costs, and the cost of Long Term Stewardship when determining which tier to follow. Each tier has advantages and disadvantages; some are presented below.

Table 2: Cleanup to screening levels

Pros	Cons
Published values provide easily understandable cleanup goals	Does not take into consideration site specific conditions
Developing work plans and cleanup goals are less time intensive	May not accurately evaluate all Chemicals of Concern
Published values allow for a defensible cleanup	Contaminants may not have a published screening level or screening level may be so low that successful remediation may be difficult
Remedial action is straightforward	Remediation may be more expensive
Inexpensive long term maintenance	
Screening levels would be safe at any site	
Allows for early cost estimate of cleanup	

Table 3: Development of site-specific cleanup goals using default exposure assumptions

Pros	Cons
Cleanup levels are generally higher than screening levels	Cleanup levels may not be as protective as screening levels
Remediation may be less expensive than cleaning to screening levels	Long term maintenance may be expensive
	Quantitatively less powerful than formal risk assessment

Table 4: Development of site specific cleanup levels by performing formal risk assessment

Pros	Cons
Most effective means of fully understanding the environmental risks	Time intensive
Remediation may be less expensive	Quantitative methods and intensive jargon may be difficult to convey to the public
Allows for the development of work plans to be focused on specific rather than general risks	Expensive
	Long term maintenance may be more expensive
	May be less understandable and therefore less acceptable to the public

***DEQ will review and may update this document annually.*

*Care should be taken to ensure the most recent version is referenced during the project***



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