

Risk-Based Decision Making for Site Cleanup

Purpose

The purpose of this document is to explain the Department of Environmental Quality (DEQ) approach to risk assessment and encourage parties to work with DEQ before submitting a risk assessment. DEQ relies heavily on EPA's Risk Assessment Guidance for Superfund (RAGS), and EPA's Region 6 Corrective Action Strategy. DEQ's approach may be different than other states. It is to everyone's benefit to develop an approvable work plan before submitting a risk assessment.

Target Audience

The target audience is project managers, consultants, responsible parties and risk assessors. A general knowledge of risk assessment is presumed.

General Concepts

Risk Assessment is a tool that works in tandem with regulatory requirements to help guide protective cleanup decisions.

DEQ looks at current and possible future risk for all pathways of potential concern. Submitting a risk assessment that only looks at current risk and current use is unlikely to be approved. DEQ has an expectation that properties will be returned to a beneficial use, at least general industrial. A proposal to put a fence around a property and restrict access for decades is unlikely to be approved.

OAC 252:611-5-1(b) requires: "Any person proposing a remediation project relating to groundwater or required to undertake such a project by the DEQ is required to obtain prior approval by the DEQ of a site assessment plan and remediation plan."

Where feasible, DEQ prefers removal of source material that can release to the environment and will consider enforcement action as needed to ensure remediation of off-site contamination. DEQ expects that treatment or engineering controls will be used to address source material and that groundwater will be returned to its beneficial use whenever practicable. Institutional controls may be used when contamination is first discovered, when cleanups are ongoing and when residual contamination remains on site at a level that does not allow for unlimited use and unrestricted exposure after cleanup.

DEQ is required to consider applicable rules in its decision-making process. Risk assessments do not supersede regulatory requirements.



Risk-Based Decision Making for Site Cleanup

DEQ uses risk-based decision making for cleanups conducted in the Voluntary Cleanup Program, RCRA Program, Superfund Program, Site Cleanup Assistance Program and Brownfields Program in the Land Protection Division. DEQ is committed to the application of consistent and practical decision making to determine the level of cleanup that needs to occur at a site. To remain consistent between programs, risk decisions are based on three primary elements: risk assessment, risk management and applicable rules or regulations.

Risk Assessment

The initial risk assessment should evaluate risks present at the site prior to the discussion of any mitigating risk management practices.

Adequate site characterization is required to determine the risk at a site. Site characterization includes sampling an adequate list of analytes to effectively determine the nature and extent of contamination. DEQ typically requires 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. Note that site characterization is often iterative; for example, results may show that the extent of contamination is not delineated, and more sampling and analysis is indicated.

A conceptual site model (CSM) should be generated based on the delineation of contamination, both lateral and vertical extent, in all environmental media. The CSM should evaluate all possible exposure pathways. The CSM should consider potential current and future receptors, exposure pathways and exposure scenarios. The soil to groundwater pathway and vapor intrusion pathway should also be considered. Both human and ecological receptors should be considered. If an exposure pathway is deemed incomplete, specific evidence should be provided to justify that conclusion. The CSM should address the hydrogeology of the site, including lithology characterization, groundwater elevations and groundwater flow directions.

DEQ will generally use the most conservative level for screening purposes, typically those found in the EPA's Regional Screening Level (RSL) tables (See Appendix 1). If a chemical does not have a published screening level, a site-specific screening level may be established or approved by DEQ when adequate information is available. Site data less than screening levels can provide a basis for a determination that no cleanup action is warranted. Site data exceeding a screening level means further evaluation is needed.

Total Chromium does not have an RSL for soil, only a Maximum Contaminant Level for ground water. However, there are soil RSLs for Chromium III and Chromium VI. If Total Chromium is analyzed, results will not indicate if the more harmful Chromium VI is above or below its DEQ 10^{-5} soil screening level. If the Total Chromium level is above the 10^{-5} Chromium VI RSL, the Total Chromium level must be speciated to show what the level is for Chromium VI. If the Total Chromium level is below the 10^{-5} Chromium VI RSL, no speciation or additional analysis is needed.

Environmental data collected needs to be usable. If data is more than two years old, further sampling and analysis may be required. DEQ will consider, but will not always accept, data that is collected outside its oversight. An approved quality assurance project plan and work plan, including data quality objectives, should be obtained prior to data collection. Lab detection limits should be lower than the appropriate screening levels. All sampling and analytical work should be performed using a DEQ-approved work plan. Plan requirements are program dependent.

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. Site-specific data refers to measurable physical characteristics. These can include parameters such as soil types, fraction organic carbon in soil and meteorological data.



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

- any deviation from RAGS;
- approval of the Risk Assessment Work Plan;
- any deviation from DEQ or EPA default input values;
- selection of toxicity factors for atypical chemicals; and
- selection of exposure scenarios.

Please note that screening levels or cleanup levels apply to contaminated media such as soil or water. If an obvious waste or source material is found, or is known to exist from historical records, this source or waste material should be removed, treated or mitigated. DEQ prefers removal of hot spots. Hot spots may include, but are not limited to, source materials that are releasing to the environment, visible wastes, or levels of specific chemicals of concern exceeding thresholds set by DEQ policy. Ninety-five percent Upper Confidence Level Calculations will be considered on a site-by-site basis.

The soil-to-groundwater pathway should be considered when calculating site-specific cleanup levels. 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 groundwater, or leaves contamination in place that is characteristic or listed hazardous waste. The additive effects of all contaminants should not exceed the 10^{-5} level. For non-cancer risk, a hazard quotient of less than or equal to one must be demonstrated for individual constituents. For multiple constituents, the hazard index should not exceed one. Off-site risk may be required to be lower than on-site risk. Note that there are occasional differences in federal programs. As an example Superfund may use a different risk range.

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 needs to 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	Averaging Time	124 days**
Construction worker	Soil Ingestion	330 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
Adolescent trespasser	Exposure Frequency	52 days/year
Adolescent trespasser	Exposure Duration	6 years
Adolescent trespasser	Body Weight	52 kg
Daycares, Schools, Sensitive Populations	All inputs	Default residential

*Values are from EPA resources, including the Exposure Factors Handbook. Note that all EPA standard default input parameters apply in addition to Oklahoma specific input parameters. Any deviation from EPA or State input parameters will require calculation methodologies and written approval from DEQ.

**Averaging time assumes worker does not work weekends.

***Soil ingestion rate is 100 mg/day for purposes of modeling lead exposure. The lead model is designed to be used with a Central Tendency Exposure, as opposed to the higher Reasonable Maximum Exposure used for other chemicals.

For any areas that are currently or may be used for sensitive populations (daycares, schools and public high access areas), no deviations from the inputs for a default residential scenario should be made.

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, DEQ may require revised risk assessment calculations and a review of remedial goals. If new guidance is introduced, reference doses or slope factors change, or other significant input parameters change within the five-year window, DEQ may need a revised risk assessment.

Risk Management

Immediate risks and observable waste should be addressed by prompt actions that protect human health and the environment. A lengthy risk-based decision-making process is not appropriate when immediate risks are recognized, such as spills, or waste is present. Interim actions can be developed to address immediate risk, but final risk goals need to be developed to be protective of potential future uses of the site.

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 notice of remediation in the county land records (27A O.S. § 2-7-123 (C)). Any land use restrictions run with the land and will limit the future use of the property. This is an example of an institutional control (IC). If the property is cleaned up to unrestricted residential use, a notice of remediation is not required. Note that there are occasional differences in federal programs. As an example, Superfund requires a notice of remediation regardless of use.

Unless a cleanup is performed to achieve unrestricted residential use, appropriate engineering controls (ECs) and institutional controls must be in place to protect the cleanup and ensure that land use is not incompatible with site conditions. Evidence of EC or IC long-term effectiveness or a plan to monitor their effectiveness may be required.

Risk management decisions will also consider factors such as practicality, avoidance or creation of additional risk, ICs and Applicable Rules and Regulations. Calculating cleanup levels is only a portion of managing the risk sites pose to human health and the environment.

Applicable Rules or Regulations

Risk assessments provide useful information in decision making, but a risk assessment does not supersede or negate applicable rules or regulations.

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

If the risk assessment is based on groundwater modeling or if groundwater contamination remains after the cleanup, provisions must be made for long-term groundwater and/or surface water monitoring to demonstrate that the models are accurate and to verify that contamination is still characterized and controlled. Long-term groundwater monitoring may also be required if waste or a source of contamination is left in place. Such monitoring is expected to continue until the groundwater remedial goals have been reached. Long-term, periodic monitoring of groundwater and surface water may also be required. Financial assurance may be required to ensure that monitoring and maintenance of the site is performed.

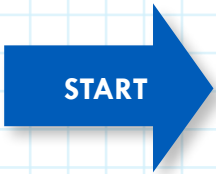
As stated above, when cleanup of contaminated property to risk-based levels is performed under a permit, order, or remediation plan approved by DEQ, DEQ is required to file a notice of remediation (27A O.S. § 2-7-123(C)).

Helpful Resources

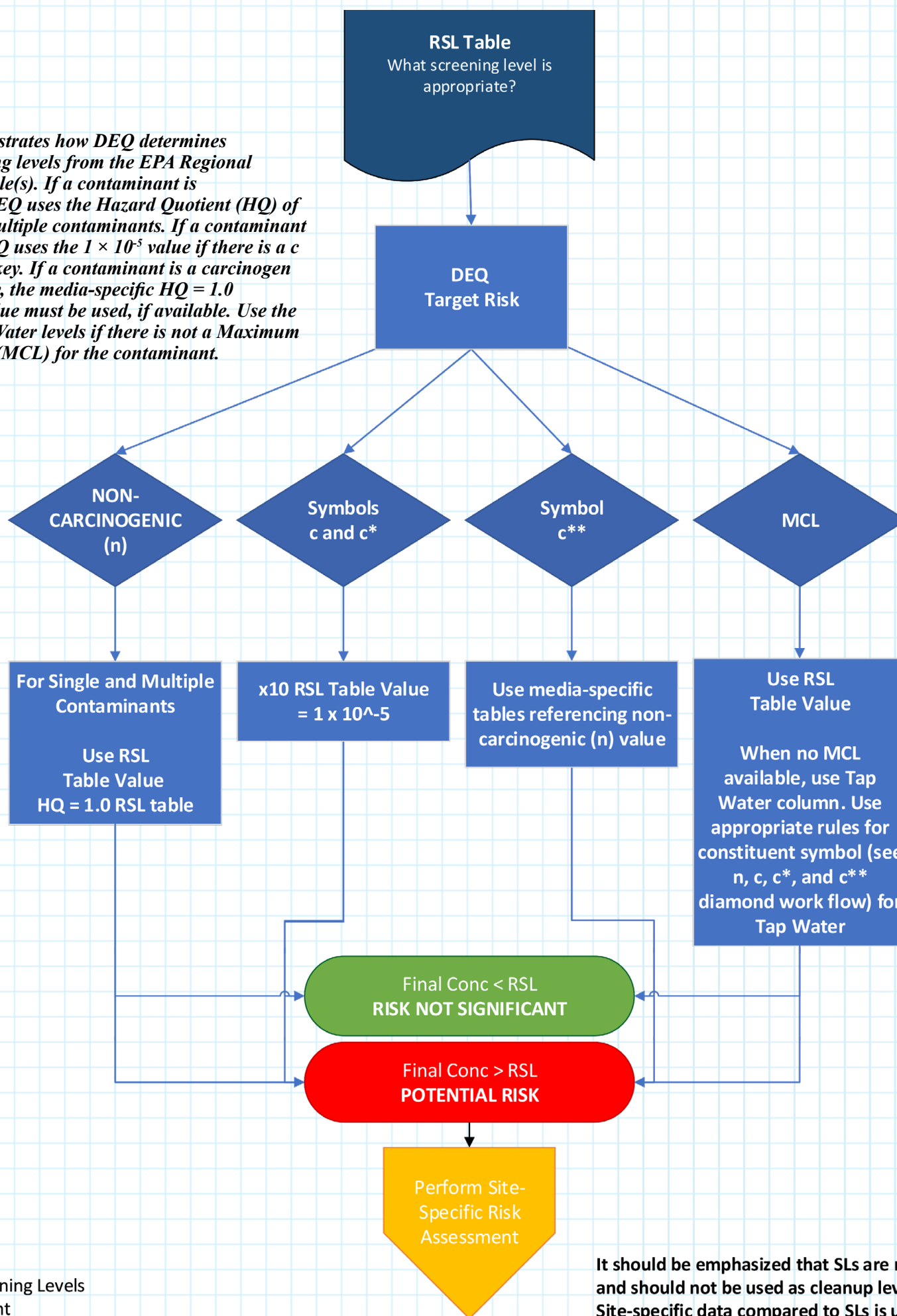
The Integrated Risk Information System (IRIS) (<http://www.epa.gov/IRIS/>) is used to obtain toxicity information regarding chemicals of potential concern. The DEQ Risk Team should be consulted when chemicals do not have published toxicity information.

1. For Human Health; soils, surface water, indoor air, and groundwater protection:
 - a. The EPA Regional Screening Levels (RSL) – <https://www.epa.gov/risk/regional-screening-levels-rsls-generic-tables>
2. For Ecological Risk; all media:
 - a. The EPA Ecological Soils Screening Level (ECO SSLs) guidance document – <https://www.epa.gov/risk/ecological-soil-screening-level-eco-ssl-guidance-and-documents>
 - b. The Oak Ridge National Laboratory (ORNL) toxicity benchmarks – https://rais.ornl.gov/tools/eco_search.php
 - c. The National Oceanographic and Atmospheric Administration (NOAA) Screening Quick Reference Tables (SQuiRTs) – <https://repository.library.noaa.gov/view/noaa/9327>
3. Other Useful References:
 - a. EPA's website for risk related issues – <https://www.epa.gov/risk>
 - b. ATSDR Toxic Substances Portal – <https://www.atsdr.cdc.gov/substances/index.asp>
 - c. Interstate Technology and Regulatory Council (ITRC), Risk Assessment Resources – <https://www.itrcweb.org/Team/Public?teamID=44>
 - d. US Fish and Wildlife Service – Regional/State Threatened and Endangered Species Information – <https://www.fws.gov/Endangered/>
 - e. DEQ promulgates Water Quality Standards for the state – <https://tinyurl.com/bdvcu77p>

Appendix - Determining Regional Screening Level (RSL) from Tables



The diagram demonstrates how DEQ determines appropriate screening levels from the EPA Regional Screening Level Table(s). If a contaminant is noncarcinogenic, DEQ uses the Hazard Quotient (HQ) of 1.0 for single and multiple contaminants. If a contaminant is a carcinogen, DEQ uses the 1×10^{-5} value if there is a c or c* in the Table's key. If a contaminant is a carcinogen with a c** in the key, the media-specific HQ = 1.0 noncarcinogenic value must be used, if available. Use the same rules for Tap Water levels if there is not a Maximum Contaminant Level (MCL) for the contaminant.



KEY
 RSL - Regional Screening Levels
 HQ - Hazard Quotient
 MCL - Maximum Contaminant Level

It should be emphasized that SLs are not cleanup standards and should not be used as cleanup levels. Site-specific data compared to SLs is used to determine which chemicals are evaluated during a site's risk assessment. Final remediation goals will be determined when the remedy is selected.

<https://www.epa.gov/risk/regional-screening-levels-rsls-generic-tables>

Regional Screening Level (RSL) Summary Table (TR=1E-06, HQ=1) May 2022

Level; H = HEAST; W = TEF applied; E = RPF applied; G = user's guide Section 5; M = mutagen; V = volatile; R = RBA applied; c = cancer; n = noncancer; * = where: n SL < 100X c SL; ** = where n SL < 10X c SL; SSL values are based on DAF=1; m = ceiling limit exceeded; s = Csat exceeded.

Contaminant	CAS No.	Screening Levels										Protection of Groundwater SSLs			
		Resident Soil (mg/kg)	key	Industrial Soil (mg/kg)	key	Resident Air (ug/m ³)	key	Industrial Air (ug/m ³)	key	Tapwater (ug/L)	key	MCL (ug/L)	Risk-based SSL (mg/kg)	key	MCL-based SSL (mg/kg)
Acetate	30560-19-1	1.9E+01	n	2.5E+02	n	1.3E+00	c**	5.6E+00	c**	6.0E+00	n		1.3E-03	n	
Acetaldehyde	75-07-0	1.1E+01	c**	4.9E+01	c**	1.3E+00	c**	5.6E+00	c**	2.6E+00	c**		5.2E-04	c**	
Acetochlor	34256-82-1	1.3E+03	n	1.6E+04	n					3.5E+02	n		2.8E-01	n	
Acetone	67-64-1	7.0E+04	n	1.1E+06	nms					1.8E+04	n		3.7E+00	n	
Acetone Cyanohydrin	75-86-5	2.8E+06	nm	1.2E+07	nm	2.1E+00	n	8.8E+00	n						
Acetonitrile	75-05-8	8.1E+02	n	3.4E+03	n	6.3E+01	n	2.6E+02	n	1.3E+02	n		2.6E-02	n	
Acetophenone	98-86-2	7.8E+03	ns	1.2E+05	nms					1.9E+03	n		5.8E-01	n	
Acetylaminofluorene, 2-	53-96-3	1.4E-01	c	6.0E-01	c	2.2E-03	c	9.4E-03	c	1.6E-02	c		7.5E-05	c	
Acrolein	107-02-8	1.4E-01	n	6.0E-01	n	2.1E-02	n	8.8E-02	n	4.2E-02	n		8.4E-06	n	
Acrylamide	79-06-1	2.4E-01	c	4.6E+00	c	1.0E-02	c	1.2E-01	c	5.0E-02	c		1.1E-05	c	
Acrylic Acid	79-10-7	2.0E+01	n	8.3E+01	n	2.1E-01	n	8.8E-01	n	4.2E-01	n		8.5E-05	n	
Acrylonitrile	107-13-1	2.5E-01	c*	1.1E+00	c*	4.1E-02	c*	1.8E-01	c*	5.2E-02	c*		1.1E-05	c*	
Adiponitrile	111-69-3	8.5E+06	nm	3.6E+07	nm	6.3E+00	n	2.6E+01	n						
Alachlor	15972-60-8	9.7E+00	c*	4.1E+01	c*					1.1E+00	c	2.0E+00	8.7E-04	c	1.6E-03