Introduction

1.1 Purpose

The Remediation Closure Guide (RCG) describes selected approaches to investigation and risk-based closure\(^1\) of contaminated or potentially contaminated sites. Its purpose is to provide for consistent application of Indiana Code (IC) 13-12-3-2 and IC 13-25-5-8.5, which form the statutory basis for risk-based cleanup in Indiana.

A companion manual, the Remediation Program Guide, provides guidance related to specific regulatory programs. Together, the Remediation Program Guide and the RCG provide a framework for investigating sites and moving them toward closure.

The procedures in the RCG are technically sound and, when used appropriately, are applicable to a broad range of sites. However, the Indiana Department of Environmental Management (IDEM) recognizes that there are many possible approaches to investigation and closure of sites, and that other procedures may be more appropriate at some sites.

**IDEM will evaluate alternative approaches on their merits.**

The RCG is a substantial revision of the 2001 Risk Integrated System of Closure (RISC) Technical Resource Guidance Document. The RCG builds on the earlier guidance, eliminating some things that proved less useful than anticipated, and introducing new material or expanding sections.

The RCG follows a broad outline, beginning with an introduction that explains the statutory basis and use of several key concepts, and sketches out an overall process. Sections 2 through 6 describe various aspects of developing a conceptual site model – essentially, a detailed description of the investigative area that demonstrates an understanding of present and likely future contaminant type(s), concentrations, and distribution. Sections 7 through 11 build on the conceptual site model, using the information it contains to evaluate potential risks to exposed or potentially exposed populations. In some cases, that evaluation will indicate the need for selection and implementation of a remedy of some kind – the topic of Section 12. Supporting materials comprise the last sections of the RCG.

IDEM will update or revise the procedures described herein as necessary. Updates will appear on the Risk-based closure web page.\(^2\) In addition, IDEM staff can provide clarification regarding updates on the contents of this volume.

---

\(^1\) Closure is IDEM’s written recognition that a party has demonstrated attainment of specific investigative or remediation objectives for contaminants in a particular area.

\(^2\) [http://www.in.gov/idem/4153.htm](http://www.in.gov/idem/4153.htm)
1.2 Applicability

As directed by IC 13-12-3-2, the RCG applies to the following IDEM remediation programs:

- Leaking Underground Storage Tank (LUST) Program
- Voluntary Remediation Program (VRP)
- Resource Conservation and Recovery Act (RCRA) Subtitle C Programs, including RCRA Treatment Storage and Disposal (TSD) facility closures, interim status TSD closures and RCRA Corrective Action projects
- State Cleanup Program (SCP)
- Indiana Brownfields Program (IBP)

Cleanups completed under these programs may use risk-based remediation objectives established by IC 13-25-5-8.5. The RCG and risk-based remediation objectives may also be applied to the closure of certain RCRA Subtitle D surface impoundments as management practices that are protective of human health and the environment.

As a non-rule policy, the RCG does not have the effect of law. If a conflict exists between the RCG and state or federal rules and statutes, the rules and statutes will prevail.

Some conditions require quick response action to mitigate any potential imminent and substantial threat to human health or the environment. Examples include:

- Releases covered under the Spill Rule
- Acute exposures to contamination
- Presence of corrosive, explosive, flammable, or toxic vapors
- Actual or imminent contamination of a drinking water supply well

The RCG does not specifically address these situations. However, where appropriate, RCG activities may proceed concurrently with emergency mitigation measures.

IDEM did not develop the RCG for use in obtaining information specific to real estate transfers. Other resources (e.g., ASTM 2002, 2005) contain guidance suited for this purpose.

---

3 While RCRA Subtitle C and D facilities may take advantage of some of the closure options afforded by the RCG, program-specific statutes and rules may require the removal of contamination. Where there are conflicts with such requirements, removal of contamination to land use specific concentrations may be required.

4 327 IAC 2-6.1
1.3 Remediation Objectives

IC 13-25-5-8.5 directs responsible parties to specify remediation objectives for sites where releases occur. The statute describes two fundamental types of remediation objectives.

The first type bases remediation objectives on the background levels of substances that occur naturally on the site. Background demonstrations are very useful when showing that site activities have not contributed contamination to the environment above naturally occurring levels. When a release has occurred, remediating the released chemical to background levels is often difficult and unnecessarily stringent.

The second type of remediation objective uses a risk-based approach. Risk-based methods recognize that there is a relationship - the dose-response relationship - between the concentration of a chemical to which a population is exposed and the likelihood that members of that population will suffer adverse effects.

Dose-response relationships differ by chemical and by type of chemical. For example, IDEM follows the United States Environmental Protection Agency (U.S. EPA) in assuming that the dose-response relationship of non-carcinogens is different from that of carcinogens (Figure 1-A).

Figure 1-A: Dose-Response Relationships

For non-carcinogens, IDEM assumes that there is a threshold dose below which adverse effects are unlikely. For most carcinogens, IDEM assumes that the probability of an adverse effect is proportional to the dose, and that there is no non-zero threshold below which the probability of an adverse effect is zero. Threshold doses and the slopes of the carcinogenic response lines (slope factors) are estimates, and they differ from chemical to chemical. All are subject to change as new data become available.

Adverse effects are unlikely when exposure to a non-carcinogen is lower than its threshold dose. Calculating acceptable environmental concentrations for carcinogens is more complicated. For carcinogens, IDEM assumes that any exposure carries some risk. IDEM follows U.S. EPA in considering an incremental carcinogenic risk of $10^{-4}$ to $10^{-6}$ as acceptable, with $10^{-5}$ as the usual target.

About 40 percent of Americans develop cancer at some point in their lifetimes (American Cancer Society, 2010). Therefore, cancer will probably occur in about 40,000 persons in an area of 100,000 residents. An incremental risk of $10^{-5}$ to that population should, on average, add one additional cancer case.

---

5 Section 6 includes procedures for determining background concentrations at sites.
The objective of a risk-based approach is to define an environmental concentration that corresponds to an acceptable level of risk to persons\(^6\) who may undergo exposure to a particular chemical. Risk-based approaches do this by using equations and assumptions that mathematically relate environmental concentrations to the risk of adverse effects, structured so that the result is a set of environmental concentrations considered acceptable, \textit{subject to the underlying assumptions}. As the underlying assumptions change, the calculated acceptable environmental concentrations also change.

Many regulatory agencies employ this general approach to generate tables of acceptable concentrations for chemicals in various media under specific exposure scenarios. Indiana statute directs the agency to calculate such numbers. IDEM calls them \textbf{screening levels}.\(^7\)

For ease of presentation in this document, IDEM has chosen to define a \textbf{contaminant} as a chemical present at a concentration above the chemical’s remediation objective. This definition is consistent with the definition contained in previous guidance, but reflects a shift in terminology away from the use of contaminant of concern. However, IDEM’s authority, and a responsible person’s\(^8\) obligation, to undertake a response action is specific to the applicable remedial statute.\(^9\) In general, IDEM’s authority, or a person’s obligation, is triggered by a release (regardless of concentration or quantity) of hazardous substances, regulated substances, hazardous waste, or petroleum.\(^10\) IDEM has chosen to refer collectively to such releases as releases of \textbf{potential contaminants}. Any unintentional reference in this guidance to a contaminant (as opposed to a potential contaminant) does not alter IDEM’s authority or a responsible person’s obligation to perform response actions.

\(^6\) Or non-human receptors, where applicable.
\(^7\) Formerly \textit{default closure levels}.
\(^8\) IDEM is using the terms responsible person, responsible party, owner, operator, and applicant interchangeably for purposes of this document. However, Title 13 contains specific definitions for the various terms.
\(^9\) See IC 13-22-13, IC 13-23-13, IC 13-24-1, and IC 13-25-4; also IC 13-25-5, the Voluntary Remediation Program, applies to releases of hazardous substances and petroleum.
\(^10\) Some of these terms overlap.
1.3.1 Screening Levels

IC 13-25-5-8.5(d)(1) – Levels of hazardous substances and petroleum calculated by the department using standard equations and default values for particular hazardous substances or petroleum.

As directed by statute, IDEM periodically calculates screening levels. IDEM relies on the values found in the regional screening level (RSL) tables (U.S. EPA, 2011b and updates) and guidance from the Regional Screening Levels User's Guide (U.S. EPA, 2011) when deriving screening levels. Appendix A describes the methods that the agency uses to calculate screening levels. Links to current and archived screening levels appear on the Risk-based closure web page.

IDEM calculates screening levels for several different exposure scenarios:

- Direct (surface soil) contact for residential and commercial/industrial users
- Direct (subsurface soil) contact for excavation workers
- Ground water exposure for residential users, including migration to ground water screening levels designed to predict future ground water concentrations arising from chemicals in soil
- Vapor exposure for both residential and commercial/industrial users

Each of these exposure scenarios differs from the others in types and/or durations of exposures to chemicals.

Screening levels applied under appropriate land use scenarios are suitable for use at any site. In practice, the protective assumptions built into the screening levels make the probable additional carcinogenic risk of using those levels under appropriate land use scenarios substantially lower than 10^-5. Non-carcinogenic effects at screening levels are also unlikely, for the same reason.

Screening levels are like “first cut” values – if chemical concentrations at a site do not exceed screening levels, the site is generally eligible for closure, though conditions may apply. An exceedance of screening levels indicates the need for additional evaluation.

1.3.2 Site-specific Levels

Sometimes the assumptions that underlie IDEM’s screening levels may not accurately reflect the physical reality of a particular site. This can have the effect of over-estimating the risk at the site. In some cases, it may even suggest the need for mitigation when none is necessary. Where this seems likely, it may prove worthwhile to collect additional data to calculate site-specific levels that more accurately characterize risk.

IC 13-25-5-8.5(d)(2) – Levels of hazardous substances and petroleum calculated using site specific data for the default values in the department’s standard equations.

For example, IDEM’s migration to ground water screening levels incorporate an assumption that the fraction of organic carbon (f_{oc}) in subsurface soil is 0.002 gram/gram (g/g). This value, while reasonable for sand, is toward the low end of the range found in Indiana subsurface soils. Many Indiana subsurface soils have organic carbon fractions higher than 0.002 g/g, and are therefore less likely to leach organic chemicals than a soil with an f_{oc} of 0.002 g/g.

---

12 [http://www.in.gov/idem/4153.htm](http://www.in.gov/idem/4153.htm)
13 Other agencies may have authority in regulating exposures to commercial/industrial populations.
14 Ground water and vapor closure typically require more than one sampling event.
By collecting and analyzing subsurface soil samples for $f_{oc}$, it may be possible to show that subsurface soil $f_{oc}$ exceeds 0.002 g/g at a particular site, and use that information to derive site-specific migration to ground water levels that are simultaneously higher and more appropriate than the screening level. See Section 9.9.1 for more information on the derivation of site-specific levels using $f_{oc}$ analysis.

*Because of the protective assumptions incorporated into screening levels, IDEM expects that site-specific levels will nearly always exceed screening levels.*

Many physical and chemical parameter values appear in the equations used to derive screening levels, and it may be worthwhile to collect site-specific data on those parameter values to calculate site-specific levels. Additional details appear in Sections 7 through 10.

As with screening levels, exceedance of a site-specific level means that further action is necessary. Such action might include remediation, risk management, and/or a demonstration utilizing appropriate lines of evidence that the risk characterization overstates the actual risk.

### 1.3.3 Risk Characterization

Screening level and site-specific level calculations begin with a predetermined level of acceptable risk and use standard equations, toxicity criteria, and exposure assumptions to solve for acceptable environmental concentrations of chemicals. In contrast, risk characterization begins with observed chemical concentrations and uses the same equations, criteria, and assumptions to solve for the resulting risk. In other words, the risk characterization and the screening level/site-specific level approaches solve for different things.

<table>
<thead>
<tr>
<th>Approach</th>
<th>Begin with</th>
<th>Solve for</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening level/</td>
<td>Target risk level</td>
<td>Screening level/Site-specific level</td>
</tr>
<tr>
<td>Site-specific level</td>
<td>Standard equations</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exposure assumptions</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Toxicity criteria</td>
<td></td>
</tr>
<tr>
<td>Risk Characterization</td>
<td>Observed chemical concentrations</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Standard equations</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exposure assumptions</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Toxicity criteria</td>
<td>Risk level</td>
</tr>
</tbody>
</table>

Risk characterization also includes a qualitative component that identifies key assumptions and bias, and states the limitations and uncertainties associated with the risk assessment. A complete risk characterization then integrates the quantitative and qualitative assessments. While the screening level/site-specific level approach determines only whether or not observed chemical concentrations exceed screening levels or site-specific levels, the risk characterization approach estimates the actual risk level and conveys the range of information considered and used in developing the assessment. In short, risk characterization clarifies the scientific basis for decisions, while screening levels or site-specific levels do not, by themselves, give a true picture of the assessment. Risk characterization is a powerful approach that allows comparison of the risk estimate to the target risk range ($10^{-4}$ to $10^{-6}$). U.S. EPA uses risk characterization to evaluate risks and the necessity of remedial action at Superfund and RCRA sites. There is more clarity in a risk characterization because the magnitude of any risk exceedance is both quantified and qualified.
For example, if soil arsenic is present for residential direct contact at a representative concentration of 10 milligrams per kilogram (mg/kg), it clearly exceeds the screening level of 5.5 (mg/kg). However, it is not apparent whether the observed concentration results in an exceedance of the target risk range. A risk characterization using the same screening level exposure assumptions reveals that the soil arsenic poses a potential $2.6 \times 10^{-5}$ cancer risk. It is then possible to compare this numeric risk estimate to the IDEM screening level target risk of $10^{-5}$ and the $10^{-4}$ to $10^{-6}$ target risk range. Although the numerical comparisons are important, the limitations and uncertainties identified in the risk characterization (e.g., low confidence due to use of average exposure parameters at an elementary school yard, versus high confidence due to use of screening level exposure parameters at an industrial facility) should also inform decisions about the site.

Non-carcinogenic risk assessments where the target hazard quotient is 1 may employ a similar analysis, although a hazard risk range is not suitable. Section 7 provides more information on the components of risk assessment. Section 7.5 provides more information on the target risk range.

1.3.4 Risk Management

Indiana statute permits derivation of site-specific levels based on other site-specific factors, including remedies that incorporate various risk management strategies. Risk management strategies reduce or eliminate specific exposure pathways through engineering controls (ECs) or institutional controls (ICs).

IC 13-25-5-8.5(d)(3) – Levels of hazardous substances and petroleum developed based on site specific risk assessments that take into account site specific factors, including remedial measures, restrictive covenants, and environmental restrictive ordinances that (A) manage risk; and (B) control completed or potential exposure pathways.

ECs physically limit contaminant contact or migration. Examples include engineered caps, slurry walls, vapor mitigation systems, sheet piling, etc.

ICs include legal restrictions on the use of a property. Some examples are prohibitions on residential use, limits on the extraction or use of ground water, or restrictions on soil excavation. Environmental restrictive covenants (ERCs) or environmental restrictive ordinances (EROs) are types of ICs.

Effective ICs or ECs reduce or eliminate exposure via specific exposure pathways and remove those pathways from the risk evaluation. However, effective risk management may require an ongoing commitment to monitor, operate, and/or maintain the control. The ongoing commitment will vary with the nature of the control, and could range from periodic inspections designed to monitor compliance with the terms of an ERC, all the way up to operation and maintenance of a complex engineered system.
1.4 Process Overview

Figure 1-B is an overview of the process that IDEM anticipates most sites will follow as they move toward closure. There are two basic closure types. Unconditional closures are true “walk away” closures that leave the site environmentally suitable for any future use. All other closures are conditional.

Conditional closure means that IDEM’s closure approval depends on one or more ongoing activities or restrictions that reduce exposures to levels acceptable for a particular land use. Examples include (but are not limited to) restrictions on residential use, construction and maintenance of a physical barrier, or installation and operation of an active system.

Closures are usually conditional whenever chemical concentrations exceed residential remediation objectives.

An adequate conditional closure will involve implementation of one or more measures that together prevent unacceptable exposure. Active remediation is not always necessary, though IDEM expects that active remediation will, in many cases, reduce the number and/or scale of necessary future activities or restrictions. The party implementing a remedy is free to weigh the relative costs and benefits of various options. However, closure always requires a demonstration that site-related chemical concentrations remaining from a release do not pose an unacceptable risk to human health or the environment.

Any preceding investigative work must be sufficient to support development of an adequate conceptual site model and allow informed decisions about the selection and implementation of potential remedies, if any. Many sites will have contamination in more than one medium. Site closure will require meeting closure requirements in all affected media.

---

15 Under RCRA, the term closure refers to a series of formal procedures required to minimize the need for maintenance and control, minimize or eliminate post-closure releases of hazardous waste, hazardous constituents, leachate, contaminated run-off, or hazardous waste decomposition products to the environment.

16 New information about the presence of contaminants at a site may require post-closure responses, and IDEM may require further action where the conditions that formed the basis for IDEM’s approval of closure have changed or not been met.
Figure 1-B: Closure Process Overview

1. **Begin**

2. **Investigation sufficient to evaluate preliminary options**

   - **Attempt unconditional closure?**
     - **Y**
       - **Investigation and/or remediation necessary prior to evaluating unconditional closure**
       - **Meet unconditional closure criteria?**
         - **Y**
           - **Conditional closure** (with further obligations)
         - **N**
           - **Continue seeking unconditional closure?**
             - **Y**
               - **Investigation sufficient to evaluate preliminary options**
             - **N**
               - **Select conditional remedy**
                 - **IDEM approves?**
                   - **Y**
                     - **Implement conditional remedy**
                   - **N**
                     - **Evaluate against conditional criteria**
                       - **Meet conditional closure criteria?**
                         - **Y**
                           - **Conditional closure (with further obligations)**
                         - **N**
                           - **Unconditional closure (no further obligations)**
                 - **Any additional investigation or work necessary to select conditional remedy**
                   - **Y**
                     - **Select conditional remedy**
                   - **N**
                     - **Continue seeking unconditional closure?**
                       - **Y**
                         - **Investigation sufficient to evaluate preliminary options**
                       - **N**
                         - **Meet unconditional closure criteria?**
                           - **Y**
                             - **Conditional closure** (with further obligations)
                           - **N**
                             - **Unconditional closure (no further obligations)**