

4.0 Conducting Tier 3 – Evaluation of Remedial Alternatives

4.1 Objectives of the Tier 3 Evaluation

The Tier 3 *Evaluation of Remedial Alternatives* is initiated when the results of the Tier 2 BERA indicate that site-related COPCs pose unacceptable risks to one or more assessment endpoints. A risk management decision is subsequently made that additional evaluation in the form of remedy development and evaluation is warranted, and the site moves on to Tier 3 of the Navy ERA process (Figure 4.1). In this tier, remedial alternatives (including a no-action one) are developed with the goal of reducing risks (ecological and/or human health) to acceptable levels. These alternatives then undergo an ecological evaluation against a set of criteria (the nine CERCLA remedy evaluation criteria) and a final remedy is selected.

The ecological evaluation conducted in Tier 3 has a different focus than the ERAs conducted in Tiers 1 and 2, but it addresses the same set of ecological resources evaluated in the earlier tiers. In the Tier 1 and Tier 2 ERAs, the objectives of the assessments were to characterize ecological risks posed by site-related COPCs and support a remedial decision regarding the need for remediation. In contrast, the objectives of the Tier 3 ecological evaluation are to evaluate alternative remedies for risk reduction, and to support the selection of a preferred remedy. The remedial alternatives are evaluated with regards to:

- The effectiveness of reducing risks to acceptable levels,
- Potential ecological impacts related to remedy selection, and
- Residual risks.

The selected remedy must strike a balance between human health and ecological concerns. It is important to note that remedial alternatives that reduce risks to human health may not necessarily reduce risks to, or be protective of, ecological resources (and visa versa). Depending on the nature of the site and the particular remedy, greater ecological impacts may be incurred from remedy implementation than from the COPC exposure itself. The Tier 3 ecological evaluation must also integrate socioeconomic and political issues (as appropriate) with ecological concerns into the remedy evaluation process. The evaluation of remedial alternatives is accomplished within the application of the nine CERCLA remedy evaluation criteria.

4.2 Integrating the Risk Assessment Team into the Remedy Development Process

The RPM should integrate the risk assessment team into the remedy development process at the earliest possible stage. Per the NCP, the final remedy must be protective of both human health and the environment, and remedy selection includes the evaluation of long-term and short-term impacts to, and protectiveness of, the environment. The risk assessment team should be included early in the remedy development process to ensure that ecological issues and concerns are given timely consideration. This early ecological input may lead to the elimination of some ecologically incompatible alternatives from further consideration before too much time and effort is invested in them. Early ecological input will also assist in the early identification of ecologically friendly technologies that may be appropriate for further development and evaluation in Tier 3.

4.3 Preliminary Remediation Goals

The NCP [40CFR300.430(e)(9)(iii)(A)] requires that remedial alternatives “...be assessed to determine whether they can adequately protect human health and the environment, in both the short-term and long-term, from unacceptable risks posed by hazardous substances, pollutants, or contaminants present at the site by eliminating, reducing, or controlling exposures to levels established during development of remediation goals ...” These remediation goals (cleanup goals) are media-specific concentrations that the selected remedy must attain in order to reach the required level of risk reduction.

The development of remedial alternatives begins with the identification of preliminary remediation goals (PRGs). PRGs are risk-based media concentrations that represent remediation targets; they are not intended to be cleanup levels but rather environmental concentrations around which remedy development can begin. Other factors, such as background levels, available technology, and costs will act to modify these values into the final cleanup levels selected for the site.

4.3.1 PRG Development

PRGs may be developed from promulgated values or through the use of site-specific data collected as part of site characterization and the Tier 2 BERA. The NCP states that ARARs are to be considered for use in developing cleanup levels. Water quality criteria and standards that are protective of aquatic biota have been promulgated at the federal and state level under Sections 303 and 304 of the CWA. Thus, the national ambient water quality criteria (AWQC) and appropriate state water quality standards must be considered in developing remediation goals for the site. If a criterion or standard is available for a COPC, it can serve as a PRG during remedy development and evaluation.

In contrast, currently there are no nationally accepted or promulgated cleanup levels for soils or sediment, although some states and EPA regions have developed soil and/or sediment remediation goals or PRGs. However, these values are almost exclusively

human health based and should not necessarily be considered protective of ecological resources. If proposed for use as ecological PRGs, these values should be fully evaluated to determine their appropriateness. Because ecological soil and sediment cleanup values are generally not available, ecological PRGs for these media must be derived through either site-specific Tier 2 BERA field and laboratory data or the HQ method. The following sections discuss these approaches for developing site-specific PRG values. Additional information on PRG development is provided in the Issue Paper portion of this web site, and a case study describing an approach used by EFA North to develop PRGs for a site in EPA Region 1 is presented in the Case Study portion of this web site.

4.3.2 Using Tier 2 Site Data to Derive PRGs

During the Tier 2 risk characterization, ecotoxicity reference values (ERVs) were developed by generating COPC-specific dose-response curves and identifying NOAEL and LOAEL dose or media concentrations (see Section 3.7). Recall that exposure concentrations less than the NOAEL were considered to be indicative of acceptable risks, values exceeding the LOAEL were considered indicative of unacceptable risk, and the range between the NOAEL and LOAEL represented an area of risk uncertainty. Thus, the NOAEL-LOAEL values effectively bound a target risk range, with remediation warranted when exposure concentrations exceed this range and not warranted when exposure levels fall below this range. Therefore, these values may directly serve as PRGs (Figure 4.2).

It is important to note that the development of PRGs by this approach may not be possible if the appropriate data were not collected during the Tier 2 BERA. Thus, the requirements for developing site-specific PRGs must be considered during the study design component of Tier 2 (see Section 3.4).

4.3.3 Using the HQ Method to Derive PRGs

In the HQ method, ecological risks are estimated risk by comparing the exposure concentration of a COPC (as either an environmental concentration or a modeled dose) to an ERV for that contaminant. An unacceptable risk is indicated if the ratio of the exposure concentration to the ERV (the HQ) exceeds a value of 1. For example, a COPC dose to a receptor resulting from the ingestion of soil may be calculated using this dose model:

$$\text{Dose} = C_{\text{soil}} \times \text{IR}$$

where:

Dose	=	the daily contaminant dose,
C_{soil}	=	the COPC concentration in soil, and
IR	=	the ingestion rate of soil.

Note that this model is a simplified version of the dose models discussed earlier in the Tier 2 BERA portion of this web site, and this simple equation is presented for example purposes only. Using this example dose model, a HQ is calculated as:

$$\text{HQ} = \frac{\text{DOSE}}{\text{ERV}} = \frac{(\text{C}_{\text{soil}} \times \text{IR})}{\text{ERV}}$$

To derive a PRG using this approach, the HQ is set to 1.0 and the equation is solved for the soil concentration:

$$\text{C}_{\text{soil}} = \frac{\text{ERV}}{\text{IR}}$$

The calculated soil concentration represents the PRG concentration below which no unacceptable risks would be expected.

4.4 Ecological Evaluations and the Nine CERCLA Evaluation Criteria

Tier 3 evaluates each remedial alternative (including the no action alternative) from an ecological perspective against the nine CERCLA remedy evaluation criteria identified in the NCP [40 CFR 300.430(e)(9)(iii)]:

1. Overall protection of human health and the environment,
2. Compliance with ARARs,
3. Long-term effectiveness and permanence,
4. Reduction of toxicity, mobility, or volume through treatment,
5. Short-term effectiveness,
6. Implementability,
7. Cost, and
8. State acceptance,
9. Community acceptance.

The ecological evaluation of each alternative should make use of the data collected as part of the Tier 2 BERA, and these data may directly support the evaluations associated with many of the criteria. These evaluation criteria are segregated into three categories - Threshold Criteria, Primary Balancing Criteria, and Modifying Criteria.

While evaluating alternatives per the nine criteria, it is important that the RPM keep in mind the overall goals of the Tier 3 remedy evaluation. These goals are to identify a remedy that 1) reduces ecological and human health risks to acceptable levels, 2) balances risk reduction between human health and ecological concerns, and 3) will not result in a level of ecological harm that outweighs the risk reduction benefits.

4.4.1 Threshold Criteria

The Threshold Criteria are:

1. Overall protectiveness of human health and the environment, and
2. Compliance with ARARs.

Threshold Criteria must be met for an alternative to be acceptable. The BERA provides direct information on the COPCs and their ecotoxicity, the assessment endpoints most at risk from the COPCs, and information on other ecological resources at the site and the surrounding locale. This information is directly applicable to an evaluation of overall protectiveness of the environment. Similarly, the BERA likely used some COPC-specific ARARs (such as AWQC) as ERVs to estimate ecological risks.

In evaluating alternatives relative to overall protectiveness of the environment, the risk assessment team should include considerations of:

- Potential habitat destruction by each remedial alternative,
- The types of habitat potentially impacted by each alternative,
- The areal extent of potential impacts of each alternative,
- The occurrence of similar habitat in surrounding areas,
- The risks of selecting no action compared to potential ecological harm resulting from remedy implementation, and
- The ability of the potentially impacted habitats to recover.

For example, a remedial alternative may require dredging of a wetland area in order to achieve an 80% reduction in ecological risk. However, dredging would also completely destroy the wetland, resulting in 100% loss of the ecological resource at risk from the contaminant, and recovery of the lost wetland would be unlikely, take a very long time, or require extensive planting and management. In this case, overall protectiveness might not be considered as great as originally thought.

Evaluation relative to compliance with ARARs should consider:

- Chemical-specific ARARs, such as water quality criteria for protection of aquatic life,
- Location-specific ARARs, such as the wetland protection component of the CWA or Executive Orders protecting wetlands, and
- ARARs triggered by remedy implementation, such as the Endangered Species Act.

4.3.2 Primary Balancing Criteria

The Primary Balancing Criteria are:

3. Long-term protectiveness and permanence,
4. Reduction of toxicity, mobility, or volume,
5. Short-term effectiveness,

6. Implementability, and
7. Costs.

Each remedial alternative must be evaluated relative to what extent the alternative provides a balance of trade-off among these five criteria, with an emphasis on long-term effectiveness and reduction of contaminant toxicity, volume, or mobility through treatment.

The Tier 2 BERA likely employed a variety of toxicity tests and generated toxicity data (e.g., dose-response curves) that can be used to evaluate each alternative for potential toxicity reduction. Information on COPC mechanisms of ecotoxicology and assessment endpoint susceptibility may be useful in evaluating long-term permanence and short-term effectiveness. Data regarding the nature and distribution of ecological resources at the site can provide information helpful in identifying potential implementation impacts. The nature and distribution of ecological resources may also affect implementability. For example, implementability may be limited to certain times because of concerns regarding disturbance of endangered species.

Evaluations of long-term protectiveness and permanence should consider:

- Whether COPC input to the site will continue from other sources,
- The reliability of institutional or engineering controls in reducing ecological risks,
- The residual risks to the assessment endpoints, and
- The recovery potential of the impacted habitats.

With regard to institutional controls, the RPM should keep in mind that effectiveness differs markedly between human and ecological receptors. For human receptors (such as children or recreational users), there are a number of institutional controls that can effectively control site access and thus exposure. Ecological receptors however, because of their mobility, size, or behavior, do not respond to institutional controls in a similar manner. For example, land use restrictions will have no effect on access and activities of ecological receptors at the site, and reduced human access may actually increase use of the site by wildlife. Similarly, wildlife may burrow under, climb through, or go over (by climbing, flying, or leaping) fencing that successfully restricts human access. Thus, some institutional controls may have very little long-term protectiveness of ecological resources, and thus not be adequately provide overall protectiveness (Threshold Criteria No. 1).

Evaluations of toxicity, mobility, or volume reduction should consider:

- Whether the remedy will reduce toxicity sufficiently to bring risks to acceptable levels, and
- Whether the remedy will reduce the likelihood of the contaminants migrating to other habitats (both on- and off-site) currently not at risk.

The ecotoxicity profiles developed as part of the Tier 1 SRA and Tier 2 BERA, together with the previously developed SEVs and ERVs can be used to directly evaluate toxicity reduction identified for a remedy.

The evaluation of short-term effectiveness should consider:

- The ecological impacts expected with implementation, together with the effectiveness and reliability of associated mitigation measures, and
- Whether the impacted habitats will recover in a “short” time period.

Although the relationship between the BERA and evaluations of remedy costs may not be immediately obvious, large cost differences may be associated with different levels of risk reduction. For example, the cost of a 100% risk reduction for a particular assessment endpoint might be 10 times the cost of attaining a 90% risk reduction for the same endpoint. Thus, Tier 3 should evaluate the consequences to overall remediation costs of different risk reduction levels. The BERA should provide the data for identifying PRGs associated with different levels of risk reduction.

4.3.3 Modifying Criteria

The Modifying Criteria are:

8. State Acceptance, and
9. Community Acceptance.

Depending on the extent to which the state and the public have been involved in Tier 1 and, especially, Tier 2, acceptance by these groups of the need to remediate may be readily forthcoming. The extent to which this acceptance translates into the evaluation of the remedial alternatives will be strongly affected by the specifics of each alternative and will likely be related as much if not more to issues dealing with human health implications and costs rather than to ecological issues.

4.5 Land Use Considerations

Current and future land use can play a large role in remedy selection. Different land use settings will have different risk drivers and thus produce different interpretations of unacceptable and acceptable risks. Consequently, PRGs and remedies (and associated implementation impacts and residual risks) will differ under different land use settings.

Current land use will play a critical role in the determination of risk acceptability and risk drivers. Industrial sites, for example, typically support limited habitat and biota. Because of this general absence of receptors, little risk to ecological resources may be anticipated and the primary risk driver will likely be human health. As a result, PRGs and remedial alternatives will be targeted more towards human health risk reduction, and ecological impacts of remedy implementation will likely be minimal. In a rural setting, however, ecological receptors will be more common, and both human health and ecological

resources may be the risk drivers. For these sites, the PRGs and remedial alternatives will have to be more comprehensive, and the potential for ecological impacts from remedy implementation can be expected to be greater. In contrast, a recreational or wildlife habitat land use setting supports the most extensive and diverse biota, and human receptors will likely be limited to visitors and site workers. Risk drivers, as well as the subsequent PRGs and remedial alternatives, will likely be more ecology-oriented than under the other land use scenarios. In addition, the greatest potential for ecological impacts from remedy implementation may be expected for a recreational/wildlife land use.

Future land use, if known, must also be considered in remedy selection. For example, suppose a site currently contains quality grassland habitat that because of lead concentrations in the soil poses unacceptable risks to wildlife. Under current conditions, the PRGs and remedial alternatives would be directed towards reducing risks to wildlife to acceptable levels. However, if the site occurs at a BRAC facility and future land use is being identified as residential, then wildlife would not be the appropriate receptor for which PRGs and remedial alternatives would be targeted. Rather, human receptors would be the likely risk driver and focus of remedy selection.

4.6 Monitoring

Following remedy selection, the remediation decision is documented in a Record of Decision and remediation is initiated. The risk assessment team must develop a monitoring program that evaluates not only the effectiveness of the remedy in reducing ecological risk, but also the effectiveness of any mitigation measures identified to address potential implementation impacts.

In the Tier 2 BERA, a CSM was developed that described the relationship among the COPC and assessment endpoints. Ecological risks were then identified to the assessment endpoints, and a remedy was identified to reduce those risks. To develop a monitoring program, the risk assessment team should compare the mode and predicted level of risk reduction of the selected remedy to the CSM and identify those aspects of the CSM that would provide the best determination of remedy effectiveness. For example, if the selected remedy is designed to reduce risks by eliminating a complete exposure pathway, the monitoring plan should consider ways in which to evaluate how effectively the exposure pathway is being eliminated.

4.6.1 Monitoring Program Goals and Exit Criteria Considerations

During the development of a monitoring program, it is essential that the goals, objectives, and termination criteria for the program be identified before any commitment to monitor. If these are not specified, the Navy may be committed to collecting the data for an open-ended period of time (i.e., perpetual monitoring), and the data may not adequately evaluate remedy effectiveness. The development of a monitoring program should consider the following questions:

- What aspect of the remedy is being monitored?
- How is the monitoring metric related to remedy effectiveness?
- At what point is monitoring no longer needed? (What measurable, concrete exit criteria signify successful effectiveness?)

The nature of the monitoring will be a function of what the monitoring program is intended to address. If there is concern about implementation impacts, a monitoring program should be implemented to track and evaluate the effectiveness of the mitigation measures identified for use during remedy implementation. For example, if the site is located adjacent to a wetland and the selected remedy includes excavation of surface soils, there is likely a concern regarding runoff of soils from the excavation area into the wetland. Mitigation measures may include the use of siltation fences or installation of catchment basins to collect runoff and thereby limit siltation of the wetland. In this case a monitoring program would be designed to evaluate the integrity and effectiveness of the mitigation measures. This type of monitoring program differs from one that would be developed to evaluate remedy effectiveness, which likely would include chemical analysis of environmental media and some form of risk characterization. Additional information on developing monitoring plans can be found in the [Issue Papers](#) portion of this website.

4.6.2 Ecological Monitoring when the BERA Identifies Acceptable Risks

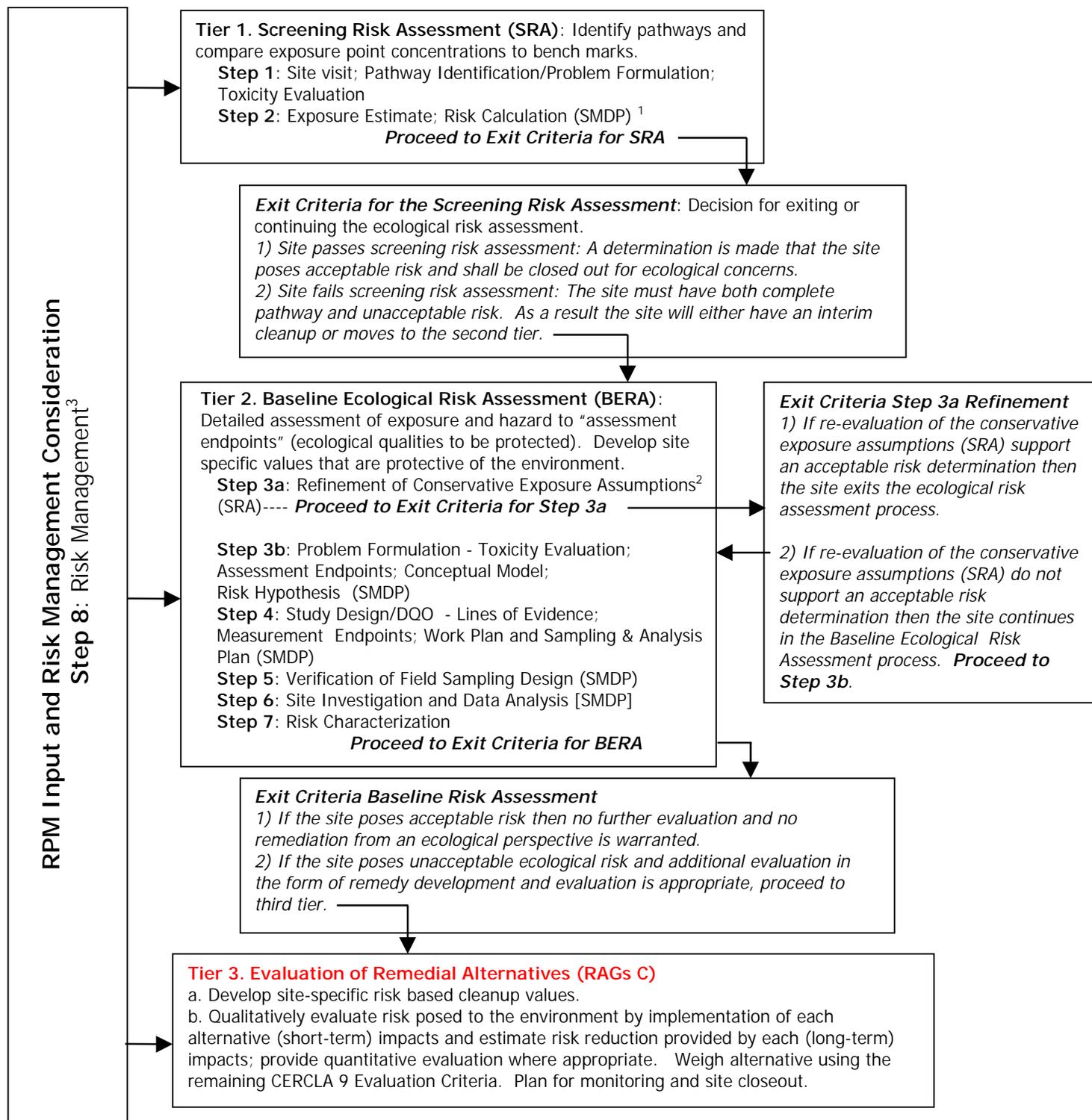
In general, ecological monitoring to evaluate remedy effectiveness will not be warranted at sites where the Tier 2 BERA identified only acceptable ecological risks. However, ecological monitoring may be necessary to ensure that ecological resources are not impacted during remedy implementation and/or operation. Such a monitoring program could be especially necessary if quality habitat or other ecological resource is present in the immediate area of the site and could potentially be disturbed as a result of remediation. For example, it may be appropriate to monitor nesting waterfowl if noise and human activities associated with remedy implementation could disturb nesting activities. Such a monitoring program would not address COPC-related risks, but rather physical stressor risks. Ecological monitoring may also be appropriate for sites where a no action, institutional control, or natural attenuation remedy has been selected and implemented. However, it may be more cost effective and timely to monitor contaminant levels directly rather than ecological responses, and only initiate ecological data collection if contaminant transport to previously unaffected areas is indicated.

Before initiating an ecological monitoring program, the RPM should discuss the need for such monitoring with their team. Monitoring goals and exit criteria must be clearly specified, and the availability of cost-effective, defensible biomarkers that could be used in lieu of toxicity testing, field investigations, or other ecological studies, should be investigated.

4.6.3 Regulator Concurrence

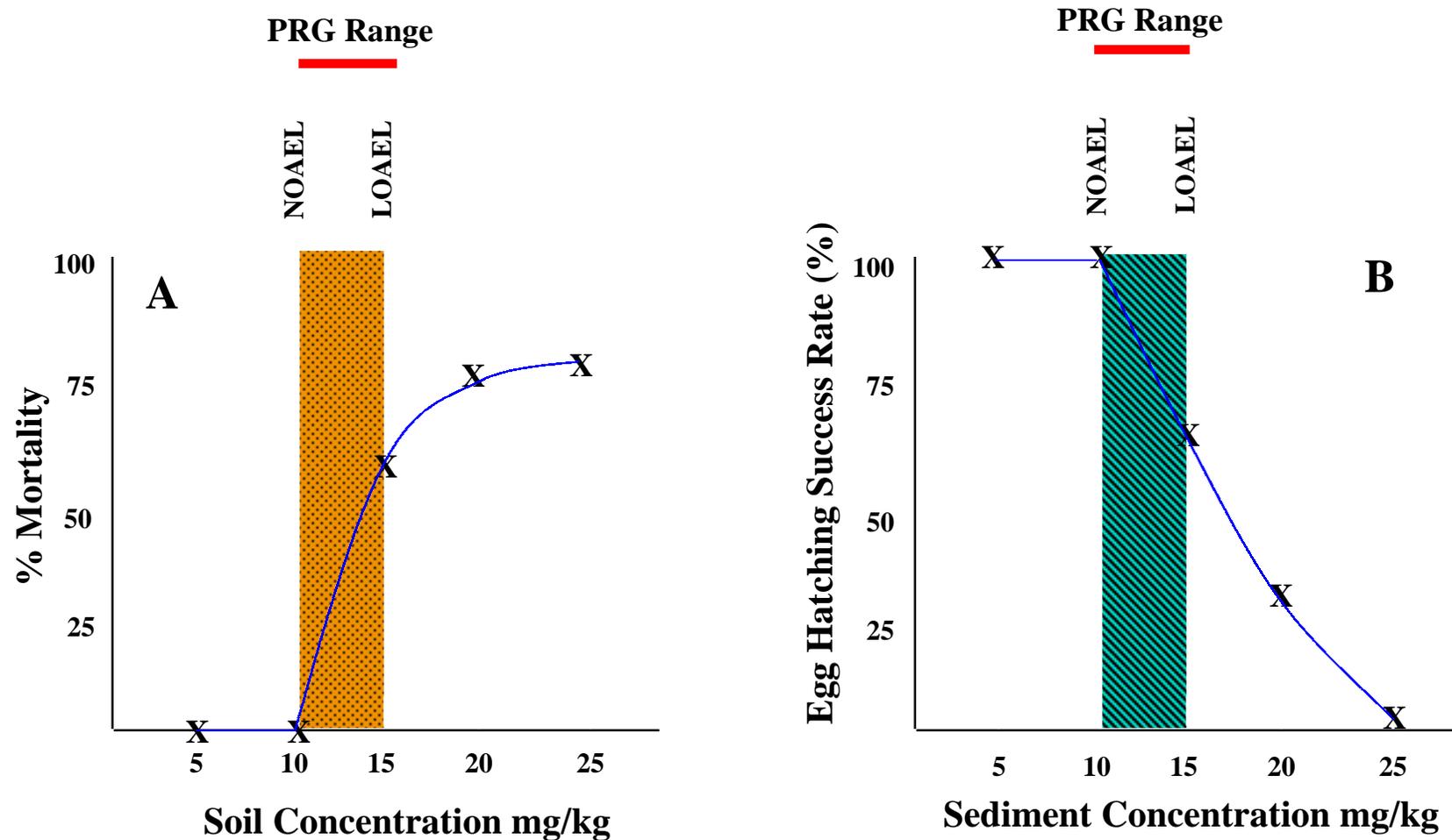
Regulator concurrence will be necessary before implementation of a monitoring program. Because the Navy risk assessment team and the regulators have been working together throughout the ERA process, there should be comparable understanding among all parties regarding the goals and objectives of the selected remedy. A similar understanding of the monitoring program will be necessary. To accomplish this understanding, the risk assessment team should clearly identify the goals, objectives, and exit criteria for the monitoring program, and provide all supporting information and rationale. This step is especially important for the exit criteria. Remember that the monitoring program must be scientifically defensible and have clearly identified goals and exit criteria.

Figure 4.1 Navy Ecological Risk Assessment Tiered Approach



Notes: 1) See EPA's 8 Step ERA Process for requirements for each Scientific Management Decision Point (SMDP).
 2) Refinement includes but is not limited to background, bioavailability, detection frequency, etc.
 3) Risk Management is incorporated throughout the tiered approach.

Figure 4.2 Use of Dose-Response Curves to Develop Preliminary Remediation Goals



In graph A, earthworm toxicity was evaluated along a soil contamination gradient. The concentration of 10 mg/kg was the highest concentration at which no adverse effects were observed, and this concentration represents the NOAEL. The concentration of 15 mg/kg represents the lowest soil concentration at which adverse effects were observed, and this concentration represents the LOAEL. In graph B, trout egg hatching success was evaluated along a sediment contamination gradient, and the sediment concentrations of 10 mg/kg and 15 mg/kg represent the NOAEL and LOAEL sediment concentrations, respectively. The site-specific PRGs for soil and sediment represent the concentration ranges between the NOAEL and LOAEL values.