Subject: Use of Risk-Based Numbers in the Remedial Response Process Overview

Introduction

The Division of Environmental Response and Revitalization (DERR) Risk Goal Workgroup was chartered by the DERR Issues Coordination Committee (ICC) to identify areas or methodologies within the remedial response process that may be affected by the use of a single excess lifetime cancer risk goal for human health and to provide a recommendation on a process to address those areas. Several values and processes were identified that could be impacted by the use of a single carcinogenic risk goal, rather than the risk range. In addition, several inconsistencies in terminology and practices were identified within the DERR Remedial Response program regarding the use of risk-based values. The following discussion identifies these values and provides a recommendation for a consistent approach for these areas or processes that may be affected by the use of a fixed excess lifetime cancer risk (ELCR) goal.

This Overview Paper does not address ecological risk-based levels in the remedial response process. For information on that, refer to the DERR Ecological Risk Assessment Guidance Document.

Background

The DERR has a number of tools available to the enforcement program. These include in part: 1) stand-alone interim actions or removals; and, 2) the traditional Remedial Investigation and Feasibility Study (RI/FS) and Remedial Design and Remedial Action (RD/RA) process, which may be federal-lead or state-lead (the latter with or without federal involvement).

Stand-alone interim actions or removals generally do not require comprehensive investigation or risk analysis such as those required with an RI/FS. The actions taken may or may not be considered a “final” remedy depending on site-specific circumstances and the scope of the action. These stand-alone interim or removal actions are distinct from the interim actions or removal actions conducted within the context of the RI/FS process (see Attachment A, #2).

The Remedial Investigation/ Feasibility Study (RI/FS) process represents the methodology that the Superfund program has established for characterizing the nature and extent of risks and hazards posed by uncontrolled hazardous waste sites and for evaluating potential remedial options. Per the National Contingency Plan (NCP), acceptable exposure levels for known or suspected carcinogens are generally concentration levels that represent an excess upper bound lifetime cancer risk to an individual of between 1E-4 and 1E-6 (*i.e.*, “risk range”) using information on the relationship between dose and response.

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Generally, the DERR Remedial Response Program has utilized the risk range defined within the NCP for site enforcement and cleanup decisions. DERR has adopted a cumulative, fixed excess lifetime cancer risk goal of 1E-5 see: Human Health Cumulative Carcinogenic Risk and Non-carcinogenic Hazard Goals for DERR Remedial Response and Office of Federal Facility Oversight.

Because a change in the risk goal may impact the selection or use of risk-based values used throughout an RI/FS (*e.g.*, screening levels, data quality objectives (DQOs), preliminary remediation goals etc.), the process was evaluated to identify key numerical values that may be used by various DERR personnel (Site Investigation Field Unit, risk assessors, site coordinators etc.). In addition, information on the use of remedial or cleanup values for other types of remedial actions (*e.g.*, interim actions, removals conducted within the RI/FS process) are briefly discussed in this document.

During the workgroup's initial discussions, it became clear that confusion was common with the terminology and uses of the various numerical values employed during the RI/FS process. Additionally, the source of the values lacked consistency. Various risk-based values including the U.S. EPA Region 3, Risk-based Concentrations (RBCs); U.S. EPA, Region 9 Preliminary Remediation Goals (PRGs); U.S. EPA Soil Screening Levels (SSLs); the Voluntary Action Program (VAP) generic numeric standards (GNS); as well as site-specific values based on Superfund guidance for developing remediation goals have been used, depending on the Site, personnel and the stage in the remedial response process.

Therefore, to facilitate a better understanding of the process, the workgroup developed/provided:

- a graphic representation of the general RI/FS process that identifies the terminology, locations, and uses of numerical values within the RI/FS process (Attachment A);
- a process overview and recommendations on appropriate use of the generic values (Attachment A);
- the definitions of commonly used terms (Attachment B); and,
- the rationale for the selection of the source of the generic values (Attachment C).

A summary of the recommendations is provided below:

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Recommendations Summary:
The Risk Goal work group recommends that when possible, all "generic" values (those not based on site-specific information) used in the human health risk evaluation process, be selected from the same source. By doing so, consistency within the remedial response process can be better achieved. The U.S. EPA Region 9 Preliminary Remediation Goals (Region 9 PRGs) are recommended by the Risk Goal Group as the source of the generic values. These values are "generic" as they are based on common U.S. EPA default exposure parameters, are conservative in nature, and therefore, would be appropriate for use, particularly if site-specific information is limited. Given that the Region 9 PRGs are derived using a single chemical hazard goal of 1 and a risk goal of 1E-6, some adjustment to the values may be necessary depending on the use of the values.

For screening purposes, (*e.g.*, screening compounds out of a human health risk assessment) it is recommended that the Region 9 PRGs be used at an order of magnitude below the DERR risk and hazard goals (*i.e.*, use the values cited in the Region 9 PRGs for compounds with a carcinogenic endpoint and, 1/10 the values for compounds with non-cancer endpoint). For other uses where generic target media concentrations are needed, (*e.g.*, interim stages in the remedial process where target cleanup concentrations are used), flexibility is required by the user(s). Some circumstances may necessitate the use of more protective values and therefore, the Region 9 PRGs based on 1/10 the DERR risk goal may be appropriate; in others, use of the Region 9 PRGS at the DERR risk goal would be adequate. See below for information on the suggested use of the Region 9 PRGs in the RI/FS process.

Clean-up values not based on the traditional RI/FS approach (*e.g.*, Source Control Interim Actions, (SCIAs)) should be evaluated to ensure that the remedy meets the DERR risk and hazard goals. Should generic values be used in the selection of remediation values, then the Region 9 PRGs equal to the risk and hazard goals should be used. For sites where multiple contaminants are a concern, an evaluation and adjustment (where needed) of the PRGs may be required to ensure that the site-wide risks and hazards to potential receptors meets the DERR risk goal.

Site-specific cleanup or remediation values (those developed following the completion of the baseline risk assessment, *e.g.*, site-specific PRGs, or those identified in the Decision Document, respectively) should be developed for individual compounds at the DERR risk and hazard goal (*i.e.*, 1E-5 excess lifetime cancer risk and non-cancer hazard of 1). These site-specific PRGs/chemical-specific remedial objectives are media and chemical-specific goals that should also be evaluated and adjusted, as appropriate, to account for exposure to multiple compounds. This evaluation and potential adjustment(s) is site-specific and is determined based on the expected exposures and associated risks for the selected cleanup alternative.

Attachment A: Process Overview

Attachment A provides an overview of the RI/FS process with a focus on the use of human health risk-based values within that process. Figure 1 and the following discussions based on the diagram should help to familiarize and standardize the terminology of numeric values used in the RRP. It is assumed that the basic RI/FS process is understood, as minimal specifics regarding the process are given in the following text. The risk goal workgroup also presents their recommendations in the discussions as to the source and use of values to be used in the RRP.

General caveat:
The information provided below is specific to the changes that should be made to the values used in the current RI/FS process due to the selection of the fixed 1E-5 ELCR goal. Issues such as the identification and selection of ARARs, leaching to ground water evaluations, development of PRGs or clean-up values for sediments or surface waters, and the development of PRGs based on potential exposures to ecological receptors, have not been addressed. The decision to employ a fixed human health ELCR goal generally would not impact these topics or procedures. The methods presently employed to address these topics and procedures should be continued in their current forms.

In addition, the recommendation to use the U.S. EPA Region 9 PRGs in some form may or may not be used for the evaluation or remediation of media associated with spills or other emergency response actions. The risk goal workgroup did not consider these activities or the application of the Region 9 PRGs to these types of situations. It does however seem like a logical and consistent use of the values if they are applied to these situations.

Figure 1.
Identification of Risk-Based Values used in the Remedial Response/CERCLA Process

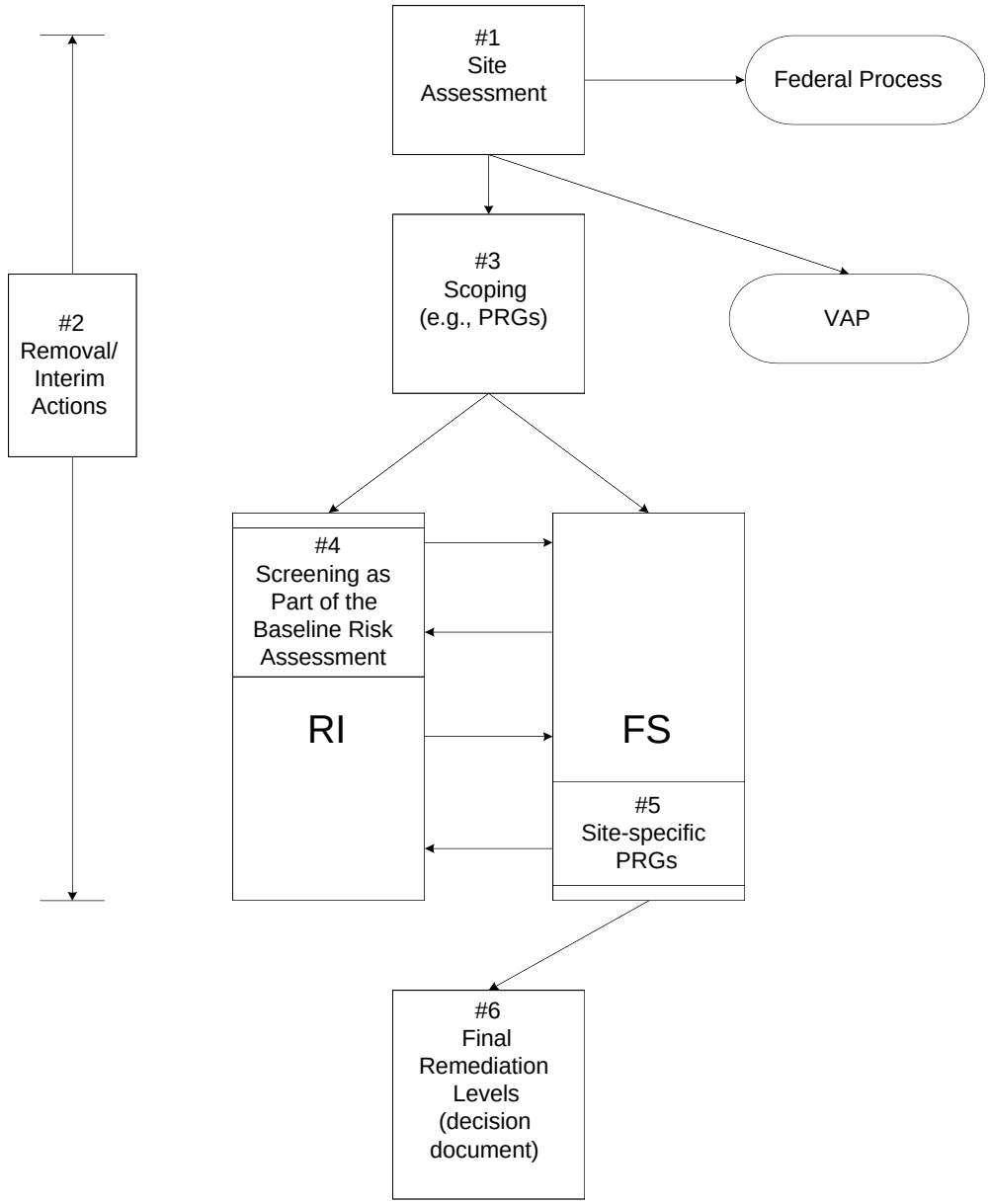

Figure 1 identifies areas within the remedial response program from site discovery to the decision document, where numeric risk-based values are needed or used in the decision making process. The focus in the figure is on the human health evaluation in the State process. However, the figure may also be applicable to Federal sites. The following sections are numbered consistently with Figure 1 and include further explanation of the selection and use of the values. For information on how ecological risk-based values are used, refer to the DERR Ecological Risk Assessment Guidance Document.

Numbers Used in the Remedial Process

Below is a discussion of the utility and appropriate use of human health risk-based numbers at different stages in the RRP. To facilitate appropriate use, the minimum level of site information that is necessary to use the numbers is also discussed. Generally, for screening purposes in the baseline risk assessment or to ensure that chemical analytical methods are sensitive enough that data can be screened and be useful in the baseline risk assessment, the Region 9 PRGs should be used at an order of magnitude below the DERR risk and hazard goals (*i.e.*, use the values cited in the Region 9 PRGs for compounds with a carcinogenic endpoint and 1/10 the values for compounds with non-cancer endpoint).

For other values used in the RI/FS process that rely upon generic values, the Region 9 PRGs should be used at the DERR risk and hazard goal (1E-5 excess lifetime cancer risk and non-cancer hazard of 1).

1) Site Assessment:

Purpose:

Screening values are often used in the site assessment process to help prioritize projects, and determine the likely path a site might take to address possible contamination (*e.g.*, Federal or State referral, Voluntary Action Program (VAP), targeted brownfield assessment, etc.). Some screening values are also necessary as part of the PreCERCLIS evaluation, as well as in other pre-remedial site assessments, such as Integrated Assessments to evaluate the threat posed by the site as part of process leading to Federal oversight of an RI/FS.[1] A variety of values have been used in the site assessment process. These values are essentially the same list of values that were identified above with the addition of the Voluntary Action Program (VAP), generic numerical standards (GNS). This includes the use of the VAP- GNS as a basis of a No Further Remedial Action Planned (NFRAP) decision or discontinuation of the evaluation of a site.

Level of site information required:

Site assessments are conducted prior to a detailed site investigation and baseline risk assessment or the development of remedial goals for the site. The level of site-specific information on the nature and extent of contaminants of concern is often variable or limited.

[1] A separate evaluation of site-related releases is conducted comparing site concentrations to background concentrations when the site is scored using the Hazard Ranking System (HRS) in the Federal process. The HRS Scoring occurs later in the Pre-Remedial process, when the site is evaluated for inclusion in the National Priority List (NPL).The HRS scoring procedure does not use "generic" values, but does use values that are related to the toxicity and concentration of the compounds. These values are contained within the scoring software and generally cannot be altered by the users.

Recommendation:
For site assessments that employ human health risk-based values, it is recommended that the U.S. EPA Region 9 PRGs be used at an order of magnitude below the DERR risk goal (ELCR 1E-5, HQ, HI =1). Specifically, the "screening" value for each chemical of concern would be 1/10 the residential PRG listed on the table for non-carcinogenic compounds and the value for carcinogenic compounds. This recommendation is based on the fact that the full nature and extent of contamination, media impacted and receptors exposed may not be known at this stage. Therefore, to be protective of human receptors exposed to multiple contaminants, an adjustment is recommended. Flexibility in adjusting the PRGs is possible at sites with a single or few contaminants; the goal is to ensure that at the end of the site assessment process, an appropriate decision (*e.g.*, "No Further Remedial Action Planned", low priority, or high priority) is made for the site.

Note: This recommendation should also be evaluated by Site Assessment Workgroup(s) to ensure that this approach would be appropriate for other evaluations such as targeted brownfield assessments.

2) Removal Actions, Interim Actions (RA, IA)

Section 2 identifies interim actions that may be taken throughout the RI/FS process. This is indicated in the figure by the line that runs throughout the RI/FS process. Interim actions or removal actions are taken when a threat is identified that needs to be addressed prior to the completion of the RI/FS. These actions may be time-critical (needing attention within six months), non-time critical (greater than six months is acceptable for the action), or an emergency (within hours of the identification of the threat) depending on the urgency of the response. These actions are intended to manage, eliminate or mitigate the threat or potential exposure(s) to contaminants or other hazards until such time as the RI/FS can be completed and a final remedy is selected for the site. Often, risk-based values are not needed for these actions. For example, individuals may have their drinking water supplies switched to one that is not affected by the site following the identification of contaminants in the water supply. Also, limited removals of contaminated media may be required to contain the contamination or to ensure that additional media are not contaminated.

Level of site information required:
These removal or interim actions are generally taken without the completion of a baseline risk assessment or the development of remedial goals based on site specific information (generally the baseline risk assessment is being conducted when the removal or interim action is taken). The level of site information may range from minimal to extensive, but should be sufficient to support the removal or interim actions taken.

Recommendation:
In the few cases where risk-based values are needed to complete an interim action, then it is recommended that the U.S. EPA Region 9 Preliminary Remediation Goals (PRGs) be used at the risk and hazard goals without the need for multiple chemical adjustment. Specifically, the value for each chemical of potential concern would be the residential PRG listed on the table for non-carcinogenic compounds and 10 times the value for carcinogenic compounds. A risk assessment based on the residual contamination is generally completed following the removal or interim actions as part of the RI/FS process.

3) Scoping:

Purpose:
Scoping is the initial planning phase of the RI/FS process. Some numeric values are used in the scoping process to assist with various aspects of site evaluation (*e.g*., data collection and evaluation, the Data Quality Objectives (DQOs), Preliminary Remediation Goals (PRGs) etc.), initial remedial alternatives selection and for various decision making steps throughout the completion of an RI/FS. Values are used, for example, to help determine the minimum detection limits required for analytical methods here and in some cases to aid in defining the extent of contamination at a site.

PRGs are developed as part of the scoping process. PRGs support the RI/FS in a variety of ways (*e.g.*, ensure that the FS is being completed concurrently with the RI, all appropriate remedial options are evaluated, the volumes of contaminated media can be estimated etc.). The PRGs are re-evaluated as site characterization data and information from the baseline and ecological risk assessments become available (generally following the completion of the risk assessments).

Level of site information required:
The level of site information at this stage is at times limited, and the full nature and extent of contamination is often not known.

Recommendation:
The numeric values used in the scoping process are a function of the manner in which the data will be used. For example, if a screening step in the baseline risk assessment using risk-based values (see #4 below) is anticipated, then analytical detection limits need to be at or below these levels when ever possible. In other cases (*e.g*., if there is only a single chemical of concern, or the values are being used to estimate the extent of contamination), the PRG may be used at the DERR the risk and hazard goal. The use of the DQO process should help ensure that data are of acceptable quality for the intended purposes of those data.

Also, PRGs may not be available for all media of concern (example, indoor air or fish tissue concentrations), or all receptors of concern (example, recreational users). These types of issues should be discussed and be agreed upon by the site management team prior to extensive sampling and analysis of a site when the sampling and analysis plan (SAP) is developed.

4) Baseline Risk Assessment Screening Values:

Purpose:
A risk-based screening step as part of the baseline human health risk assessment may be used for reducing the numbers of chemicals evaluated in the risk assessment (*i.e.*, chemicals with identified concentrations below a level of concern may be excluded from further evaluation). Therefore, the purpose of the screening step is simply to focus the baseline risk assessment on the primary contaminants of concern at the Site in each specific exposure medium of concern.

Level of site information required:
At the screening stage of the human health risk assessment, site-specific information necessary to complete the human health baseline risk assessment should be available. This includes information on impacted media, the nature and extent of contamination, identification of current and potential receptors or populations etc.

Recommendation:
It is recommended that the U.S. EPA Region 9 PRGs be used with an adjustment (1/10 the values based on non-cancer effects). Specifically, the remediation goal for each chemical of concern would be the residential value listed on the PRG table for carcinogenic compounds and 1/10 the value for non-carcinogenic compounds. Please see Use of U.S. EPA's Screening Levels as Screening Values in Human Health Risk Assessments for additional details.

5) Site-specific PRGs:

Purpose:
Site-specific PRGs are the result of the initial PRGs that have been modified or re-calculated based on the values and assumptions used in the baseline risk assessments and any other pertinent information from the completed site investigation (RI). These values are not considered generic as site-specific data are used in their derivation. These values are to be used when the remedial alternatives are evaluated using the remedy selection criteria identified in the NCP, and at a minimum, these PRGs must meet the "threshold criteria" of (1) protection of human health and the environment and (2) compliance with ARARs (*e.g.*, surface water standards, MCLs).

Level of site information required:
At this stage, the risk assessments are complete. All impacted media, chemicals of concern, and receptors populations have been evaluated to the extent necessary to support a remedy.

Recommendation:
Using the PRGs (# 3 above) and other information, site, chemical and media specific remediation goals (note: these may be incorporated into the remedial action objectives) are evaluated and developed to be used in the early stages of the FS. These site-specific PRGs are developed using the RAGS approach of rearranging the risk assessment equations to derive remedial goals based on a desired risk and hazard goal (*e.g.*, 1E-5 excess lifetime cancer risk goal and hazard goal of 1). These values should also be discussed and approved by the site management team prior to use. Following the completion of the site-specific PRGs/remedial action objectives, these values are then used in the development and selection of the potential remedial alternatives. The existing CERCLA methodology is recommended for remedy selection in conjunction with the DERR Risk Goal TDC for defining acceptable exposures.

6) Final Remediation Levels:

Purpose:
Final remediation levels are determined as part of the selection of the site remedy. They are to be evaluated based on the potential exposure to multiple compounds that may exist following the implementation of the selected remedy. These values have been refined throughout the process leading up to remedy selection, have been evaluated in conjunction with the various remedial options retained following the detailed analysis of alternatives, and have been offered to the public via the preferred plan and revised as appropriate based on their comments. Once finalized, the values are memorialized in the decision document for the site.

Level of site information required:
The RI/ FS is complete and approved, the preferred plan has been developed and revised based on comments by the public.

Recommendation:
The existing process used for remedy selection and the determination of final remediation levels should be used with the incorporation of the DERR Risk Goal TDC. The NCP also allows for modification of the PRGs during the final remedy selection based on “balancing” and “modifying” criteria and factors relating to uncertainty, exposure, and technical feasibility (section 1.5, RAGS volume 1, Part B, Development of Risk-based Preliminary Remediation Goals, EPA/540/R-92/003). The existing CERCLA guidance (OSWER directive Role of the Baseline Risk Assessment in Superfund Remedy Selection Decision, OSWER

Directive 9355.0-30) should also be used with a modification from a 1E-4 to a 1E-5 excess lifetime cancer risk goal. For ground water, the current approach identified in the NCP regarding MCLs (NCP 300.430(e)(2)(i)(B) through (D)) and remediation goals shall be used with the substitution of the 1E-5 value to replace the 1E-4 value.

Attachment B: Commonly Used Terms Associated with Risk-Based Values used in the CERCLA/Remedial Response process

1) Acceptable exposure levels (Risk Goal):
The National Contingency Plan (NCP) defines the acceptable exposure levels as: “(f)or known or suspected carcinogens acceptable exposure levels are generally concentration levels that represent an excess upper bound lifetime cancer risk to an individual of between 10^{-4} and 10^{-6} using information on the relationship between dose and response" (NCP §300.430(e)(2)(i)(A)(2)). This is the definition most associated with the term risk range and "risk goal"and has to be altered to be consistent with the 1E-5 risk goal as adopted by DERR.

For systemic non-carcinogenic toxicants, the NCP states that “acceptable exposure levels shall represent concentration levels to which the human population, including sensitive subgroups, may be exposed without adverse effects during a lifetime or part of a lifetime, incorporating an adequate margin of safety” NCP §300.430.(e)(2)(i)(A)(1). U.S. EPA Guidance for Superfund (RAGS, vol 1 part A, Human Health Evaluation Manual (EPA/540/1-89/002) and RAGS vol 1 part B, Development of Risk-based Preliminary Remediation Goals (EPA/540/R-92/003)) further defined the non-cancer hazard goal as the HQ or HI equal to one.

The DERR Remedial Response program has adopted a human health cumulative excess lifetime carcinogenic risk goal of 1E-5 and a cumulative non-cancer hazard equal to a hazard index (HI) of 1, for all receptors and land uses. Using the carcinogenic risk and non-cancer hazard goals and other site-specific information (*e.g.*, baseline risk assessment, technical and economic feasibility, long-term and short-term effectiveness, etc.), the risk manager(s) shall select an appropriate remedy for the site. The defined risk goal should be applied as a *goal*, recognizing the need to retain flexibility during the evaluation of remedial alternatives within the feasibility study and the final remedy selection.

2) Point of Departure:
The NCP defines the point of departure and states: “(t)he 10-6 risk level shall be used as the point of departure for determining remediation goals for alternatives when ARARs are not available or are not sufficiently protective because of the presence of multiple contaminants at a site or multiple pathways of exposure" NCP 300.430 (e)(2)(i)(A)(2). The point of departure is used to derive PRGs for use in the FS with the understanding that U.S. EPA prefers that clean-ups be completed at the more protective end of the risk range (*i.e.*, 1E-6 ELCR). This approach also helps ensure that when multiple compounds are present at a site that the site-wide risk falls within the acceptable risk range.

The concept of a point of departure for determining potential remedial goals does not generally apply once a decision is made on the use a fixed risk goal. The remedial cleanup values are generally developed based on the desired goal and adjusted to ensure that once the remedy is complete, the site will meet the intended risk goals. Therefore, the 10^{-5} risk level and the non-cancer hazard goal of 1 shall be used as value for determining remediation goals for alternatives when ARARs are not available or sufficiently protective. These remediation goals are consistent with the site-specific remediation goals or chemical-specific remedial action objective developed following the completion of the baseline risk assessment (# 6 in Attachment A).

3) Preliminary Remediation Goals (PRGs):
PRGs are initial chemical specific, individual clean-up goals that (1) are protective of human health and the environment and (2) comply with ARARs. They are developed early in the process based on generic information and are modified to reflect the results of the baseline risk assessment. In general, PRGs provide remedial design staff with targets to use during analysis and selection of remedial alternatives (RAGS B, 1991).

Recently, confusion has been raised by the use of the Region 9 PRGs as part of a step in the baseline risk assessment process for reducing the numbers of chemicals evaluated in the assessment. The data evaluation process in RAGS A identifies various methods to reduce the number of compounds evaluated (*e.g.*, frequency of detection, background). With the publication of the Region 9 PRG tables, Region 9 (and other Regions) allows the screening of potential chemicals of concern from further evaluation in the human health baseline risk assessment if concentrations are below the PRGs. This presumably is based on text that states: "(t)he PRG concentrations presented in the table can be used to screen pollutants in environmental media, trigger further investigation, and provide initial cleanup goal if applicable." (Introduction of communication from Standford Smucker, U.S. EPA Regional Toxicologist to PRG mailing list, titled: Region 9 Preliminary Remediation Goals (PRGs) 1999). The Risk Goal workgroup has tried to clarify the issue in the Overview paper.

4) Final Remediation Levels:
Final remediation levels are chemical-specific clean-up levels that are documented in the decision document. They may differ from preliminary remediation goals (PRGs) or site-specific PRGs because of modifications resulting from the consideration of various uncertainties, technical and exposure factors, as well as all remedy selection criteria outlined in the National Oil and Hazardous Substances Pollution Contingency Plan (NCP) (RAGS Part B, section Definitions, 1991). In the ROD, it is preferable to use the term "remediation level" rather than "remediation goal"in order to make clear that the selected remedy establishes binding requirements (RAGS B, section 1.5, 1991).

Attachment C: Rationale for Selection and Adjustment of Values

Given that several sources of values are available for application in the remedial response process, and that most have been used to some extent, the Risk Goal workgroup evaluated the commonly used resources as part of making its recommendations. Specifically, the U.S. EPA, Region 3 Risk-Based Concentration Table (RBC), Region 9 Preliminary Remediation Goals (PRGs), Waste Management Clean-Up Program subcommittee (WMCUPs) and Ohio EPA, DERR, VAP Generic Numerical Standards (GNS) were evaluated in some detail. The Region 3 RBCs were initially eliminated based on the fact that unlike the other sources, the values do not include dermal exposures. The WMCUPs values were, in part, eliminated owing to the status of that workgroup and work product, although they were evaluated for comparison purposes.

The main debate for the source of values was between the VAP GNS and the U.S. EPA Region 9 PRGs. To facilitate the selection, the Risk Goal group prepared a “Pros and Cons” table (Table 1) to identify key differences between the two sources of values. A comparison table (Table 3) was also made to quantitatively estimate the differences between the sets of values.

The key criteria for the Risk Goal group that support the selection of the U.S. EPA Region 9 PRGs are: greater consistency with the CERCLA process, greater number of chemicals with values, more frequent updates, and that DERR Remedial Response has more consistently accepted the Region 9 PRGs for sites in the Remedial Response Program. These points are further presented in Table 1.

In general, the values (VAP GNS and Region 9 PRGs) are not that different when the adjustment to the risk goal is made (generally, VAP values are approximately 2-5 times greater than the Region 9 PRGs, (see Table 3)). This may be the result of the use of the FI term that is part of the VAP GNS calculation. While this may be consistent with the approach that is used for site evaluation (sampling and determination of exposure point concentration) within the VAP process, the Risk Goal group concluded that an FI of 1 is more appropriate for generic use (although it can be altered on a site-specific basis) in the Remedial Response Program, as the investigation methods are slightly different within the RI/FS process. Further, for some volatile organic compounds (VOCs), the VAP GNS exceed the Region 9 PRGs by approximately an order of magnitude. This is largely due to the route-to-route extrapolation approach that U.S. EPA Region 9 used to estimate exposures via the inhalation pathway and changes in toxicity criteria since the last VAP rule revision. The approach used to develop the VAP GNS did not use the blanket extrapolation methodology but evaluated the compounds individually to determine an appropriate method for evaluation and subsequent generic standard derivation. Given all of the data on the two sources of values, the Risk Goal group selected the U.S. EPA Region 9 PRGs as the preferred source.

After an evaluation of the screening process and the Remedial Response Process as a whole, the general recommendation of Risk Goal work group is to use the U.S. EPA Region 9 PRGs. These values are also to be adjusted as described above for non-carcinogenic compounds when generic values are needed. This general recommendation carries a caveat however, that identifies that flexibility is needed and site-specific information may necessitate the adjustment of the Region 9 PRGs at one or multiple points in the process to ensure that the site is health protective. This is a decision that would be made by the site management team.

Table 1. Pro and Con Information for the Use of U.S. EPA Region 9 PRGs and the VAP Generic Numerical Values as "Source" values

VAP Standards		**Region 9 PRGs**	
Pro	Con	Pro	Con
Promulgated rules for Ohio ("legally safe" levels under VAP guidelines)			Not promulgated (general guidance)
	Fewer chemicals (~120) with values than Region 9 PRGs	More values (~280) than VAP	
	Maintained by Ohio EPA	Maintained outside of OEPA (Greater and specific resources dedicated to maintenance and updates by U.S. EPA)	
	Updates are less frequent (every 5 years based on Statutes)	Updated more frequently (*i.e.*, annually)	
	Do not have pathway specific values available	Pathway specific values available (not known if frequently used)	
	Less specific to CERCLA sites (sampling considerations built into standards (e.g., use of the FI term))	More closely follow CERCLA process	
	Less use outside of Ohio	Generally accepted throughout the USA and history of use within Remedial Response Program	

The Region 9 PRGs are calculated based on an excess lifetime cancer risk goal of 1E-6 (an order of magnitude below the DERR risk goal of 1E-5) and a hazard quotient equal to 1 (same hazard level as DERR). Based on the two site-specific examples presented in the Risk Goal Group meeting, all approaches were considered protective and would likely not impact the decisions made at most sites. The group could not come to a unanimous decision. Therefore, a vote was taken to decide the issue of adjustment of the U.S. EPA Region 9 PRGs. Results of the voting were as follows:

1 vote for PRGs with no adjustment
3 votes for 1/10 risk goal (adjusting the Region PRG non-cancer values by 1/10)
1 vote for multiple chemical adjustment below the risk goal

The group therefore decided, based on the majority vote, to adjust the Region 9 PRGs so that they are at an order of magnitude below the DERR Risk Goal, when used for screening. This recommendation is reflected in the Overview paper and screening TDC.

Table 2. Options and Pros and Cons of Adjusting the Region 9 PRGs for Use in the Remedial Response Process (for screening purposes)

Option #1 Values at DERR Risk Goal without MCA[1]		**Option #2 Values at DERR Risk Goal with MCA**		**Option #3 Values @ 1/10 DERR Risk Goal without MCA**		**Option #4 Region 9 PRGs as given by U.S. EPA (*i.e.*, 1E-6 cancer risk goal and HQ =1)**		***Option #5 No Screening or Use of Generic Values***	
Pro	***Con***	***Pro***	***Con***	***Pro***	***Con***	***Pro***	***Con***	***Pro***	***Con***
Consistent with U.S. EPA PRG methodology, may not be consistent with screening in baselineRA	*Would require adjustment to Region 9 PRG cancer values (x 10)*	*Most precise method for addressing cumulative chemical exposure*	*Slightly more time consuming.*	*More protective than no adjustment*	*Not as precise or protective with many detected compounds (>10)*	*Easiest to use (no adjustment to Region 9 PRG tables required)*	*Public perception of greater protection from carcinogens but not from non-carcinogens (ease of explanation)*	*Most protective*	*No generic values available as a resource to focus site assessment and for PRGs*
	Does not consider cumulative risks and hazards		*less user friendly*	*Consistent with some past screening approaches*	*Would require adjustment to Region 9 non-cancer values (1/10)*	*consistent with U.S. EPA methodology using full risk range*	*does not consider exposure to multiple non-carcinogens*		
can be used for site assessment			*not usable for site assessment*	*can be used for site assessment*		*can be used for site assessment*			
				Public perception of greater protection/ ease of explanation					

[1] *MCA= multiple chemical adjustment. This adjustment is made to account for the effects as the result of exposures to multiple contaminants. This procedure may or may not be based on toxic endpoints of the chemicals under evaluation and involves an adjustment to the values based on the numbers of compounds being evaluated.*

Table 3. Comparison of VAP GNS and Region 9 PRGs Adjust to an ELCR of 1E-5

Chemical	CAS Number	VAP NonCancer (mg/kg)	Region 9 NonCancer (mg/kg)	Region 9: VAP	Residential Soil Std VAP Cancer (mg/kg)	Region Cance (mg/k
Ethylbenzene	100-41-4	1.5E+03	1.9E+03	1.243	NA	8.9E+(
Styrene	100-42-5	4.6E+03	4.4E+03	0.953	NA	NA
Heptachlor Epoxide	1024-57-3	1.0E+00	7.9E-01	0.793	1.2E+00	NA
Dimethylphenol, 2,4 -	105-67-9	1.5E+03	1.2E+03	0.815	NA	NA
Dichlorobenzene, 1,4 - (p)	106-46-7	1.6E+03	4.8E+02	0.302	9.5E+01	3.4E+(
Dichloroethane, 1,2 -	107-06-2	1.7E+03	8.5E+00	0.005	1.0E+01	2.8E+(
Acrylonitrile	107-13-1	4.3E+00	7.3E+00	1.696	3.7E+00	2.1E+(
Ethylene Glycol	107-21-1	1.5E+05	1.2E+05	0.815	NA	NA
Vinyl Acetate	108-05-4	4.1E+02	4.3E+02	1.038	NA	NA
Methyl Isobutyl Ketone (MIBK)	108-10-1	7.0E+02	7.9E+02	1.124	NA	NA
Trimethylbenzene, 1,3,5	108-67-8	1.9E+01	2.1E+01	1.119	NA	NA
Toluene	108-88-3	5.9E+02	6.6E+02	1.112	NA	NA
Chlorobenzene	108-90-7	1.5E+02	1.5E+02	1.004	NA	NA
Phenol	108-95-2	4.6E+04	3.7E+04	0.797	NA	NA
Hexane, *n* -	110-54-3	7.1E+01	1.2E+02	1.701	NA	NA
Pyridine	110-86-1	7.7E+01	6.1E+01	0.794	NA	NA
Bis (2-ethylhexyl) Phthalate(BEHP & DE	117-81-7	1.5E+03	1.2E+03	0.815	7.6E+02	3.5E+(
Octyl Phthalate, di(*n*) -	117-84-0	1.5E+03	2.4E+03	1.629	NA	NA
Hexachlorobenzene	118-74-1	6.2E+01	4.9E+01	0.788	6.9E+00	3.0E+(
Anthracene	120-12-7	2.3E+04	2.2E+04	0.952	NA	NA
Dinitrotoluene, 2,4 -	121-14-2	1.5E+02	1.2E+02	0.815	NA	NA
Dioxane, 1,4 -	123-91-1	NA	NA		9.8E+02	4.4E+(
Dibromochloromethane	124-48-1	1.5E+03	3.8E+02	0.255	1.3E+02	1.1E+(
Tetrachloroethene	127-18-4	2.6E+02	3.6E+02	1.397	1.3E+02	1.5E+(
Chlordane	12789-03-6	3.4E+01	3.5E+01	1.034	2.8E+01	1.6E+(
Pyrene	129-00-0	1.7E+03	2.3E+03	1.362	NA	NA
Xylenes, Total	1330-20-7	6.6E+02	2.7E+02	0.417	NA	NA
Polychlorinated Biphenyls	1336-36-3	1.1E+00	NA		3.8E+00	2.2E+(
Dichloroethene, *cis* - 1,2	156-59-2	7.6E+02	4.3E+01	0.057	NA	NA
Dichloroethene, *trans* - 1,2 -	156-60-5	1.5E+03	6.9E+01	0.046	NA	NA
Chromium (III)	16065-83-1	1.2E+05	1.2E+05	0.977	NA	NA
Methyl *tert* - Butyl Ether (MTBE)	1634-04-4	5.3E+03	5.7E+03	1.085	NA	6.2E+(
Chromium (VI)	18540-29-9	2.3E+02	2.2E+02	0.970	6.6E+03	3.0E+(
Indeno(1,2,3-c,d)pyrene	193-39-5	NA	NA		1.1E+01	6.2E+(
Benzo(b)fluoranthene	205-99-2	NA	NA		1.1E+01	6.2E+(

Benz(a)anthracene	56-55-3	NA	NA		1.1E+01	6.2E+0
Lindane	58-89-9	2.1E+01	2.1E+01	1.005	7.6E+00	4.4E+0
Dinitrotoluene, 2,6 -	606-20-2	7.6E+01	6.1E+01	0.804	NA	NA
Aniline	62-53-3	5.8E+00	4.3E+02	73.694	1.9E+03	8.5E+0
Tetrachloroethane , 1,1,1,2 -	630-20-6	2.3E+03	5.2E+02	0.224	9.5E+01	3.2E+0
Formic acid	64-18-6	1.5E+05	1.2E+05	0.815	NA	NA
Methanol	67-56-1	3.8E+04	3.1E+04	0.804	NA	NA
Acetone	67-64-1	7.3E+03	1.6E+03	0.215	NA	NA
Chloroform	67-66-3	1.1E+02	3.6E+00	0.032	7.3E+00	NA
Hexachloroethane	67-72-1	7.7E+01	6.1E+01	0.794	7.9E+02	3.5E+0
Benzene	71-43-2	9.8E+00	7.1E+00	0.724	6.7E+01	6.0E+0
Trichloroethane, 1,1,1 -	71-55-6	9.9E+02	2.0E+03	2.002	NA	NA
Endrin	72-20-8	2.3E+01	1.8E+01	0.797	NA	NA
Methoxychlor	72-43-5	3.9E+02	3.1E+02	0.783	NA	NA
Dichlorodiphenyldichloroethane (DDD)	72-54-8	NA	NA		4.1E+01	2.4E+0
Dichlorodiphenyldichloroethene (DDE)	72-55-9	NA	NA		2.9E+01	1.7E+0
Aluminum	7429-90-5	7.5E+04	7.6E+04	1.015	NA	NA
Mercury	7439-97-6	7.8E+00	2.3E+01	3.008	NA	NA
Silver	7440-22-4	3.9E+02	3.9E+02	1.003	NA	NA
Thallium	7440-28-0	6.2E+00	5.2E+00	0.833	NA	NA
Antimony	7440-36-0	3.1E+01	3.1E+01	1.009	NA	NA
Arsenic, Inorganic	7440-38-2	2.2E+01	2.2E+01	0.984	6.8E+00	3.9E+0
Barium and Compounds	7440-39-3	5.4E+03	5.4E+03	0.995	NA	NA
Beryllium and Compounds	7440-41-7	1.5E+02	1.5E+02	1.029	3.3E+04	1.1E+0
Cadmium	7440-43-9	3.5E+01	3.7E+01	1.058	4.4E+04	1.4E+0
Cobalt	7440-48-4	1.4E+03	1.4E+03	0.986	NA	9.0E+0
Vanadium	7440-62-2	7.0E+02	5.5E+02	0.782	NA	NA
Zinc and Compounds	7440-66-6	2.3E+04	2.3E+04	1.020	NA	NA
Vinyl Chloride	75-01-4	3.8E+01	3.9E+01	1.019	3.7E+00	7.9E-0
Methylene Chloride	75-09-2	1.9E+03	2.0E+03	1.028	2.5E+02	9.1E+0
Carbon Disulfide	75-15-0	3.5E+02	3.6E+02	1.015	NA	
Dichloroethane, 1,1 -	75-34-3	5.8E+02	5.1E+02	0.873	NA	NA
Dichloroethene, 1,1 -	75-35-4	6.8E+02	1.2E+02	0.182	1.6E+00	NA
Trichlorofluoromethane	75-69-4	4.9E+02	3.9E+02	0.787	NA	NA
Dichlorodifluoromethane	75-71-8	1.2E+02	9.4E+01	0.782	NA	NA

Toxaphene	8001-35-2	NA	NA		1.0E+01	4.4E+0
Acenaphthene	83-32-9	4.6E+03	3.7E+03	0.800	NA	NA
Diethyl Phthalate	84-66-2	6.1E+04	4.9E+04	0.801	NA	NA
Di-n-butyl Phthalate	84-74-2	7.6E+03	6.1E+03	0.804	NA	NA
Butyl Benzyl Phthalate	85-68-7	1.5E+04	1.2E+04	0.815	NA	NA
Nitrosodiphenylamine, *n* -	86-30-6	NA			2.2E+03	9.9E+0
Fluorene	86-73-7	3.1E+03	2.7E+03	0.886	NA	NA
Carbazole	86-74-8	NA	NA		5.3E+02	2.4E+0
Hexachloro- 1,3 - Butadiene	87-68-3	1.5E+01	1.8E+01	1.222	1.4E+02	6.2E+0
Pentachlorophenol	87-86-5	1.3E+03	1.4E+03	1.062	5.1E+01	3.0E+0
Trichlorophenol, 2,4,6 -	88-06-2	NA	6.1E+00		1.0E+03	4.4E+0
Methylnaphthalene, 1 -	90-12-0	5.4E+03	NA		NA	NA
Naphthalene	91-20-3	5.4E+01	5.6E+01	1.035	NA	NA
Dichlorobenzidine, 3,3 -	91-94-1	NA	NA		2.4E+01	1.1E+0
Benzidine	92-87-5	2.3E+02	1.8E+02	0.797	4.7E-02	2.1E-0
Silvex (2,4,5 TP)	93-72-1	6.2E+02	4.9E+02	0.788	NA	NA
Dichlorophenoxyacetic acid, 2,4 -	94-75-7	7.6E+02	6.9E+02	0.903	NA	NA
Dichlorobenzene, 1,2 -	95-50-1	1.5E+02	1.1E+03	7.355	NA	NA
Trimethylbenzene, 1,2,4	95-63-6	2.2E+01	5.2E+01	2.346	NA	NA
Trichlorophenol, 2,4,5 -	95-95-4	7.7E+03	6.1E+03	0.794	NA	NA
Trichloropropane, 1,2,3 -	96-18-4	4.5E+02	3.3E+00	0.007	1.5E+00	5.0E-0
Isopropylbenzene (Cumene)	98-82-8	1.8E+03	5.7E+02	0.318	NA	NA