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A STRATEGY FOR END POINT CRITERIA FOR SUPERFUND REMEDIATION

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A Strategy for End Point Criteria for Superfund Remediation

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INTRODUCTION

Since the inception of cleanup for hazardous waste sites, estimating target cleanup levels has been the subject of considerable investigation and debate in the Superfund remediation process. Establishing formal procedures for assessing human health risks associated with hazardous waste sites has provided a conceptual framework for determining remediation goals and target cleanup levels (TCLs) based on human health and ecological risk consideration. This approach was once considered at variance with the concept of the pre-risk assessment period; that is, cleaning up to the background level, or using containment design or best available control technologies. The concept has been gradually adopted by the regulatory agencies and the parties responsible for cleanup.

In the early stage of the concept, the U.S. Environmental Protection Agency (EPA)[1] developed advisory levels for cleanup at hazardous waste sites contaminated with polychlorinated biphenyls (PCBs). The development of the advisory levels was one of the first attempts to set the remediation objectives based on the goal of protecting public health from exposure to the contaminants released into the environment. Subsequently, EPA[2] used similar approaches to assess risks associated with dioxin-contaminated sites. Although no attempt was made to derive TCLs in this dioxin assessment, the procedure could have been applied in reverse order to derive multimedia pathway TCLs based on the single-media TCLs corresponding to a reference dose and a reference risk for noncarcinogenic and carcinogenic effects, respectively. The EPA's recent publications[3,4] formalize some of these approaches in the form of guidance. However, there are still a handful of research areas that are not adequately addressed in this guidance or in other literature sources.

Evaluation of cleanup strategies at the outset of the planning stage will eventually benefit the parties responsible for cleanup and the oversight organizations, including regulatory agencies. Development of the strategies will provide an opportunity to promote an improvement in the pace and quality of many activities to be carried out. The strategies should help address the issues related to 1) improving remediation management activities to arrive at remediation as expeditiously as possible, 2) developing alternate remediation management activities, 3) identifying obstructing issues to management for resolution, 4) adapting the existing framework to correspond to the change in remediation statutes and guidelines, and 5) providing the basis for evaluating options for the record of decision process.

The efforts of evaluating the TCLs are a dynamic process because of the time and resources required and, in the meantime, the direction of the effort could change. For example, while Pacific Northwest Laboratory (PNL) was evaluating TCLs for a U.S. Department of Energy (DOE) site, the EPA interim guidance[4] was published. This required evaluation of the existing effort and some mid-course correction. Developing strategies required some research efforts and seeking a mutually acceptable solution to various issues.

This paper will discuss some of the issues and the research efforts that were addressed as part of the strategies requiring future discussion and comment. Specifically, the strategy at PNL concerning development of criteria for TCLs was targeted to 1) establish end point criteria for estimating health-based TCLs using regulatory procedures; 2) solve some of the pressing technical issues; 3) devise a soil zone division and land use restrictions to make the best use of the land, without sacrificing the goal of protecting human health; 4) establish site-specific activity patterns corresponding to pertinent land uses and exposure pathways; 5) evaluate the effectiveness of institutional controls on the target cleanup levels; 6) establish a consistent basis for determining TCLs for chemicals and radionuclides; and 7) identify other important issues that need to be addressed.

These activities are carried out in conjunction with remedial investigations. Some of the new research areas that needed to be incorporated in the strategy are elaborated in the following.

TECHNICAL ISSUES

The procedure in all of the documents deriving the health-based TCLs involves applying the risk assessment equation to back-calculate a target soil cleanup level corresponding to reference doses (RfDs) for noncarcinogens and an assumed point of departure (10^{-4}-10^{-6} risk) for carcinogens. The TCLs termed the preliminary remediation goals (PRGs) in the EPA document[4] are first estimated for single exposure pathways. PRGs are needed when the Applicable or Relevant and Appropriate Requirements(ARARs) are not available. These single PRGs need to be modified to account for the additive nature of exposure from other pathways or multimedia pathways. These multimedia TCLs would be more stringent than the single pathway PRGs, if each of these other pathways contributes significantly to the overall exposure. The estimation of media-specific, single-pathway PRGs is straightforward because simple exposure and risk equations, along with default contact rate values (i.e., 2 L/d for water, etc.), will provide the desired answers.

In using some of these procedures for a DOE site, additional technical issues need to be addressed. These can be highlighted as discussed in the following.

Volatilization

The volatilization process could be an important pathway when remediation involves volatile compounds. Hwang and Falco[5] provide a procedure for estimating the target soil cleanup levels for volatile constituents which were incorporated in the EPA guidance for the onsite, surface contamination scenario. For many volatile compounds, the onsite inhalation of vapor volatilized from the surface contaminated soil can be the pathway driving the TCL. As volatilization occurs over time, the concentration of these volatiles on or near the vicinity of the soil surface decreases. This process will affect exposure pathways associated with the soil on the soil surface including ingestion of soil and dermal contact with soil. The EPA guidance ignored the need for correcting for soil contaminant concentration resulting from contaminant depletion resulting from this process.

When volatilization is important and affects contaminant concentration on the soil surface, the target single pathway cleanup levels pertaining to soil ingestion, dermal contact, and other surface soil-related pathways should be corrected for the extent of concentration decrease due to volatilization. The correction to be applied for an average depth of z cm from the surface can be represented by

$$Cs(z,T) = \frac{Cso}{z} \int_0^z \mathrm{erf}\left(\frac{x}{\mathrm{SQRT}\ (F\ T)}\right) dx \qquad (1)$$

where $Cs(z,T)$ = soil contaminant concentration averaged over the exposure period T and the soil depth z from the surface; Cso = target soil cleanup level; z = soil depth from the surface over which the concentration is averaged; SQRT = square root of the term inside the bracket; erf = error function; and $F = D\ E^{4/3}/(E + d_s(1\text{-}E)\ K_d/H)$; D = effective molecular gas-phase diffusivity; E = soil porosity; d_s = true density of soil; K_d = soil water partition coefficient; and H = Henry's law constant.

When volatilization is significant, this correction should be applied to the single pathway PRGs (used interchangeably with TCLs subsequently) to account for the decrease in contaminant concentration along the average soil depth of z. The strategy should consider the volatilization process and make proper evaluations for determining the TCLs and selecting institutional control alternatives.

The driving force for volatilization is the partial pressure of the volatile component in the soil pores in the immediate vicinity of the contaminated soil. Under the condition of equilibrium between the contaminant in the air in the pores and that on the soil (termed soil-air equilibrium and represented by Kas $ug/cm^3/ug/g$), the partial pressure will reach a maximum value when the soil is saturated with the contaminant. Above this saturated condition, the increase in the soil contaminant concentration will not increase the volatilization rate. Since the pure component vapor pressure corresponds to the maximum vapor concentration, the maximum soil concentration should be obtained by Cv/Kas where Cv is the vapor phase concentration in ug/cm^3 corresponding to the pure component vapor pressure (Hwang and Falco[5]; EPA[1]). The constraint on the maximum soil-air concentration should be related to the pure component vapor pressure rather than the solubility limit of a compound in water as indicated in the EPA guidance[4].

Leachate-to-Ground Water Dilution

Leachate generated from a hazardous waste site will be subject to dilution as it migrates through the unsaturated zone, the ground water zone, and surface water.

If the contaminated soil affects ground water or surface water, the TCL should protect the health of the public who uses the water for drinking and who is simultaneously exposed to the same contaminant from other pathways. Estimating the TCL level involves relating the contaminant concentration in ground water to that in soil through modeling of fate and transport of the contaminant in leachate. The leachate-to-ground water dilution factor can be defined as C_{gw}/C_L, where C_{gw} and C_L are the contaminant concentration in ground water and leachate, respectively. This dilution factor will be most conservative if it is evaluated for a well location in an aquifer beneath the remediation site under steady-state condition. The leachate-to-surface water dilution factor can be defined in a similar fashion, or as C_{sw}/C_L, and represents a degree of dilution in surface water when the contaminant in the leachate reaches a receptor which uses the surface water.

The cleanup strategy should identify the most appropriate location in the ground water or in the surface water where these dilution factors should be estimated. This location will be dependent upon assumptions regarding land classification and institutional controls (described in later sections). The strategy needs to consider the point of compliance where such dilution factors need to be derived based on site-specific conditions. If models need to be used for estimation, criteria for choice of model need to be indicated in the strategy as prescribed in an EPA document for model selection[6,7]. Several regulatory agencies used a factor ranging from 0.05 to 0.01, but these factors should be more accurately estimated based on site-specific conditions and model selection criteria.

Leaching and Multimedia Partitioning

The process of depleting the contaminant concentration in soil includes leaching, volatilization, wind erosion, runoff, and biodegradation. The change in soil contaminant level due to volatilization has been addressed above. Leaching could be another major process for making the change for some of the mobile contaminants. EPA[8] analyzed this phenomenon as first-order depletion kinetics. Since the depletion process is dynamic, the changing soil concentrations should be corrected in an incremental fashion, or as an average value over the exposure period. The correction to be applied for the change is given by the EPA as

$$Cs(t) = Cso\ e^{-K_L t} \tag{2}$$

where Cs(t)/Cso represents the ratio of the contaminant concentration in soil at some time t to the original remediation concentration; t is time; and K_L is a first-order depletion constant that can be evaluated by

$K_L = R / (K_d d_b D) + E/(d_b D) + 0.69/t_{1/2}$ where R = time-averaged recharge rate; K_d = soil-water partition coefficient; d_b = bulk density of soil; D = depth of contaminated soil; E = soil runoff rate; and $t_{1/2}$ = biodegradation half-life.

If volatilization and leaching are two major processes affecting the soil contaminant concentrations, the ratio of the rate at which a contaminant will leave the original waste area will represent the degree of partitioning between the water and air phases due to releases. This partition ratio can be used to adjust the contaminant concentration level derived based on the volatilization or the leaching process. For example, if the ratio of emission rate to leaching rate averaged over a time period is 0.7 and if the soil contaminant concentration averaged over an exposure period is 100 ppm, the average soil contaminant concentration resulting from the combined process of volatilization and leaching will be 100/1.7 = 59 ppm. Similarly, if the soil contaminant concentration based on the volatilization process is 143 ppm, the soil contaminant concentration resulting from the combined process is 143 (0.7/1.7) = 59 ppm. The identical result should be obtained in either way as shown above. When all the leaching, runoff, and biodegradation process is important, the soil contaminant concentration should be based on K_L as given above rather than leaching only.

Dermal Absorption

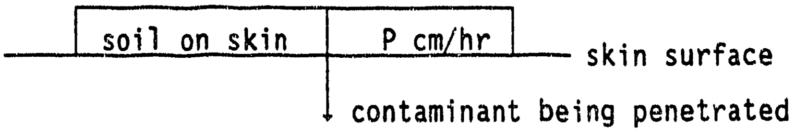
Many chemicals on soil or in solution with water can penetrate through the human skin when coming in contact with humans dermally. This scenario might be particularly pertinent for many low molecular weight organics. EPA recently issued an interim guidance[9] for assessing dermal exposure for contaminant in water solution. In many situations the organics mixed with soil can penetrate the skin when dermal contact with the human skin occurs. The EPA's interim guidance does not address this situation although the consideration of this pathway is recommended in the PRG guidance[4].

The interim EPA guidance[9] deals with estimating the intake through the human skin using the permeability constants. The method of using permeability constants is intended to be applicable when the human skin is immersed in the contaminated liquid medium. The liquid medium could include water containing the contaminants in solution. The contaminants for which data on permeability constants are provided in the literature and the EPA guidance are mostly organic solvents. Organic solvents dissolved in water or pure organic solvents are used to obtain the permeability constants.

Few documents in the literature address the extent of penetration when the skin comes in contact with the contaminated soil. Shu et al.[10] provide an absorption factor of 0.03 % for 2,3,7,8-TCDD based on an experiment using Times Beach soil. Because of this deficiency in estimating the extent of dermal absorption of contaminants in soil through the skin, many exposure assessors tend to assume an arbitrary absorption factor to complete the dermal exposure analysis. Some researchers tend to refer this factor as bioavailability.

An estimating technique is presented here for obtaining the absorption factor for a contaminant in soil coming in contact with the skin. The estimation technique makes use of the permeability constants and the concept of two types of bioavailability. One type is the rate of absorption through the skin, and the other type is the availability of the contaminants on soil for absorption. The former will be referred to as the contact bioavailability and the latter as the external bioavailability. The combined effect is termed the absorption factor, AF. The permeability constant, P, is a measure of a penetration rate of a contaminant in liquid form through the skin and is commonly expressed in units of cm/hr. When animal data based on pure solvents are provided as the absorption rate per unit surface area R $mg/cm^2 \cdot hr$, it can be converted to the permeability constant by $P = R/d_o$, where d_o is the density of the organic solvent, mg/cm^3.

The process of penetration through the skin is schematically shown in the diagram below. As the contaminant in soil penetrates through the skin, the contaminant concentration in soil will slowly diminish. This phenomenon will be more prominent in the soil layer that is in immediate contact with the skin.



A mass balance on the contaminant in soil can be made as follows:

$$-S\frac{dC}{dt} = C \times 10^{-3}\ d_b\ P\ B_e \tag{3}$$

where S = amount of soil on skin, kg/cm^2; C = contaminant concentration in soil, mg/kg; d_b = bulk density of soil, g/cm^3; B_e = external bioavailability, dimensionless; and 10^{-3} = conversion factor, kg/g. Equation (3) is a mass balance on an absorbing contaminant indicating that the rate of disappearance of the contaminant in soil is equal to the amount of the contaminant being penetrated through the skin per unit time.

Integration of Equation (3) from the initial remediation concentration of C_o (or $C = C_o$ at time $t = 0$) yields

$$\frac{C}{C_o} = e^{-Qt} \tag{4}$$

where Q is defined by

$$Q = 10^{-3}\ \frac{d_b\ P\ B_e}{S} \tag{5}$$

Since the instantaneous absorption rate, A $mg/cm^2 \cdot hr$, is equal to $A = -S\ dC/dt$, the absorption rate can be presented by

$$A = S\ C_o\ Q\ e^{-Qt} \tag{6}$$

The average absorption rate over an exposure period T, $\bar{A}$ is

$$\bar{A} = S \frac{C_o}{T} (1 - e^{-QT}) = \frac{S\ Co}{T} AF \qquad (7)$$

The external bioavailability factor, Be, can be estimated based on the consideration of the soil-water partition coefficient. If it can be assumed that the contaminant in the dissolved phase is more readily absorbable than that in the adsorbed phase, the following formula can be derived:'

$$B_e = 1/(1+K_{oc}\ (OC)) \qquad (8)$$

Example 1: Animal data show that the rate of absorption of pure toluene through the skin is found to be 14 $mg/cm^2 \cdot hr$. Estimate the absorption factor of toluene on the soil after 1 hour of dermal contact with the soil.

Solution.
$P = R/d_o = 14/867 = 0.016$ cm/hr where $d_o = 867$ mg/cm^3 is used. From Equations (8) and (5), Be = 0.13 and Q = 1.26 hr^{-1}, respectively, where $d_b = 1.7$ g/cm^3, $S = 2.77 \times 10^{-6}$ kg/cm^2, $K_{oc} = 339$ for toluene and 2% organic carbon in the surface soil is assumed. From Equation (4), the absorption factor, AF, is $AF = 1 - C/C_o = 0.72$. This indicates that about 72% of the toluene on soil was absorbed through the skin in a matter of a day if the average contact time with soil per day is about 1 hour before washing the hands.

Example 2: Estimate the single pathway target cleanup level (or Preliminary Remediation Goal (PRG) after the EPA terminology) for the route of dermal contact with soil contaminated with toluene assuming that the dermal contact period before washing the soil is about 1 hour. The RfD for toluene is 0.2 mg/kg•day.

Solution.
The EPA-recommended intake equation is $(C_o)(S)(SA)(AF)/70 = RfD$ where SA = surface area of the skin available for dermal contact, cm^2, the average adult body weight is 70 kg, and Equation (7) was used for the average intake over time T. Using the absorption factor estimated above of AF = 0.72, the remediation target cleanup level for the dermal route is $C_o = 1700$ mg/kg.

The model has not been validated by any skin absorption data. It will be interesting to validate the model using experimental data, particularly with the human absorption data.

LAND CLASSIFICATION

An unnecessarily stringent cleanup plan will not serve the purpose of protecting public health, but at the same time will severely burden the parties responsible for remediation. Certain pathways are associated with certain layers of the soil zone extending from the soil surface to ground water. For example, soil ingestion and dermal contact with soil are pathways associated with the surface soil. The soil located relatively deep in the soil zone will not be available for these pathways.

Consideration of different soil zones in the vertical direction of soil layer could result in a strategy which provides different cleanup levels at the different soil zones, meets the regulatory requirements for each soil zone, and yet protects the public health from the contaminants migrated into the environment. Each zone could be designated for land use categories from which exposure pathways can be defined. For example, a surface soil zone of the land evaluated for remediation may be defined as the soil contained within depth relevant to normal daily activities (i.e., 5-m depth from the surface). Other pathways, such as particulate wind erosion from the surface or vegetable intake, can be eliminated from the evaluation for the land use associated with the subsurface soil zone. This is because the subsurface soil is not exposed to the surface and is not susceptible to wind erosion and because beyond a certain depth, the vegetable roots cannot penetrate for contaminant uptake.

The soil layer below this soil zone, but up to the surface of a water table, will belong to the subsurface soil zone. The ground water layer can be evaluated as part of the surface or the subsurface soil zone, or as a ground water zone when it is suspected the ground water may or may not become the source of drinking water. The matrix of the strategy for land classification for the evaluation of corresponding target cleanup levels can be concisely presented in a tabular form as follows:

	Evaluation Format for Target Cleanup Levels		
	Surface Soil Zone	Subsurface Soil Zone	Ground Water Zone
Unrestricted Use			
Restricted Use			
Exclusive Use			

Each soil zone can be categorized according to restrictions for its use. The unrestricted use will pertain to the remediated land for use without any restrictions and could involve the land use comprising the residential use, commercial/industrial use, agricultural use, or recreational use. The most stringent target cleanup level among those evaluated for all of these land uses will be appropriate target cleanup levels. The restricted use will be limited to a certain use category with or without institutional controls. The most likely candidate for this use should be designation of the land for industrial use. The pathways pertinent to the industrial use of the land should be identified for evaluating the single pathways target cleanup levels. Exclusive use is considered pertinent if the land will be designated for such use as waste disposal without the use of ground water. Some institutional controls may be appropriate for this land use restriction as well. Some higher level of reference risk within the risk range of 10^{-4} and 10^{-7} may be allowed for the exclusive use category.

INSTITUTIONAL CONTROLS

Many exposure pathways may be eliminated or made unimportant by instituting certain measures. Some measures that can be considered for reducing the risk levels to the public may be as follows:

- Public access to the site will not be allowed.
- The land will be remotely located from the population area or the land designated for unrestricted use.
- Ground water will not used as drinking water and ground-water use may be limited to industrial use, such as cooling water, etc.
- Some areas may be fenced off, and only authorized workers will be allowed to enter.
- Doses of radioactivity allowed for workers may be higher than for the general public.
- Activities leading to excessive air emissions due to volatilization or wind erosion may be curtailed by instituting certain measures, such as immediate covering of the waste or the foaming process.

Specific measures that can be incorporated in the early stage of strategy development include covering the soil surface with clean soil, fencing off the remediated area, and covering the soil surface with a flexible membrane liner. These measures may be considered under each of the restricted use and the exclusive use categories.

RELATIONSHIP BETWEEN THE LAND CLASSIFICATION AND THE ACTIVITY PATTERNS

Derivation of health-based target cleanup levels requires many assumptions. One of the most important groups of these assumptions relates to activities patterns of the local population, which will be one of the first tasks to evaluate at the outset of the strategy development. It should involve defining exposure routes, developing the relationship between land use categories and technical exposure assumptions, and describing an approach to estimating end point criteria, including an illustration of the difference in the end point criteria between carcinogenic and noncarcinogenic compounds.

The relationship being developed can be developed in a tabular form. The EPA's supplemental information regarding the activity pattern can be used as a guide, but activity pattern assumptions should be based on site-specific conditions and information. For a task conducted for a DOE site, the development of the relationship included dividing the soil zone into the three zones as described above. Each soil zone was assigned its use categories, including the unrestricted use, restricted use, and exclusive use. Under each use category, pertinent exposure pathways were identified. For each exposure pathway, PNL developed site-specific activity patterns. When site-specific information was not available, default values were assigned with identifying footnotes. Generally speaking, these default values based on EPA guidelines.

The developed activity patterns can be used repeatedly when single-pathway TCLs are evaluated for each chemical and radionuclide of concern. (The tabular format of the developed activity patterns cannot be presented here because of its length.) Exposure factor assumptions described above for each zone and each category of land use will be used to estimate single pathway intakes from human exposures to the select contaminant.

TOXICITY ASSESSMENT

Most of the toxicity values are obtained from EPA's existing documents. For DOE sites having mixed waste, pertinent toxicity data on chemicals and radionuclides are compiled. When toxicity information is not provided in the EPA documents, the procedure provided in the International Commission on Radiological Protection[11] (ICRP) is the basis for estimating radiation exposure.

SINGLE PATHWAY CLEANUP LEVEL

In order to make the process of analysis more comprehensive, first, the cleanup end point corresponding to a single route of exposure related to a particular land use scenario for a zone of use (surface soil zone, subsurface soil zone, or ground water zone) should be estimated. Second, the exposure from multiple routes of exposure should be considered for each of all reasonable land uses.

The usefulness of tabulating target cleanup levels for single exposure routes is to identify the parameters that are required in the risk assessment and the exposure route that corresponds to the highest cleanup level in the absence of exposure from multiple pathways. The cleanup level which considers exposures from multiple pathways can be derived next. The end point criteria corresponding to the point of departure for the carcinogenic risk level or the noncarcinogenic reference dose need be developed, based on available information applicable to the example substances. The time period for averaging carcinogenic risk is a lifetime

(70 years). The noncarcinogenic effect is evaluated to prevent deleterious health effects upon chronic, subchronic, or short-term exposure to the substance. Parameter values and assumptions needed to conduct calculations should be clearly presented.

The procedure used in deriving the single pathway cleanup levels can follow the EPA's guidance, Risk Assessment Guidance for Superfund: Volume 1, Human Health Evaluation Manual, Part A[3]. However, this procedure should be used in reverse order to estimate the target cleanup level. In the process, models and pertinent parameter values need to be used. The exposure factors given in this guidance are superseded by the EPA OSWER Directive 9285.6-03, dated March 25, 1991.[12] This Directive lists different exposure factors for different land use considerations; site-specific exposure factors should be used when available. Where there is a discrepancy between the two, a compromise should be made to suit a site-specific situation. The parameters and their values assumed for each of the land use categories need to be summarized as part of the section above, RELATIONSHIP BETWEEN THE LAND CLASSIFICATION AND THE ACTIVITY PATTERNS. The cleanup level is back-calculated by relating it to the intake and then relating the intake to a target risk level or reference dose to be met.

The point of departure for lifetime-averaged, carcinogenic risk recommended by EPA is 10^{-4} to 10^{-7}. Since EPA recommends that the carcinogenic risk and the noncarcinogenic hazard quotient be added when multiple chemicals are present, the cleanup level should be reduced by the factor of the number of chemicals or radionuclides producing the same toxicological effects when the number of chemicals or radionuclides is identified at a particular site under consideration for remediation. This approach is meant to be conservative. When the multiple constituents do not affect the same target organ in humans, the risk cannot be additive.

The cleanup levels derived above from single pathway exposure can be summarized showing each pathway under each land use scenario.

MULTIPLE PATHWAY CLEANUP LEVELS

When exposure from multiple pathways occurs, the total added risk associated with all the pertinent exposure routes should not exceed the point of departure for the risk level. Adding all the relevant intakes and solving for the target cleanup level are not algebraically that difficult, but involves many terms to work with. An alternate approach is to determine the contribution of each pathway to the total intake or risk and apply that percentage of contribution to an intake for a particular pathway.

These contributions can be determined at an assumed value of a soil contaminant concentration for each of the pertinent pathways. Another way is to proportion the single-pathway, soil-cleanup levels derived above. This approach is allowed because the intake or risk is directly proportional to the soil contaminant concentration. The contribution of each pathway to the total exposure derived from the apportionment of the single-pathway, cleanup levels can be tabulated.

From such a table of summary, the exposure route which represents the most critical exposure pathway can be identified and its contribution to the total exposure can be computed. This contribution is reused in the single pathway intake equation to solve for the corresponding soil contaminant concentration. The single pathway risk should be reduced by its contribution factor from the point of departure, 10^{-6}, or the cleanup level should be increased by its contribution factor from the single-pathway, cleanup level.

For example, the contribution of the vapor inhalation route to the overall risk for the commercial/industrial land use scenario is 0.9. The risk equation pertaining to the inhalation of vapors can be written

$$1\text{x}10^{-4}\ \text{Cs}\left(\frac{\text{mg}}{\text{m}^3}\right) \text{x} \left(20\frac{\text{m}^3}{\text{day}}\right) \text{x}\ \frac{1}{70}\ \text{kg x}\ \frac{8\text{x}250\text{x}20}{24\text{x}365\text{x}70}\ \text{x CP}\left(\frac{\text{mg}}{\text{kg.d}}\right)^{-1} = 0.9\text{x}10^{-6} \quad (9)$$

Note that CP is the cancer potency factor, the contribution of this route of exposure to the risk is a fraction of the total risk, 10^{-6}, and the ambient air concentration related to the soil contaminant is obtained from the release rate and transport analysis as $1\text{x}10^{-4}$ Cs mg/m^3, with Cs being soil contaminant concentration in mg/kg. The exposure period of 8 hours per day, 250 days per year, and a 20-year exposure period is averaged over the 70 years lifetime expressed in days. If CP = 0.13 (mg/kg•d), solving for Cs gives Cs = 4 ppm. In this case, the target cleanup level based on the multiple exposure pathways essentially did not change because the contribution by the vapor inhalation pathway was dominant. Similar equations can be written for the routes other than the inhalation route. Although the contribution of either one of these other routes to the overall risk may be different, the resulting target cleanup level will be the same. Instead of solving the single pathway risk equation using the fractional contribution, all of the single pathway risks can be summed equating this to 10^{-6}, and the resulting equation can be solved for Cs. The target cleanup level will be the same, but the procedure will be more tedious.

The adjusted multiple-pathway, cleanup levels for soil for each land use scenario can be tabulated along with the permissible levels for other media. The levels for air and water are essentially single-pathway, permissible levels not to exceed the risk level allowed. The exposure parameters for different land use scenarios can be varied as indicated previously in the evaluations for the single-pathway, cleanup levels.

NEEDS FOR FURTHER RESEARCH

Science should form the foundation for policy decision. Without sound scientific knowledge, the decision made may not be defensible. In addition to increasing the understanding of the natural phenomena of fate and transport and toxicological effects, research is also needed in collecting appropriate data and interpreting such data. Regulators should support such effort so that some of the scientific results may not be misused in the regulatory context.

CONCLUSIONS

The goal for estimating end point criteria should be directed toward providing the applicable ARARs or PRGs in the Remedial Investigation and Feasibility Study (RI/FS) process. Development of a strategy for the end point criteria based on the baseline risk assessment will expedite the remediation process by identifying the sources which require interim action, no further action, and further field investigation at the early stage of the RI/FS process.

When ARARs are not available, the TCLs, as highlighted in this paper, should represent the end points that can be considered sufficient to protect human health. The estimated TCLs can provide a means to compare the stringency of ARARs in protecting human health.

Because many of the components needed in the strategy development are still an emerging area, only some of the issues could be addressed in this paper. Many additional areas need to be investigated in the process of the strategy development. Some of the pertinent issues addressed reflect site-specific problems. For other sites, important issues may be entirely different.

This paper has attempted to highlight some of the issues pertinent to developing a strategy for end point criteria and to offer solutions to some recurring problems.

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