On the use of uncertainty propagation methods for estimating health risks

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Abstract

State-of-the-art risk assessment models are applied in the reassessment of baseline risks and remedy selection at a Superfund Site for which a Record of Decision (ROD) has been issued. One objective is to demonstrate the differences between state-of-the-art risk assessment models and those used in the original RODs. The cost/benefit of several remedial alternatives is also considered for each site.

Risks are assessed using improved models that incorporate the uncertainties and variability of the input parameters. In addition, parameter distributions have been advanced which are more scientifically and technically defensible than the United States Environmental Protection Agency’s (EPA) default point estimate values. Application of these state-of-the-art methods, which are endorsed in new guidelines and by the Science Advisory Board (SAB), may result in more realistic risk estimates, and hence may ultimately result in very different decisions regarding cleanup.

Introduction

The United States Environmental Protection Agency (EPA) currently performs risk assessments in support of the decision making process regarding remedy selection for sites on the National Priority List, the so-called Superfund Sites. Because of uncertainty in risk assessment models and data, the U.S. EPA uses a conservative approach which can exaggerate typical risk estimates and can lead to the selection of very costly, resource-intensive, and time-consuming remedies. Such conservative risk assessments may thus lead to a misallocation of resources. This paper examines the use of more realistic state-of-the-art
models and currently available data to reassess the risks and their uncertainties for a Superfund Site, reevaluates the remedy selection in terms of cost-benefit, and then explores the impact of the original cleanup criteria employed. Alternative remedies and cleanup goals are also considered with respect to costs, benefits (in terms of risk reduction), and uncertainty.

In assessing the potential human health risks associated with exposure to environmental contaminants, U.S. EPA originally recommended considering only a “reasonable maximum exposure” (RME) [1], defined as the “highest exposure that is reasonably expected to occur.” In practice the RME is a conservative estimate, calculated by assuming and combining a series of conservative and worst-case parameters in the U.S. EPA exposure models, as well as selecting conservative values for the environmental contaminant concentrations. In so doing, the applicability of the calculated risk, which is sometimes called a point estimate, and the confidence one has regarding this point estimate, becomes questionable for decision making. It should be acknowledged that others have made these points, and in response, the U.S. EPA has issued its 1992 Exposure Assessment Guidelines in an attempt to remedy this conservativeness.

The RME approach, as well as other point estimate approaches, has several major limitations due to the inherent parameter uncertainties in the exposure models, including the environmental contaminant concentrations. The inherent uncertainties in cancer potency factors and reference doses also contribute to uncertainty in risk. In general, these uncertainties can result from natural variability of site-specific and temporal parameters, measurement and extrapolation errors, and/or the inherent lack of knowledge regarding biological, chemical and physical processes.

The advent of inexpensive computing has facilitated convenient adaptation of uncertainty propagation in risk assessment. Commercially available computer programs such as Crystal Ball® and @Risk® enable the user to represent uncertain variables using probability distributions and to propagate these distributions throughout the risk assessment models. In addition to characterizing the uncertainty in the risk, the resulting risk distribution can be used to estimate the mean, median, and other percentile risks. Using these values, a more informed decision regarding remedy selection can be made. For this paper, the risk assessment for the Paoli Rail Yard in Pennsylvania was chosen to be reassessed. This Superfund Site was issued a ROD in 1992.

Methodology

The quantitative estimation of health risks due to potentially chronic exposures of low concentrations of toxic chemicals is a combination of four steps:
1. The quantification of the source term including its chemical and physical state,
2. A characterization of environmental transport and fate including biological, chemical and physical transformations that may take place,
3. A characterization of exposure, including its rate and duration, and
4. A quantification of the health effects, usually characterized by a dose/response relationship.

For the Paoli Rail Yard, measured contaminant concentrations were available and employed by U.S. EPA. The use of measured contaminant concentrations is an attempt to capture the existing risk without regard to natural dilution or degradation processes. The analyses presented in this paper uses these measured contaminant concentrations in conjunction with U.S. EPA developed exposure and dose/response models. Conservative parameter value selection for these exposure and dose/response models is the primary contributor to over-conservativeness, and thus inadequacy, in the U.S. EPA approach.

To address the inadequacies of the current U.S. EPA approach to risk assessment, the uncertainties and variability’s in the exposure parameters are first evaluated. Parameter uncertainty accounts for the inherent lack of knowledge as well as measurement and extrapolation errors. Parameter variability accounts for the natural variability of site-specific and temporal parameters as well as human physiological behavior. After determining which parameters require reassessment, the corresponding uncertainties and variability’s are quantified. The most effective quantification method is to assign each parameter a cumulative probability distribution function or a probability density function. These distribution or density functions can take several different forms (e.g., normal, log-normal, uniform, triangular, etc.). The determination of which form of distribution function to assign to each parameter, as well as the distribution of the parameter, depends on both site-specific data and judgment based on statistical analysis. The distributions used in this paper are assembled from site-specific data, existing data in the most current literature, and professional judgment, and are considered to be the most up-to-date description of the parameter.

After characterizing the uncertainty and/or variability associated with each parameter, the uncertainty in the risk can be estimated. For the risk assessments presented in this paper, the commercially available software package called Crystal Ball® (Version 3.0.1, January 1994, Decisioneering Corporation, Denver, CO) is used. Crystal Ball® propagates the distribution of the parameters throughout the calculation of the risk. This propagation results in a distribution function for the risk.

Crystal Ball® uses a Monte Carlo (MC) simulation in order to propagate the distributions. The MC method is commonly used to propagate distribu-
tions because of its simplicity, general applicability and asymptotic exactness [2]. The MC simulation calculates the risk several thousand times by drawing parameter values randomly from the distribution functions. Each value of risk has a corresponding probability. Certain values within each distribution function will be drawn more frequently due to their higher probability, or likelihood. Others will be drawn less frequently. The end result is a distribution of the risk with corresponding probabilities.

The risks that are projected to result after remedial activities have been completed are termed the residual risks. These risks exist because it is typically not required to clean any particular environmental media completely nor may it be technically feasible. Thus a small portion of the contaminant will remain in the environment, which results in a potential for human exposure.

These residual risk assessments have a slightly larger uncertainty than the baseline assessments because uncertainties are introduced additionally from the degree of effectiveness of the remedial activity itself. And as discussed above, natural processes such as dispersion, dilution and degradation are neglected in the determination of residual risk.

Paoli Rail Yard

Site Background
The Paoli Rail Yard encompasses a 28 acre rail yard as well as the 400 acre watershed (including three tributaries) surrounding it. Included within the rail yard are three main structures and five distinct track areas. The three structures are the car shop, power house, and freight house. Storage and maintenance of passenger rail cars are the main uses of the rail yard [3].

During the Remedial Investigation (RI), several environmental media were characterized, including soil, groundwater, air, surface water, stream sediment, building surfaces, and aquatic organisms. Polychlorinated biphenyls (PCBs) were found to be the primary contaminant of concern. The PCBs (predominantly Aroclor 1260) were detected in rail yard soils, residential soils, stream sediments, and fish. The populations at risk were considered to be rail yard workers, nearby residents, and persons who consumed fish. The routes of exposure considered by U.S. EPA for rail yard workers and nearby residents included incidental soil ingestion and inhalation of vapor and particulate phases. In addition, U.S. EPA considered a sub-population of fish consumers. In calculating the exposure the U.S. EPA default values were applied [1,4].

Risk Results
Baseline Risk The risks associated with the current conditions (i.e., before any remedial activities) at the rail yard were assessed by U.S. EPA. This base-
line risk assessment applied to both rail yard workers and nearby residents, and considered the exposure routes mentioned in the previous section. U.S. EPA’s risk assessment was deterministic in that it relied upon point estimates for exposure parameters. As such, U.S. EPA’s risk assessment did not account for uncertainty or variability in the exposure parameters.

In order to determine the uncertainty in the estimate of the risk, UCLA reassessed the baseline risk using distribution functions for certain exposure parameters and implementing a MC simulation using Crystal Ball® (5000 simulations were run). In order to simplify this assessment, only the soil ingestion exposure route for rail yard workers was considered.

The results of the U.S. EPA and MC baseline risk assessments for the rail yard workers are shown in Table 1. Only the 10\text{th} percentile, median, mean and the 90\text{th} percentile are shown in the table to represent the spread in the MC risk distribution.

<table>
<thead>
<tr>
<th></th>
<th>EPA</th>
<th>MC 10\text{th}</th>
<th>MC Median</th>
<th>MC Mean</th>
<th>MC 90\text{th}</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soil Ingestion</td>
<td>1.6 X 10^{-3}</td>
<td>4.0 X 10^{-4}</td>
<td>2.0 X 10^{-6}</td>
<td>9.4 X 10^{-6}</td>
<td>1.9 X 10^{-5}</td>
</tr>
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The MC risks are seen to be up to four orders of magnitude smaller than U.S. EPA risks. In fact even the 90\text{th} percentile MC risk is much smaller than the U.S. EPA risk. The difference between the U.S. EPA risk and the 90\text{th} percentile MC risk is approximately 84 fold. The difference between the U.S. EPA risk and the mean MC risk is approximately 170 fold. These comparisons show the effect on risk estimates of using “best estimate” distribution functions to describe exposure parameters, rather than U.S. EPA default values. Applying either the U.S. EPA or MC methodology is expected to have a dramatic effect on the costs and benefits associated with the remedy selection.

**Residual Risk** To assess the cost/benefit of the remedial alternative chosen by U.S. EPA in the ROD, the U.S. EPA alternative and two other remedial alternatives are evaluated. These are:

1. **The EPA Alternative:** The remedial activities chosen by U.S. EPA for the rail yard include excavation, solidification and on-site disposal of soils containing PCB concentrations greater than 25 parts per million (ppm). The total cost of these actions is $27.1 million.

2. **Alternative 1:** The first alternative’s remedial activities for the rail yard include asphalt paving of soils with PCB concentrations greater than 25 ppm. The total cost of these actions is $7.2 million.
3. Alternative 2: The second alternative’s remedial activities for the rail yard include excavation of soils (including the on-site cell) containing PCB concentrations greater than 2 ppm, off-site incineration and off-site (landfill) disposal of ash. The total cost of these actions is $91.5 million.

The resulting residual risks to rail yard workers as well as the estimated costs for the three alternatives mentioned above are shown in Figure 1.

![Figure 1. Baseline and residual risk distributions for workers due to soil ingestion. Note that the residual risk for Alternative 1 is zero because of the asphalt paving.](image)

Figure 1 does not show any results for Alternative 1. This is due to the fact that all of the soil samples in the U.S. EPA data set were greater than 25 ppm. Thus with an asphalt covering which effectively reduces the PCB exposures to zero, because the effective source term becomes zero, the risks are in turn reduced to zero. This calculation of zero risk assumes that the asphalt cover will be a permanent seal. Although the U.S. EPA calculations utilize the same data set, the residual risks are nonzero. U.S. EPA assumes that a remedial activity will reduce the contaminant concentration to the cleanup criteria and thus the soil concentration in this case becomes 25 ppm.

Again, the residual risk using U.S. EPA’s default values is seen to be conservative. Using the MC methodology of applying “best estimate” distribution
functions, the projected residual risks are seen to be one to three orders of magnitude smaller than the U.S. EPA’s projections.

These results and those of the baseline risk assessment, show that the determination of parameter values, as well as the assessment method, can have a very dramatic effect on the estimated present and projected risks. As will be shown in the next section, parameter values and assessment method also has a large impact on the cost of mitigating the environmental contamination to reduce risks.

Cost/Benefit Analysis

To evaluate the impact of each risk assessment method on remedy selection, as well as the effectiveness of each remedial alternative, a cost/benefit analysis is performed. The costs associated with each remedial alternative are compared with the benefits achieved, i.e., reductions in risk as determined by each method. In comparing the assessment methods, the costs of each remedial activity remains constant while the risk reduction changes for each method. In this case, a clean up criteria is specified as part of the remedial alternative (see previous section) and the residual risks are calculated. Figure 2 illustrates the risk reduction for both the U.S. EPA and MC approaches for the EPA Alternative. This figure indicates that the U.S. EPA methodology exaggerates the cost/benefit. Moreover, the MC approach yields residual risks below the de minimus value of $1 \times 10^{-6}$ for all cases considered.

![Figure 2. Risk reduction following the EPA Alternative.](image-url)
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Conclusions

As a result of the review and reassessment of the risk assessment performed for the Paoli Rail Yard site, it can be concluded that, as noted in the Introduction, U.S. EPA default values do exaggerate the benefit because the unremediated site risks, calculated using default values, are two to three orders of magnitude greater than the more realistic MC approach. The U.S. EPA recommended expenditure of $25 million results in a residual risk that is larger than the unremediated mean value MC risk. Lastly, an expenditure of $7.2 million, in conjunction with the Monte Carlo approach, drives the risks below $1 \times 10^{-6}$, which is usually considered to be the de-minimus level.

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References