HUDSON RIVER SUPERFUND PROJECT

APPROACH FOR PERFORMING HUMAN HEALTH RISK ASSESSMENT: ESTIMATING POTENTIAL PCB EXPOSURE FROM FISH CONSUMPTION

May, 1995

prepared by:

ChemRisk®
A Division of McLaren/Hart
Stroudwater Crossing
1685 Congress Street
Portland, Maine 04102
(207) 774-0012

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A Division of McLaren/Hart
Environmental Engineering

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Hudson River Superfund Project: Approach for Performing Human Health Risk Assessment: Estimating Potential PCB Exposure from Fish Consumption

1.0 INTRODUCTION

In 1990 the U.S. Environmental Protection Agency (EPA) began a reassessment remedial investigation and feasibility study (RRI/FS) for the Hudson River PCB-contaminated sediment Superfund site. Subsequently, EPA issued a summary report (Phase 1 Report), project plans that described data collection and analysis activities, and a data collection program was initiated. As part of the data analysis activities, EPA began the development of a computer model for simulating PCB fate and transport in the Upper Hudson River.

In the EPA Phase 1 Report, a preliminary human health risk assessment was prepared. This preliminary risk assessment determined that consumption of PCB-contaminated fish presented the primary source of risk from potential exposure to PCBs at the site and that the final site risk assessment would focus on the fish consumption exposure pathway (EPA Phase 1 Report, B.6-46). EPA is now completing the remedial investigation portion of the RRI/FS process and is entering the phase in which the final baseline human health risk analysis is conducted, remedial action objectives are defined, and remedial alternatives are evaluated.

Since the RRI/FS was initiated, a number of significant changes have occurred in site conditions and national policy related to exposure and risk assessment. The original project plans that describe the procedures to be used for the risk assessment and the feasibility study should be updated to reflect these changes and provide important details on how risk assessment and feasibility studies will be performed. This paper highlights a number of important issues related to these aspects of the project and specifically describes how to integrate the risk assessment, the PCB-fate and transport model being developed by EPA, and the feasibility study. Since the risk assessment is central to integrating these issues, the focus of this paper is on issues related to conducting the risk assessment for the Hudson River Superfund site.

Specifically, this paper:

1. Describes how the risk assessment, the EPA PCB-fate and transport model, and feasibility study should be integrated (Section 2).

2. Describes the risk estimating methodology that should be employed (Section 3).

3. Provides the input parameters for use in the risk assessment (Section 4).

This paper focuses on issues relating to estimates of exposures to PCBs (and associated risks) by anglers fishing the Hudson River in the absence of a ban. PCB toxicological properties will be discussed in other papers. A key point that should be kept in mind is that the existing ban on all fishing in the Upper Hudson River below Bakers Falls almost certainly precludes actual exposure through the fish ingestion pathway. Consequently, the estimates of exposure that are produced by the methodology proposed in this paper will greatly overestimate current exposures and actual hazards to Hudson River anglers. Indeed, the actual exposures and hazards may be zero. → people can ignore ban

2.0 ROLE OF RISK ASSESSMENT IN THE HUDSON RIVER REASSESSMENT

At Superfund sites, risk assessments are performed in accordance with the National Contingency Plan (NCP) and relevant Agency guidance such as the Risk Assessment Guidance for Superfund: Volume I - Human Health Evaluation Manual (Part A) (RAGS) (EPA, 1989). Risk assessments under Superfund provide the key information for deciding if remedial actions are necessary and, if so, for evaluating each action in terms of its potential to reduce risks to acceptable levels. The first component of the risk assessment process is the "baseline" risk assessment that defines and quantifies potential risks to human health and the environment from contaminant sources if no remedial actions are undertaken. If unacceptable risks are identified, the "baseline" risk assessment in combination with an analysis of the Applicable, or Relevant, and Appropriate Requirements (ARARs) is used to define Remedial Action Objectives (RAOs). RAOs describe the relationships between contaminant sources and receptors. By evaluating these linkages, the source of risks can be identified and a range of remedial alternatives can be developed to either control the sources, break the linkages between the sources and the receptors, or control the receptors so exposure does not occur. The remedial action objectives form the basis for developing and evaluating remedial alternatives during the feasibility study.

The second major component of the risk assessment is a "comparative" risk analysis performed during the FS. This evaluation assesses the absolute risk reduction potential, the comparative risk reduction potential, and the short- and long-term effectiveness of each remedial alternative. Each of these measures is required in the feasibility study where alternatives are compared to the nine selection criteria (EPA, 1990). The absolute risk reduction measure is used to assess the protectiveness of each alternative to human health. The comparative analysis compares the risk reduction capabilities of each remedial alternative. Additionally, the short- and long-term effectiveness of each remedial alternative are evaluated to ensure that potential negative short-term impacts are considered as well as the ability of each remedial alternative to achieve remedial action objectives in the long-term. This interrelationship between the risk assessment, feasibility study and the selection of the appropriate remedial alternative is illustrated in Figure 1.

It is anticipated that EPA will follow this process for the Hudson River RRI/FS. The "baseline" risk assessment component of the process has not yet been prepared. Additionally, EPA has not provided much detail as to how the risk assessment will be performed, how the PCB fate and transport model will be used in the risk assessment ("baseline" and "comparative"), or how the model, risk assessment, and feasibility study will be integrated. In order to ensure that risks will be appropriately considered in the remedy selection process, it is essential for EPA to articulate it's approach on these issues before the process proceeds any further.

Figure 2 illustrates the interrelationships between the risk assessment, models and feasibility study for the Hudson River. Figure 3 provides an expanded description of the processes and tasks required to develop a risk-based selection of remedial alternatives in the feasibility study. EPA is in the early stages of the RRI/FS, with the final validation of the data collected still underway and the model development and calibration not scheduled for completion until at least June 1995. The most important and potentially difficult portion of the RRI/FS is yet to come. Due to this and the lack of detail provided on the risk assessment and the feasibility study, there are many issues that are still unresolved. These unresolved issues need to be discussed before EPA irreversibly embarks on the final project direction. In order for the RRI/FS to proceed in a scientifically sound and expeditious manner, EPA must address the issues that are discussed in detail below.

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Figure 1. Relationship Between Risk Assessment, Feasibility Study, and Remedial Alternative Selection

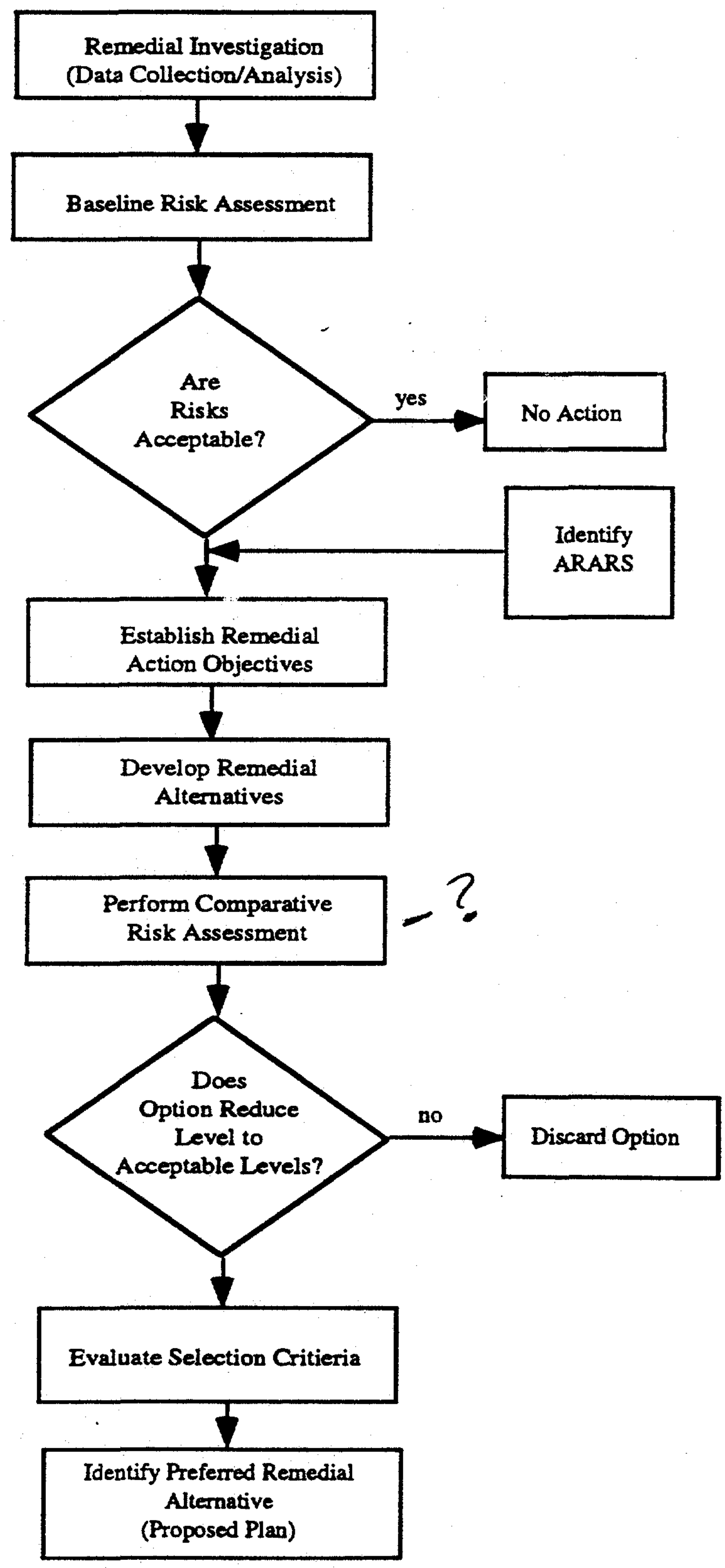


Figure 2. Relationship Between Risk Assessment, Feasibility Study, and Model

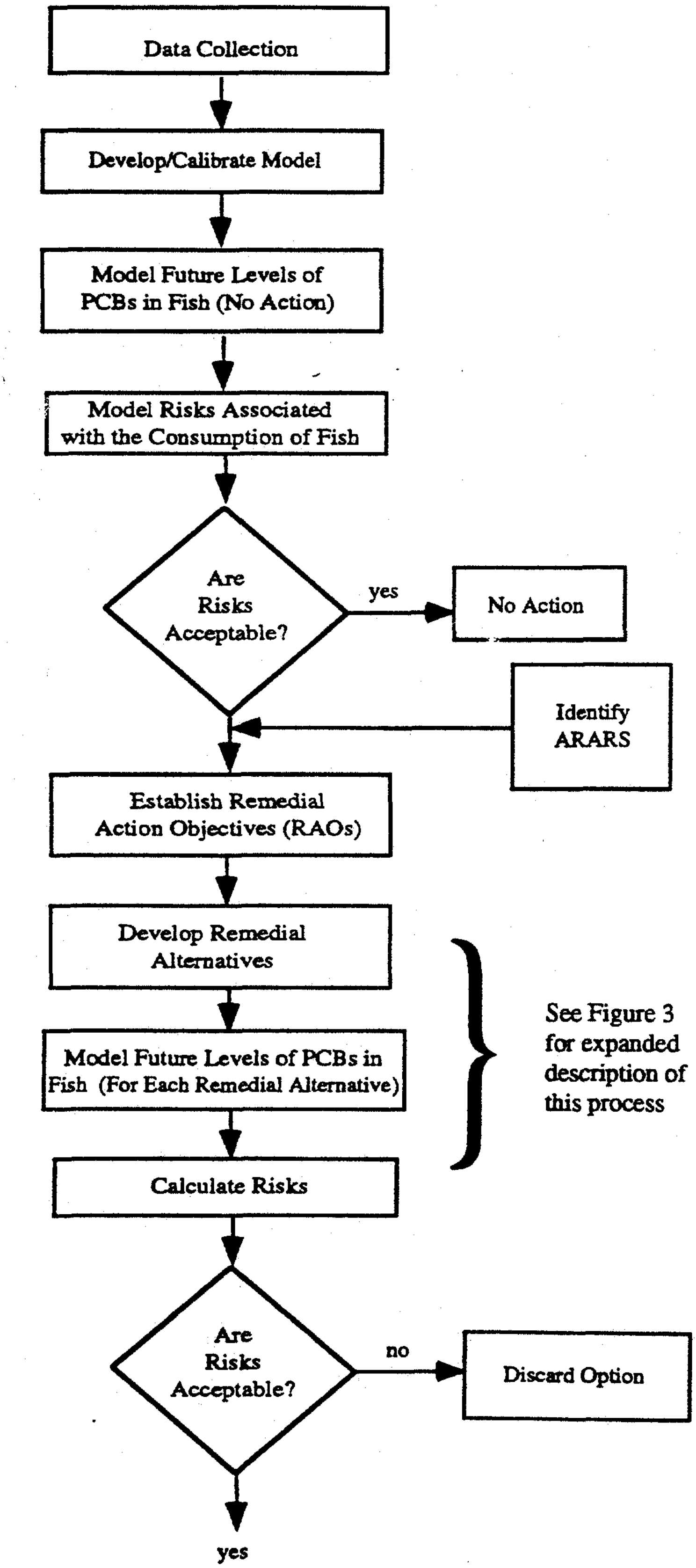
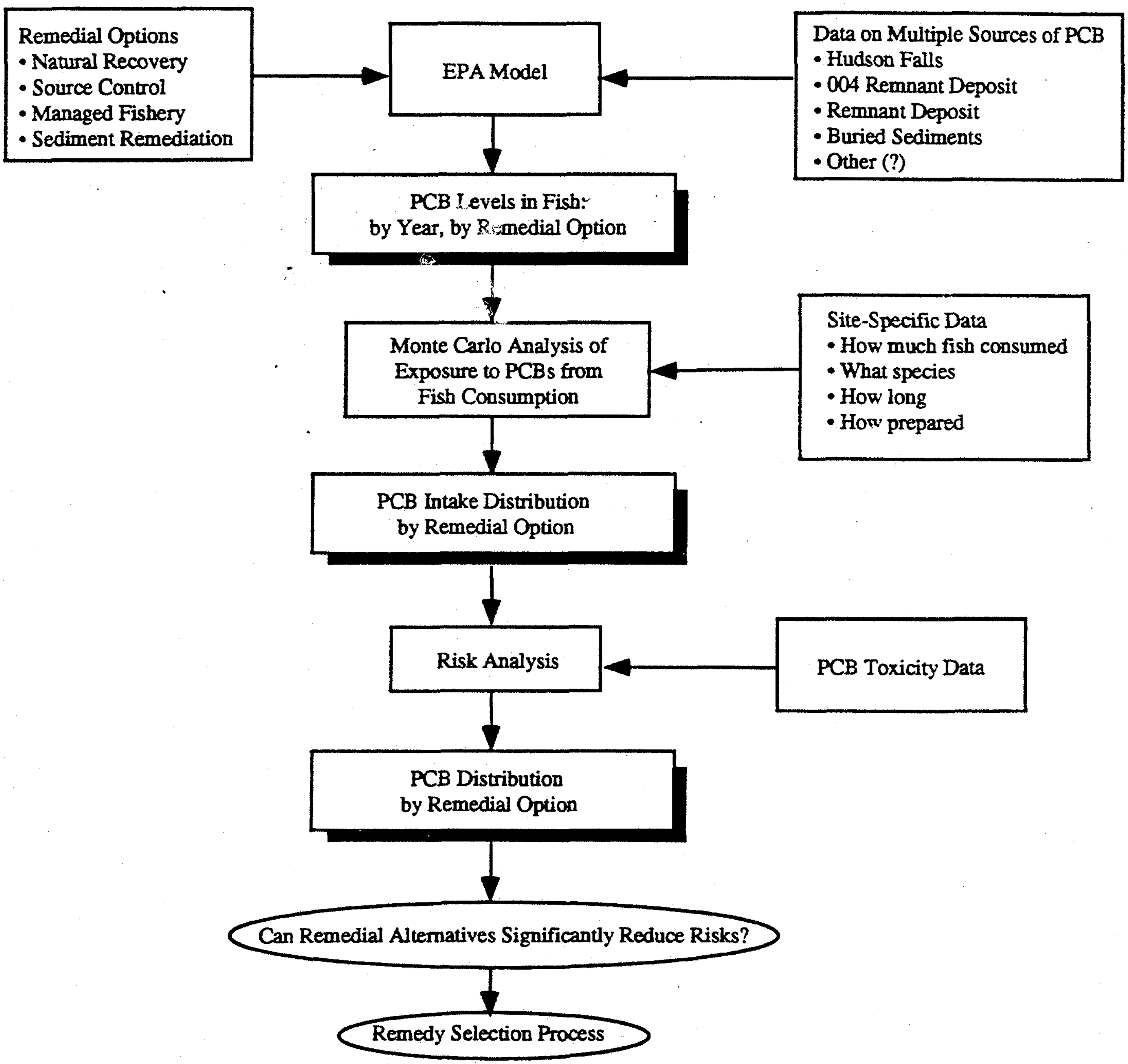


Figure 3. Framework for Comparing Risk Reduction Potential for Remedial Alternatives



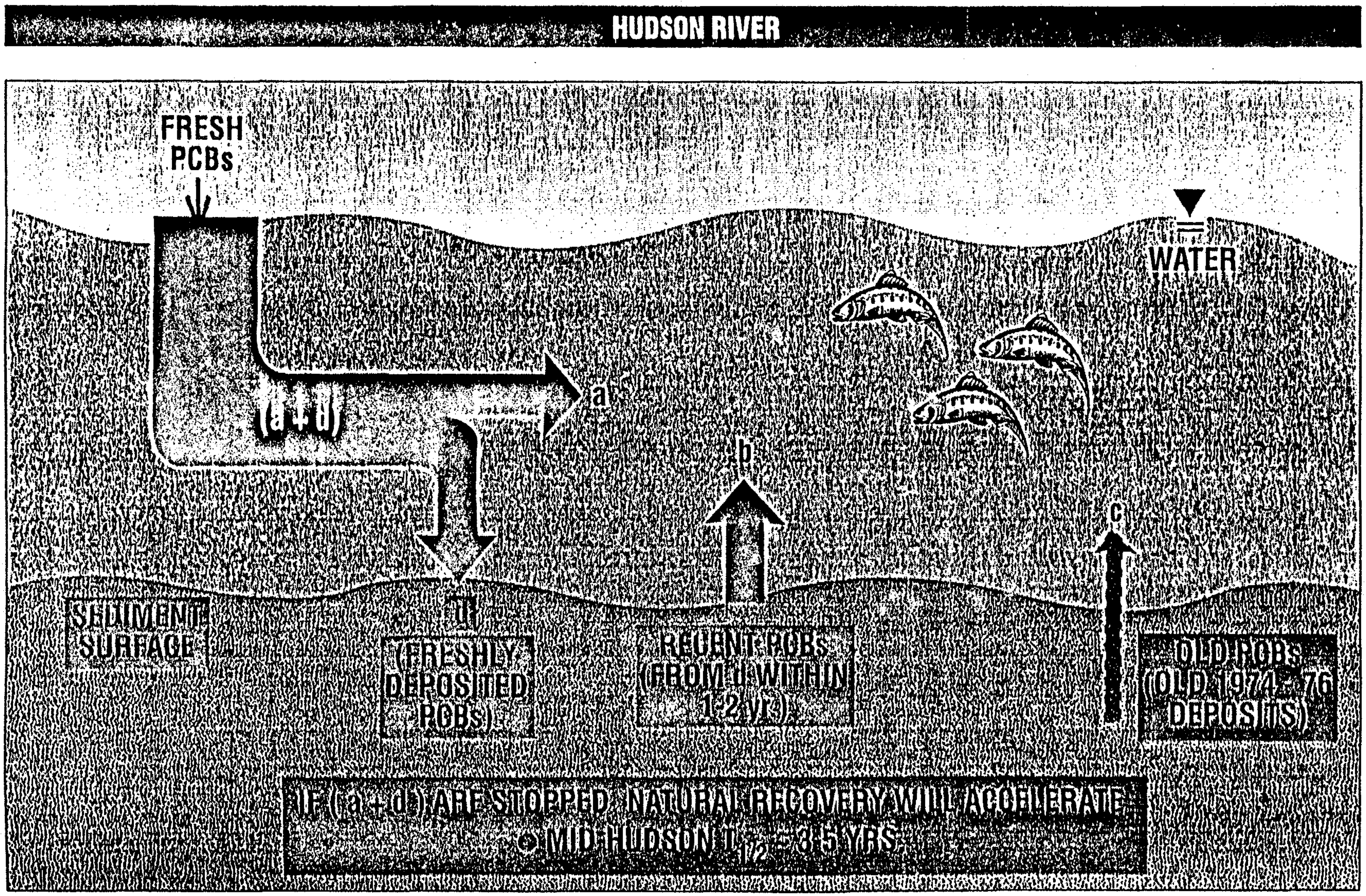
2.1 Differentiation of Source Impacts

U.S. EPA has repeatedly stated that the focus of this RRI/FS is on PCB-contaminated sediments in the Hudson River and not on other PCB sources, such as the old dredge spoil sites (See EPA Phase 1 Report, Page I-2). In the Phase I Report, EPA assumed that other PCB sources did not exist. Since the EPA began the RRI/FS, however, significant new information indicates that sources of PCBs are currently present in the Upper Hudson River upstream of Roger's Island ? ("upstream source") and have been present historically. This upstream source of PCBs appears to have at least two separate components. One component has been traced to an area near Bakers Falls and is composed of PCB oils and PCB-contaminated groundwater entering the river through fractures in the bedrock. The second component is related to contaminated sediments near the outfall (Number 004) near the Ft. Edward facility. This appears to be a small remnant deposit. The PCB contributions of these two sources have not yet been quantified. Contributions from other potential PCB sources in the Upper River may also occur. Current monitoring programs are not sufficient to identify the presence of specific sources. Since the upstream source is an important contributor to the PCBs in fish in the Hudson River, the risk assessment must be able to differentiate the impact of this source(s) from the contribution from old sediments. This is the only way EPA can properly assess the risk reduction potential from controlling upstream source(s) contrasted with the risk reduction potential of the sediment remediation in the FS. If source impact ? differentiation is not done, the analysis of remedial alternatives will not be defensible.

As described in various presentations to EPA, the upstream source(s) is composed primarily of unaltered Aroclor 1242. Unaltered Aroclor 1242 has a higher chlorination level and has a significantly higher potential to bioaccumulate in fish than the bioaltered, dechlorinated PCBs present in the sediment. Additionally, the upstream source PCBs are highly bioavailable to the fish through their presence in the water column and in the surficial sediment. By contrast, the majority of the historically-released PCBs are in buried sediments (old sediments) and are not available to the fish for uptake. These concepts are illustrated in Figure 4. The ability of the upstream source to affect PCB levels in fish was clearly demonstrated by monitoring data taken after 1991 when increased loading from the source resulted in immediate increases in PCB fish levels in the Upper Hudson River.

Figure 4.

IDENTIFIED AND CHEMICALLY-DISTINGUISHABLE SOURCES OF UPPER HUDSON FISH PCBs



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Another important feature of the upstream PCB source is its apparent longevity. In September 1991 increased activity of the upstream source, apparently due to a failure of a gate in an abandoned paper mill (Allen Mills) adjacent to the river, led to the identification of that source. As a result of this source discovery, the existing historical data were reevaluated to see if the source may have been present historically. The historical data are sparse and are also of limited use due to the relatively high laboratory detection limits for PCBs (for the water matrix). Additionally, most of the historical data were collected downstream of the remnant deposits, which makes it difficult to determine if the PCB levels were from a source upstream of the remnant deposits or were due to the remnant deposits. However, given our current knowledge on the activity of the upstream source (i.e., PCB oil in fractured bedrock), it is probable that the oil seepage from the bedrock had been occurring for some time. The limited data collected above the remnant deposits by NYSDEC in the early 1980s and by HARZA engineering in the late 1980s also are consistent with the upstream source being active during that period of time. As the PCBs in the sediments became buried with new sediment and the PCBs in the buried sediments underwent biologically-mediated dechlorination, the old PCB-contaminated sediments became a less significant source of PCBs to the water and fish. Since the mid to late 1980s, the Bakers Falls source has been key in controlling PCB levels in both the fish and the water column. As a result, the upstream source has reduced the rate of decline in PCB fish levels and has inhibited the natural recovery of the river system.

Given the importance of the upstream source in controlling PCB fish levels, EPA must determine the relative contribution of the upstream and old sediment sources to the levels in the fish. Once EPA determines which, if any, of the PCBs in the fish are derived from the old sediments, the risk assessment for the PCBs in the old sediments can proceed. The EPA Phase 1 risk assessment failed to do this and, as a result, greatly overestimated the risks posed by the PCBs in the old sediments. PCB source impact apportionment will be critical to identifying the remedial action objectives and determining which, if any, of the remedial alternatives can achieve these objectives. This approach allows a rational prioritization of remedial actions.

2.2 PCB Decline Rates

In the risk assessment, the period over which exposure occurs and the concentration to which a hypothetical receptor is exposed are critical parameters. In its Phase I Report, EPA suggested a default value of a 30-year period of exposure (EPA, 1989). If the Hudson River RRI/FS risk assessment assumes potential exposure to occur over a 30-year period, the next step in the process is to estimate concentrations in fish anticipated over this 30-year period (for both action and no-action scenarios). To do this, EPA might elect to use current values and assume no changes in fish PCB concentrations in the future. Alternatively, EPA may assume that PCB levels in fish will decline due to natural recovery processes. Assuming a constant PCB level is not supportable based on the existing river data which show significant PCB reductions over time. In fact, in its Phase I Report, EPA did assume an annual rate of decline of approximately 26 percent in it's Phase I Report. The decline of PCB fish levels over time greatly reduces exposure intake over the 30-year period when compared to a constant PCB level over the same period. Reduced intake equates to reduced risk. If this is not considered, the risk estimates will be exaggerated and scientifically not supportable.

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For the final risk assessment in the RRI/FS, the issue of decline rates is even more complicated because the PCB decline rate for each of the sources must be determined. For the upstream source, the future activity of the source is not clear at this time. GE is aggressively pursuing timely remedial solutions and is hopeful that remediation efforts will be successful. However, the technical challenges presented by the upstream source are significant. PCB oil in fractured bedrock is one of the most difficult types of contamination to control. Since it is possible that the success of remedial efforts will not be known by the time EPA's risk assessments are completed, EPA will need to make various assumptions concerning the future activity of the upstream source. Therefore, the Agency must consider a complete spectrum of possibilities, from an assumption that the upstream source is controlled completely in the near term to an assumption that remediation is unsuccessful in the long-term.

2.3 Assumed Starting Dates for Action and No-Action Alternatives

As described above, an estimate of the PCB levels in fish (by source) over a 30-year period is a necessary input into the risk assessment. Further, a decision must be made regarding the point in time at which potential exposure is assumed to begin. An appropriate starting point for angler exposure for the baseline assessment would be no sooner than the date that the Record of Decision (ROD) will be issued for the Hudson River Superfund Site. The "baseline" risk assessment is intended to reflect the potential risks if no-action is undertaken. Therefore, the soonest a no-action decision could be made is the date on which the ROD is issued.

For the comparative risk assessment of potential remedial alternatives, the starting point should be no sooner than the date on which remediation would start. As an example, if EPA issues an action ROD for sediments in 1997, any such action could not begin until at least 1999 due to the need for PRP negotiations, design, and facilities construction. Based on a 1999 start date, EPA will need to estimate PCB levels in fish from 1999-2029 for the "comparative" risk assessment for each remedial alternative. The risks for no-action must then be compared to the potential risk reductions offered by each remedial alternative during the same time period. This analysis will also need to assess the impact on fish and other adverse effects of implementing each potential remedy.

2.4 Use of Models in the Risk Assessment

The description of the above issues makes it clear that a critical input into the risk assessment will be PCB levels in fish attributable to each source in future years. This information is required for no-action and for each action scenario. The tool used to obtain this information is a technically defensible PCB-fate and transport model ("model") for the Hudson River. This model, if appropriately constructed and calibrated, will be able to apportion PCBs in fish according to the source of the PCBs. The model also provides a mechanism to simulate the effects of each remedial alternative on PCB levels in fish over time. Although EPA to date has not described how the model will be used in the RRI/FS, the description given above is an appropriate way to incorporate the model into the RRI/FS and the associated risk assessments. GE believes that the following information from the model is required for EPA to complete the risk assessment:

1. Fish PCB levels from the date the ROD is issued to 30 years in the future for the "baseline" risk assessment, including total PCB levels in fish, and an apportionment of the PCBs in fish between the old sediments and the upstream source (s).

2. Fish PCB levels from the date remediation would commence to 30 years in the future for the "comparative" risk assessment (no-action and for each remedial alternative identified). Since some combination of sediment and upstream source remediation must be evaluated, the fish PCB levels will also need to be apportioned by source.

3.0 APPROACHES FOR ESTIMATING EXPOSURES TO PCBS IN THE HUDSON RIVER RISK ASSESSMENT

Once PCB levels in fish are determined over time and apportioned by source, the next step is to estimate the potential exposure to PCBs in fish. The method used to estimate PCB intake from potential fish consumption in the Hudson River risk assessment can greatly effect the estimated risks. In the EPA Phase I Report, EPA combined "reasonable" worst case estimates of exposure in a traditional point estimate method to yield an estimate of lifetime average daily dose. As discussed below, this approach greatly exaggerates potential exposure and associated risk and is not justified because more scientifically defensible methods have been developed and accepted by the scientific and regulatory communities. This section of the paper describes a more defensible risk-estimating approach that allows site-specific conditions to be considered.

3.1 Possible Approaches for Characterizing Exposures

There are three approaches that can be used to evaluate exposure to PCBs from consumption of Hudson River fish: a point estimate approach, Monte Carlo analysis, and Microexposure Monte Carlo analysis. The point estimate approach, used by EPA in the Phase 1 Report, is the simplest of the three. This approach assigns point estimates to each of the parameters in a dose rate equation (EPA, 1989). The parameter values are a mixture of typical and "reasonable" worst case estimates that are intended to result in a "reasonable upper-bound estimate of exposure" (EPA, 1989). The second approach is the use of a Monte Carlo analysis, where the same equation is used but the point estimate for each parameter is replaced by a distribution of values. The distribution expresses the probability that a specific parameter value will occur for an angler in the exposed population. A distribution of exposures is produced that reflects the possible combinations of different values from the distributions and the probability with which they occur. The third option for exposure assessment is the Microexposure Monte Carlo analysis. This method also uses the Monte Carlo technique, but modifies the exposure equation to better integrate spatial and temporal variations in exposure parameters and to explicitly address correlations between parameters.

Limitations of the Point Estimate Approach

In developing exposure estimates, there are uncertainties associated with estimates of intensity, frequency, and duration of exposure (NAS, 1983; Paustenbach, 1989). Traditionally, regulatory agencies have sought to account for these uncertainties by favoring the use of conservative or "reasonable" worst-case estimates for exposure parameters. This approach overestimates exposures (McKone and Bogen, 1991; Cullen, 1994; Slob, 1994), and this overestimation can occur even when each parameter value itself is "reasonable" (McKone and Bogen, 1991; EPA, 1992a).

The potential for overestimation can be readily demonstrated in the following example. Let us assume that the dose rate for an individual in an exposed population is determined by three parameters A,B, and C. The values for the three parameters are assumed to vary in the exposed population according to three distributions. Finally let the RME for the exposed population be estimated based on the 95th percentile of each of the parameter distribution (a reasonable worst case estimate of the parameter values). According to the basic rules of probability, the likelihood of an individual receiving a dose equal to or greater than the RME is given by the following equation.

$$p = (1-0.95)^3$$

or

$$p = 0.000125$$

This low probability is equivalent to stating that the RME falls on the 99.9875th percentile of the distribution of doses (Figure 5). Such a high percentile may not be a reasonable estimate for the exposed population. In addition, the potential to overestimate exposure increases with the number of parameters in the exposure model.

As explained by Thompson et al. (1992), and discussed extensively in the risk assessment literature (Finkel, 1990; McKone and Bogen, 1991; EPA, 1992a; Keenan et al., 1994), there are a number of other limitations to the point estimate approach, including:

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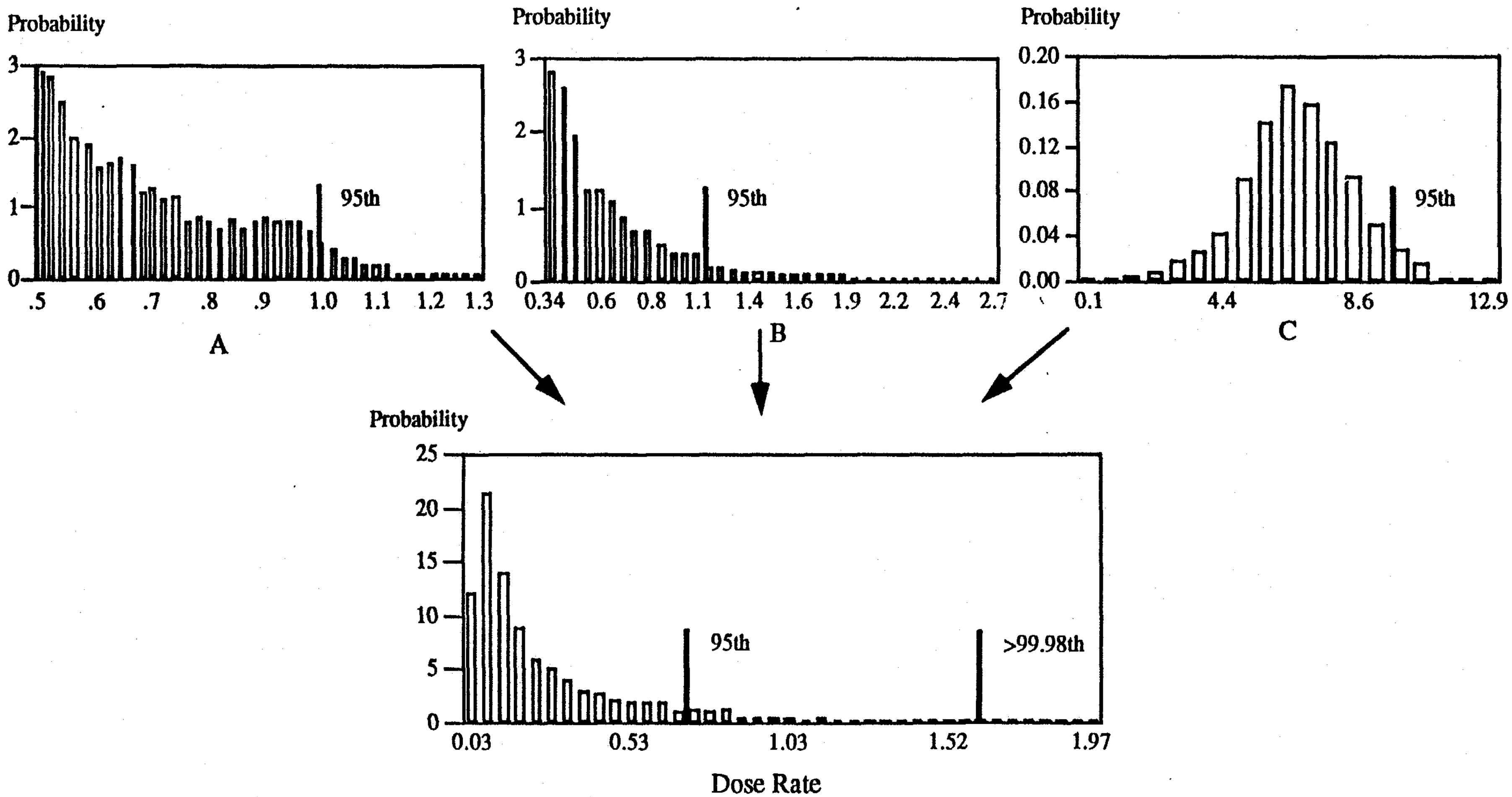
Figure 5. Use of Conservative (but realistic) Parameter Values in Exposure Assessment Can Result in Unrealistic Estimates of Dose Rates

Using the 95th percentile of each parameter results in 99.9+ percentile of actual distribution of intakes



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- the current method of selecting conservative values for exposure parameters is a poorly diagnosed process of incorporating value judgement into the scientific stage of the risk assessment/management process;
- ? - risk assessments may consider scenarios that will rarely (if ever) happen;
- the use of point estimates provides disincentives for regulatory agencies as well as risk assessors to generate a better data base for characterizing human exposure; and
- uncertainties in the final point estimates cannot be precisely quantified or even roughly estimated since many of the input parameters are at or near their maxima.

3.2 EPA Policy on Exposure Assessments

Recent changes in EPA's policies and guidelines have focused on improving risk management by presenting decision-makers with the entire range of possible risks rather than a single point estimate (EPA, 1992a, 1992b). The new policy states that numerical risk assessments should always be accompanied by a full characterization of the uncertainties, limitations and assumptions in the risk assessment. The new guidance also replaces the concept of the "maximum exposed individual" and the "reasonable maximum exposure" with a series of exposure descriptors, including individual, population and subpopulation estimates of exposure. The guidelines require that two types of individual exposure be calculated: the typical and the high-end exposure (HEE). The typical exposure is the dose rate received by an average or typical individual in the exposed population. The HEE is intended to reflect the doses received by the small but definable "high end" of the population. The primary objective in estimating the dose rate for the HEE is that the dose rate be a realistic estimate and not the result of a theoretical worst-case analysis.

The use of point estimates can only provide "subjective" estimates of the exposure descriptors such as the HEE. In contrast, Monte Carlo analysis is favored by the new approach to exposure and risk assessment. As explained by Hattis and Burmaster (1994), Monte Carlo analysis is not a new technique; it was developed by physicists 50 years ago and has been used in the fields of nuclear engineering, health physics and environmental chemistry. Monte Carlo analysis can be applied to any equation where the distributions of the parameters can be specified. Monte Carlo analysis can effectively characterize the impact of variability or uncertainty in input parameters on the estimates of dose rates in an exposed population. Such a probability distribution function provides risk managers with information necessary for regulatory decision-making. Specifically, the probability distribution function of the Lifetime Average Daily Dose (LADD) can be used to estimate the dose rates and associated risks for the typical (50th percentile) and the high-end exposures (e.g., 90th to 95th percentile) or can characterize the distribution of the individual risks in the exposed population.

In the Final Phase 2 Work Plan for the Hudson River Superfund site, EPA (1992c) endorsed Monte Carlo methods to the extent that data are available to define the distributions of values for exposure parameters. This position is consistent with the current EPA policy on Monte Carlo risk assessment, as set forth in the new *Guidelines for Exposure Assessment* (EPA, 1992a,b), that essentially requires the use of Monte Carlo analysis for sites where high quality site-specific data are available. More recently, in its draft document entitled *Estimating Exposure to Dioxin-Like Compounds*, EPA (1994) stated that "Monte Carlo techniques can be a powerful tool for expressing variability and evaluating scenarios in exposure assessments." ?

As this and the earlier issue papers document, there is an unusually large amount of information on the variation in key exposure parameters available for the Upper Hudson River. As discussed in Section 4.0, this data is more than adequate to characterize interindividual variation in the key parameters in the fish consumption pathway for the Hudson River.

3.3 Microexposure Monte Carlo Analysis

GE proposes that a state-of-the-art assessment of potential exposures to PCBs at the Hudson River site be performed using a Microexposure Monte Carlo technique. This approach is a modification of the synthetic life history approach developed by Price et al. (1991; 1992). It has been used by EPA and independent researchers to investigate residential exposure duration (Johnson and Capel, 1992; Sielken, 1994). It also has been used to evaluate childhood lead exposure (Goodrum et al., 1994) exposure to contaminants in tapwater (Harrington et al., 1995) and to evaluate exposure to dioxins from the consumption of freshwater fish (Keenan et al., 1993a,b). This approach in currently being employed in the supplemental risk assessment for Stringfellow Acid Pits Superfund Site. The approach was approved by EPA Region IX in the work plan for the site risk assessment (Pyrite Canyon Group, 1994). ? ?

Microexposure Monte Carlo, a refinement of traditional Monte Carlo analysis, provides greater flexibility in modeling exposures that vary over time, that are the sum of independent exposure events, and when the age of the angler affects the dose rate. All of these advantages are useful in the assessment of the Upper Hudson River. For example, fish concentrations vary over time. The body weight of an angler and the duration of angling are influenced by the age of an angler. Finally, long-term exposure to PCBs is a function of the consumption of many fish. Microexposure Monte Carlo simulation uses the available information on the distribution of fish concentrations to characterize the distribution of long-term exposures to PCBs.

Microexposure Monte Carlo analysis is a technique in which an individual's total exposure to a contaminant is calculated by summing the doses received by many individual exposure events. Each event is simulated using information specific to the time and location of the event. The number of events and sequence in which they occur in the individual's life can be simulated based upon information on an individual's short- and long-term behavior. Modeling long-term exposures as a summary of separate events is not new; in fact, this approach is recommended by EPA (1992d) for evaluating exposures which occur primarily during childhood, when body weights change rapidly.

~70 yrs for adult pool.

The difference between traditional Monte Carlo analysis and Microexposure analysis can be illustrated by comparing how the two techniques are used to estimate the dose used in carcinogenic risk estimates. Traditional Monte Carlo uses the same equations as the point estimate approach but replaces the point estimates with distributions. In traditional Monte Carlo, the dose rate is calculated using the following equation:

$$LADD = \frac{C \times IR \times ED}{BW \times LT}$$

where,

LADD	=	the lifetime average daily dose rate
C	=	the distribution of the average concentrations of the chemical in the medium experienced by an individual over his or her life
IR	=	the distribution of intake rates of the medium in the exposed population
ED	=	the distribution of durations of the individual's exposures
BW	=	the distribution of body weights in the exposed population at the time of exposure
LT	=	the distribution of lifetimes (converted to days) over which the dose is averaged

In contrast, Microexposure Monte Carlo analysis defines lifetime exposure as the sum of potential short-term (e.g., annual, daily) exposures represented by the following equation:

$$LADD = \frac{1}{LT} \sum_{j=1}^{\text{Duration}} \frac{1}{BW_j} \sum_{i=1}^{\text{Exposure Events}_j} C_{ij} \times IR_{ij}$$

where,

C_{ij}	=	the concentration of the contaminant in the environment that an individual is exposed to during the ith exposure event in the jth year of his or her life
IR_{ij}	=	the rate the contaminant enters the body of the individual during the ith exposure event in the jth year of his or her life
Exposure Events_j	=	the number of exposure events that occur during the jth year of the individual's life
BW_j	=	the average weight of the individual during the jth year of individual's life
Duration	=	the number of years that the individual is exposed
LT	=	a standard lifetime for humans

The Microexposure Monte Carlo technique is very useful in assessing exposures from fish consumption. In a fish consumption scenario, an angler's lifetime intake can be considered the sum of the intakes that he or she receives during each year that he or she fishes from the site. Each year of fish consumption can, in turn, be expressed as the sum of fish meals consumed during that year.

In the case of the Hudson River, the Microexposure equation would be defined as follows:

$$\text{LADD} = \frac{1}{LT} \sum_{j=1}^{\text{Angling Duration}} \frac{1}{BWj} \sum_{i=1}^{\text{Fish Consumed}} \text{Fish Concentration}_{ij} \times \text{Fish Size}_{ij} \times (1\text{-Cooking Loss}_{ij})$$

where,

angling duration	=	the period of time in years that an angler may fish the Upper Hudson
fish consumed	=	the number of fish consumed in the ith year
fish concentration$_{ij}$	=	the concentration of PCBs in the ith fish caught in the jth year
fish size$_{ij}$	=	the size of the edible portion of the ith fish caught in the jth year
cooking loss$_{ij}$	=	the fraction of PCBs lost during the cooking of the ith fish caught in the jth year.

The major advantage of Microexposure Monte Carlo analysis is its flexibility in incorporating information on temporal changes in exposure parameters. For example, PCB concentrations in Hudson River fish have varied significantly over time. Microexposure Monte Carlo modeling is able to explicitly incorporate this temporal variation into estimates of long-term dose rates. As another example, individuals change throughout their lives. Behaviors that are reasonable for one age are not reasonable for another. For young individuals, there are significant changes in body size as the individuals mature. In addition, exposure-related behaviors such as fish consumption and residential mobility also change with age. Microexposure Monte Carlo analysis allows the incorporation of age-related exposure factors into the estimates of long-term dose rates by adjusting the number of fish meals or the individual's body weight by the age of the angler for each year of exposure. As a third example, traditional Monte Carlo analysis of fish consumption has a shortcoming in that it estimates each angler's lifetime exposure by assuming that every fish consumed contains a single uniform concentration (Anderson et al., 1992). In reality fish concentrations vary from one fish to another. By modeling each fish meal separately, Microexposure Monte Carlo analysis considers the varying concentrations in individual fish.

In the assessment proposed for the Upper Hudson River site, an angler's total consumption of fish may be estimated as a series of separate exposure events (individual fish meals). The doses received from these events can be calculated independently and summed to provide estimates of chronic and lifetime exposures. In addition, the duration of an individual angler's exposure is characterized not by adoption of a distribution of durations, but is assessed using information on the angler's age at the time the exposure begins, together with age-specific rates of mobility, mortality, and angling cessation. Finally, exposure parameters such as body weight and fish consumption are also determined based on the age of the angler.

4.0 DEVELOPMENT OF DISTRIBUTIONS FOR EXPOSURE PARAMETERS

The application of Microexposure Monte Carlo analysis to the exposure assessment for the Hudson River risk assessment requires distributions of the interindividual variation in the parameters in the dose rate equation used to evaluate the exposure. The goal, as described above, is to determine the distribution of LADDs in a hypothetical population of anglers who would fish the Upper Hudson in the absence of fishing restrictions. This section presents a summary of key parameters that should be employed for the Hudson River fish consumption Microexposure Monte Carlo risk analysis.

4.1 Fish Consumption Rates

The amount of fish that anglers consume is a key parameter in the estimate of exposure to PCBs from Upper Hudson River sediments. In its Phase 1 Report, EPA (1991) recommended 30 g/day as an estimate of fish consumption by Hudson River anglers. This estimate was based on the median consumption rate reported by marine anglers in surveys by Puffer et al. (1981) and Pierce et al. (1981). The amount of fish consumed by a population of anglers varies depending on the numbers and types of waterbodies fished and the characteristics of the angler population. Fish consumption also depends on factors such as climate, fish species present, productivity, access, and the size of the angler population. In the Final Phase 2 Work Plan, EPA (1992c) expressed a willingness to develop site- or region-specific consumption rates for Hudson River anglers if appropriate data are available. The 30 g/day rate likely overestimates the intake for Hudson anglers, since consumption of self-caught marine fish is typically higher than consumption of freshwater fish. Moreover, the results from Puffer and Pierce are biased toward the frequent angler which overestimates fish consumption (Price et al., 1994).

Unfortunately, no historical survey on the fish consumption rates of anglers using the Upper Hudson River has been performed. In addition, no such survey can be performed, due to the existence of a State ordered and enforced fishing ban on the affected portion of the river. Because of the current fishing restrictions, any survey performed on the Hudson River anglers will not provide an appropriate baseline for the river. In the baseline risk assessment, the goal is to assess the risks that would occur in the absence of any regulatory controls.

There are three surveys of angler behavior that involve anglers on the Hudson River. Two mail surveys have been performed on New York anglers (NYSDEC, 1990; Connelly et al., 1992) and a creel survey (Barclay, 1993) was performed on Hudson River anglers. However, none of these surveys focused on fish consumption from the Hudson River. NYSDEC (1990) evaluated fish consumption from all recreational and commercial sources, including self-caught fish from the Hudson. Connelly et al. (1992) evaluated self-caught fish consumption, but did not estimate consumption from individual waterbodies. Barclay (1993) collected data on the frequency of self-caught fish meals, but did not calculate a fish consumption rate. In addition, the survey does not contain sufficient information to allow the calculation of a meaningful fish consumption rate for the Upper Hudson River.

based on similarities to river

Because site-specific data on fish consumption are unavailable, the Agency should base the Hudson River estimates on data from similar bodies of water or from regional data. Numerous estimates of consumption rates have been made for both the general population of the U.S. (Javitz, 1980; Rupp et al., 1980; USDA, 1980) and for recreational anglers (Soldat, 1970; Honstead et al., 1971; Pierce et al., 1981; Puffer et al., 1981; Turcotte, 1983; Landolt et al., 1985, 1987; Cox et al., 1985, 1987, 1990; Fiore et al., 1989; West et al., 1989; NYSDEC, 1990; ChemRisk, 1991a,b; Connelly et al., 1992; Richardson and Currie, 1993; Ebert et al., 1993). These studies have reported a wide range of fish consumption values and have examined consumption rates of fish taken from various types of waterbodies ranging from all waters to single bodies of water (Ebert et al., 1994).

Given this wide range of angler studies and consumption rates, the study and rate of consumption for the assessment of risk to anglers at the Upper Hudson River site should be selected carefully. The selection of a surrogate study depends on the characteristics of the population who have the potential to be exposed and the type of waterbody being evaluated. Specifically, it is critical that the study evaluate self-caught, freshwater fish over a long period of time. These criteria must be met to ensure that the fish consumption rate closely approximates consumption from the Upper Hudson. In addition, it would be preferable to use a study that evaluated consumption from a single flowing system that was similar to the Hudson. However, if a specific waterbody with appropriate characteristics cannot be identified, it may be more appropriate to use estimates generated for flowing waters only. Finally, the selected study should have collected data from a regionally appropriate waterbody.

There are a limited number of studies available in the New York/New England area that provide information on consumption of sport-caught fish from freshwater rivers and streams. The Ebert et al. (1993) and Connelly et al. (1992) studies most closely approximate hypothetical consumption from the Hudson River. Both of these studies evaluated consumption of self-caught freshwater fish by recreational anglers using a mail recall survey. Given these similarities, it is not surprising that both studies reported very similar fish consumption rates. The results of Connelly et al. (1992) indicated that the average New York angler consumes 11 meals per year of self-caught fish from New York's freshwater fisheries. If it is assumed that each meal is 227 grams in size (1/2 pound) (West et al., 1989; NYSDEC, 1990), it can be estimated that the average New York angler consumes self-caught freshwater fish at a rate of 7 g/day. This estimate is very similar to the mean rate of freshwater fish consumption by Maine anglers of 6.4 g/day from all waters reported by Ebert et al. (1993).

Although the Connelly et al. (1992) study is specific to New York State, there are several factors which limit its usefulness in the Upper Hudson River assessment. First, Connelly et al. (1992) only present a single point estimate value for fish consumption. The use of a distribution of consumption rates, however, is necessary in order to characterize interindividual variability and realistically assess the potential risks to recreational anglers. With only an average consumption rate value, it is not possible to accurately represent the range of recreational anglers, including those who ingest higher amounts of fish.

Second, the mean fish consumption rate determined by Connelly et al. (1992) represents fish eaten from all freshwaters in the State (i.e., lakes, ponds, rivers, and streams). As pointed out in Ebert et al. (1993), intake from rivers and streams is only a fraction of the intake from all freshwaters. In addition, the rate of intake from multiple waterbodies is higher than that from a single water system (Ebert et al., 1994). Given these factors, it is highly likely that the fish consumption rate in Connelly et al. (1992) overestimates the actual fish consumption rate on a single portion of the Upper Hudson River. Finally, it is important to note that the purpose of the Connelly et al. (1992) study was not to identify a consumption rate for New York anglers. Although questions were asked in the survey regarding fish consumption behaviors, those questions were aimed at estimating how the effect of health advisories altered the consumption behavior of recreational anglers.

not Huds

While the data from Ebert et al. (1993) are not specific to New York State, these data provide a more appropriate surrogate for Hudson River anglers than the Connelly et al. (1992) data. Angler demographics and fishing opportunities are similar in Maine and New York, and the mean fish consumption rates are similar for both studies (NYSDEC, 1990; Connelly et al., 1992; Ebert et al., 1993). In addition, Ebert et al. (1993) provide a complete distribution of fish intake rates for flowing waters, i.e., streams and rivers. Thus, the best region-specific data on fish consumption rates are available from Ebert et al. (1993) and should be used in the Hudson River risk assessment.

The selection of the most appropriate fish consumption rate is discussed more fully in the paper entitled *Estimating Fish Consumption Rates for the Upper Hudson River* and in the manuscripts, *The Effect of Sampling Bias on Estimates of Angler Consumption Rates in Creel Surveys* (Price et al., 1994), *Selection of Fish Consumption Estimates for Use in the Regulatory Process* (Ebert et al., 1994), and *Estimating Consumption of Freshwater Fish among Maine Anglers* (Ebert et al., 1993). EPA should use the distribution of fish consumption rates for flowing waters as developed by Ebert et al. (1993).

4.2 Species Preference

Anglers typically seek to catch certain desirable species and to reject others. Since PCB levels in fish vary by species, it is important to capture this angler preference in the estimates of exposure to PCBs. For example, if anglers tend to favor species which happen to have lower PCB concentrations, their potential exposures will be lower than the average of all the species or the upper-end species.

In the Phase 1 Report, EPA (1991) acknowledged that New York anglers do not spend equal time fishing for all species and that PCB concentrations vary from one species to another. Nevertheless, EPA (1991) chose to average the PCB concentrations from all species sampled to determine a single point estimate (95th upper confidence limit of the mean) of PCB concentration in fish tissue. In the Final Phase 2 Work Plan and Sampling Plan, EPA (1992c) expressed a willingness to refine its estimate if appropriate data were available on species preference.

Recent studies by the New York State Department of Environmental Conservation indicate that New York anglers preferentially select for certain species in both fishing effort and consumption (NYSDEC, 1990; Connelly et al., 1992). In many cases, the species selected were those that accumulate lower levels of PCBs, often because these most desirable species have relatively low lipid contents as compared to other species present in the Upper Hudson. Since the species of fish sampled by EPA for PCB tissue analysis are not necessarily consumed by recreational anglers in amounts proportional to their sampling frequencies, the risk assessment for the Upper Hudson should consider both the tissue levels of PCBs in various fish species, and angler preferences.

Information on species preference specific to the Upper Hudson River is unavailable. However, data on angler preference in freshwater rivers in New York similar to the Upper Hudson River are available from Connelly et al. (1992). Based on these data, it is possible to identify species preferences among New York anglers that can be used as a surrogate for Hudson River anglers. Connelly et al. (1992) collected information on fishing behaviors (e.g., species caught, waterways fished) and fish consuming behaviors (e.g., species eaten, preparation techniques used) of licensed anglers. In order to use these data for the Upper Hudson, it is necessary to identify rivers and streams with characteristics and species similar to the Upper Hudson. Such an analysis results in a list of fish species likely caught in the Upper Hudson and the probability of how often these species are eaten. By taking this approach, a probability distribution that accurately reflects species consumption preferences of Hudson River anglers can be developed. The paper entitled *Determining the Intake of Hudson River Fish by Species* provides a complete discussion of this issue and recommends the appropriate input parameters for the Microexposure Monte Carlo analysis.

4.3 Reduction of PCBs in Fish Tissue from Cooking Processes

Exposure to PCBs from fish consumption depends on the PCB concentration in the fish as they are consumed in a meal. If the cooking process reduces the amount of PCBs in a fish or fish fillet, then the dose the angler receives is reduced. In its Phase 1 Report, EPA (1991) estimated PCB levels in fish tissue from raw samples. EPA (1991) dismissed the impact on PCB levels from various cooking processes, citing an absence of a consensus in the published literature that cooking reduces PCB concentrations in fish. In the Final Phase 2 Work Plan, EPA (1992c) agreed to revisit this issue.

Although EPA acknowledges studies that report PCB reduction from cooking, the variability in these data has led EPA to conclude that the effects of cooking do not warrant consideration. Reported reductions have varied over an extremely large range and have not been reported in a consistent manner. This inconsistency has hampered comparisons and compilations of results to date. To address this issue, Sherer and Price (1993) analyzed the available literature to determine if a pattern could be identified. The authors converted the results of each study to a percent loss of PCBs on a total mass basis, which allowed them to determine an average PCB loss for each cooking method. This analysis indicates that the current literature justifies a reduction in PCB concentrations with cooking practices. The amount of PCB loss depends on the percent lipid in the fish and the specific cooking method used. Fish fillets with high concentrations of lipids tend to lose more PCBs during the cooking process, and cooking methods that remove fat (e.g., frying) tend to be more effective in reducing PCB tissue levels.

The recent summary of PCB literature demonstrates cooking processes likely used are effective at removing PCBs from fish (Sherer and Price, 1993). In addition, research shows that freshwater anglers in the region typically use cooking methods that reduce PCB levels in self-caught fish (Connelly et al., 1992; ChemRisk, 1991a). Anglers are more likely to select preparation methods that lead to greater reductions in PCBs (e.g., frying) than methods that do not substantially reduce PCB concentrations, such as eating raw fish or making fish soup. Thus, the amount of PCBs per fish consumed by Hudson anglers is substantially less than reported in analyses of uncooked fillets and should be incorporated into the Hudson River risk assessment. In fact, the New York State Department of Environmental Conservation (NYSDEC, 1991) recommends certain cooking practices as a means of reducing exposure to organochlorines in fish. Information on the frequency that freshwater anglers use various cooking methods is available from Ebert et al. (1993) and Connelly et al. (1992).

The paper entitled *Evaluating the Impact of Cooking Processes on the Levels of PCBs in Fish* and the manuscript *The Effect of Cooking Processes on PCB Levels in Edible Fish Tissue* (Sherer and Price, 1993) provide a full discussion of this issue and give the recommended values to use in the Microexposure Monte Carlo analysis.

4.4 Duration of Exposure

EPA estimates exposure in terms of the lifetime average daily dose or LADD. The LADD received by an angler is influenced by the number of years he or she fishes the Upper Hudson River, i.e., the longer the duration, the higher the LADD.

In its Phase 1 Report, EPA (1991) estimated a duration of 30 years as the time an angler may consume fish from the Hudson River. This conservative estimate is based on a 1983 survey by the U.S. Bureau of Census on household occupancy times and represents the 90th percentile for the number of years an individual is likely to reside at the same residence. Although residential mobility is an accurate predictor of exposure duration for many sources of contamination that occur in or near the home, the duration of time an individual remains in one residence may not be a reasonable predictor of the duration of angling from a particular waterbody. Exposure from consuming recreationally caught fish will only affect those individuals who continue to fish the waterbody of concern regardless of their current residence. Therefore, residential mobility alone is not a reliable surrogate for the prediction of exposure duration for fish consumption.

For the Upper Hudson, GE proposes to define the exposure duration as the time an angler begins fishing and continuing until the angler no longer catches and consumes fish from the Hudson River. The point at which an angler stops fishing varies with the individual angler and is influenced by three factors: (1) mobility; (2) mortality; and (3) the decision to give up fishing. The duration of exposure can only be properly estimated when all of these factors are considered.

When evaluating mobility, it is necessary to go beyond a strict consideration of residential mobility because changes in household location may not lead to changes in fishing behavior. Only when an individual moves a sufficient distance will a change be made in preferred fishing locations. Although interstate or U.S. regional mobility data could be used to estimate the number of individuals who give up fishing each year, interstate moves would not account for intrastate moves that would result in a change in angling practices. County mobility may be the most appropriate scale at which to measure the gain or loss of potential Hudson River anglers due to distance. These data are available by age, gender, and race from the U.S. Bureau of Census and can be used to develop a distribution of the probability of moving at each age.

? opposite for anglers v general pop

Mortality also determines how long an individual angler catches and consumes fish. Anglers tend to be individuals who are older than the general population (ChemRisk, 1991a). Standard actuarial mortality tables predict the life expectancy of a given angler and whether that individual remains a member of the population of living anglers. Age- and gender-specific data on mortality are available from the New York State Department of Health and the National Center for Health Statistics and can be used to develop a distribution of the probability of dying at each year of an angler's life.

An angler may lose interest in the sport of fishing and give it up for a number of reasons. In fact, at every age there is a certain probability that an individual will permanently give up the sport. However, due to the difficulty of collecting these data, no study has evaluated this phenomenon directly. Information on the age structure of recreational anglers has been reported by ChemRisk (1991a) and can be used to indirectly gain insight on the fraction of anglers who permanently give up fishing at different ages. The age-structure data indicate that a sizable fraction of anglers give up fishing between the ages of 30 and 60.

A probabilistic analysis of angler behavior can characterize the date and age that an angler gives up fishing based on age-specific data on mortality, mobility, and angler practices. This type of information can be used to determine the age-specific probability that an individual will permanently stop fishing. The paper entitled *Estimating Exposure Duration for the Hudson River Risk Assessment* provides a full description of this issue and recommends the values to be used in the Microexposure Monte Carlo analysis.

5.0 SUMMARY AND RECOMMENDATIONS

Given the magnitude of the physical, chemical and biological impacts of the potential remedial decision on the Hudson River and the associated costs, it is necessary for EPA to clearly demonstrate the benefits and risks of any proposed action. In doing so, EPA must fully utilize the vast amount of information available concerning the river and use analysis tools that will help reduce the uncertainty in the risk/benefit analysis. When faced with uncertainty, regulatory agencies, such as EPA can adopt very conservative assumptions that often tend to grossly overestimate baseline risks and potential benefits of remedial actions. Alternatively, EPA can thoroughly analyze the data in hand and embrace the refined and proven tools of exposure assessment that are now readily available. The approach for the development and utilization of risk assessments for the Hudson River RRI/FS project as outlined in this paper, will still yield results that are conservative (i.e., do not underestimate potential exposure). However, given the state of development of risk management science, the outlined approach will provide a more accurate estimate of the risk/benefit of any remedial action for the Hudson River than more traditional approaches adopted to analyze this type of problem.

To complete the Hudson River Risk assessment, the EPA should do the following:

1. Use the PCB-fate and transport model to estimate PCB fish levels 30 years into the future for action and no-action scenarios. This is a key input into the risk assessment.
2. Clearly identify all sources of PCBs entering the Upper Hudson River.
3. Determine separately the risk associated with PCBs in fish originating from the upstream source and the old sediments (Baseline Risk Assessment).
4. Evaluate the risk reduction potential of each remedial alternative compared to the no-action alternative. This analysis must include an assessment of the relative contribution of PCBs to the fish from the upstream source(s) and the PCBs in the old sediments (Comparative Risk Assessment).
5. Employ the Microexposure Monte Carlo technique as the technique for estimating risk.

6. Use reasonable exposure values and distributions (i.e., those relevant to the Hudson River site) in the risk assessment as described in Section 4.0.

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