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May 24, 1995

Mr. Bryan Olson
U.S. Environmental Protection Agency
Waste Management Division
J.F. Kennedy Federal Building
HRR-CAN3
Boston, MA 02203

RE: Use of Monte Carlo Analysis for Risk Assessments at Pittsfield/Housatonic Sites

Dear Mr. Olson:

As you know, the General Electric Company (GE) proposes to use probabilistic methods, namely Monte Carlo analysis, to characterize exposures in the risk assessments to be conducted at the GE sites covered by the RCRA Corrective Action Permit issued by EPA to the GE-Pittsfield facility. Such methods are allowed by the Massachusetts Contingency Plan (MCP) and by EPA's exposure assessment guidance, initially adopted in 1992 and recently updated in February 1995. However, EPA Region I risk assessors have indicated in prior discussions that they do not intend to accept use of probabilistic techniques for the risk assessments at the GE sites unless permitted to do so by Region I management. As a result, you suggested some time ago that we prepare a memorandum describing the Monte Carlo technique and the way in which we intend to use Monte Carlo analysis in the risk assessments for the GE sites.

At our request, GE's risk assessment consultants at ChemRisk have prepared such a memorandum. A copy is enclosed. It provides an overview of the Monte Carlo methodology, a description of EPA guidance on this subject, and a discussion of the benefits of Monte Carlo analysis in addressing variability and uncertainty in the risk assessment process. It also describes the way in which ChemRisk intends to use Monte Carlo analysis in the risk assessments for the GE sites, and it identifies the exposure parameters for which ChemRisk intends to use distributional data in that analysis.

As also noted in that memorandum, in addition to using Monte Carlo analysis to develop distributions of exposure and risks, we intend to calculate point estimates of exposure and risk, using conventional risk assessment methods, for comparison with the results of the Monte Carlo assessment.

Area Environmental and Facility Programs
General Electric Company
100 Woodlawn Avenue Pittsfield, MA 01201

We would appreciate it if you could forward this memorandum to the appropriate officials at Region I. After the Agency has reviewed this memorandum, we would like to have the opportunity to discuss further with EPA our proposal to use Monte Carlo analysis in the risk assessments, in accordance with the MCP and EPA guidance. In the meantime, please do not hesitate to call me if you have any questions about this important issue.

Very truly yours,

Ronald F. Desgroseilliers /ecw

Ronald F. Desgroseilliers
Manager – Area Environmental
and Facility Programs

Enclosure

cc Douglas J. Luckerman, Esq., EPA
Celeste Philbrick-Barr, EPA
Mary Ballew, EPA
J. Lyn Cutler, DEP
Alan Weinberg, DEP
Stephen F. Joyce, DEP
Robert Bell, Esq., DEP
Stephen P. Winslow, Esq., DEP
Margaret Harvey, DEP
Andrew J. Thomas, Jr., Esq., GE
Jeffrey G. Ruebesam, GE
John D. Ciampa, GE
Ellen S. Ebert, ChemRisk
James R. Bieke, Esq., Shea & Gardner
Public Information Repositories

ChemRisk
A Division of McLaren/Hart
Environmental Engineering

Stroudwater Crossing
1685 Congress Street
Portland, ME 04102
207.774.0012
FAX 207.774.8263

TECHNICAL MEMORANDUM

TO: EPA Region I / Massachusetts Department of Environmental Protection

FROM: Jane McCrodden
Ellen Ebert
Russell Keenan

DATE: May 24, 1995

SUBJECT: The Role of Monte Carlo Analysis in Characterizing Uncertainty and Variability in Exposure and Risk Assessment

Introduction

More than ten years ago, the risk assessment methodology was developed to evaluate hazards posed by exposure to developmental and reproductive toxicants, mutagens, carcinogens, and systemic toxicants. Many existing environmental criteria and some of our nation's occupational health standards have, at least in part, been based on the results of low-dose extrapolation models and exposure assessments (Ruckelshaus, 1984; OSTP 1985; Ames, 1987; Preuss and Ehrlich, 1987). Tolerances for pesticides residues, drinking water guidelines, ambient water quality criteria, air standards, as well as exposure limits for contaminants found in various media at RCRA facilities or at hazardous waste sites have been developed using these techniques (Paustenbach, 1989a). Most recently, risk assessment has been modified to evaluate potential impacts on fish, wildlife, endangered species, and selected flora due to chemicals or other stressors (EPA, 1992a).

The goal of any risk assessment is to estimate the likelihood of an adverse effect on humans, wildlife, or ecological systems from possible exposures to chemical or physical agents. The components of the risk assessment model have been refined during the last five years, dramatically so in the case of the exposure assessment component. A growing acceptance and application of

these advances can be found in the 1992 Environmental Protection Agency (EPA) *Guidelines for Exposure Assessment* (EPA, 1992b), in the 1993 Science Advisory Board review of the *Risk Assessment Guidance for Superfund: Volume I - Human Health Evaluation Manual (RAGS)* (SAB, 1993), and in EPA's 1995 *Guidance for Risk Characterization* (EPA, 1995).

In developing exposure estimates, there are typically variabilities and uncertainties associated with estimates of intensity, frequency, and duration of exposure (NAS, 1983; Paustenbach, 1989b). Traditionally, regulatory agencies have sought to account for these variabilities and uncertainties by favoring the use of either conservative or worst-case estimates for exposure parameters. As explained by Thompson et al. (1992), and discussed extensively in the risk assessment literature (Finkel, 1990; McKone and Bogen, 1991; Keenan et al., 1994), the results of this approach are point estimates of exposures that are of limited value because:

- risk assessors and risk managers have no means of assessing the degree of conservatism in an assessment;
- risk assessments may consider scenarios that will rarely (if ever) happen;
- the estimates are typically based on the multiplication of several upper bound values, which will lead to an overly conservative risk estimate, often on the order of the 99.99th percentile;
- the method of using upper bound point estimates of several exposure parameters is an inadequate characterization which incorporates value judgment into the scientific stage of the risk assessment/management process; and
- uncertainties in the final point estimates cannot be determined since many of the input parameters are at or near their maxima.

Characterizing the variability and uncertainty in an assessment of human health risks to chemical agents is important to risk managers at both the state and federal levels. Recent changes in EPA's policies and guidelines have focused on improving risk management by presenting decision-makers with the entire spectrum of plausible risks rather than a single point estimate (EPA, 1992b; 1995). A mathematical technique favored by the new approach to exposure and risk assessment is Monte Carlo analysis (MCA). It relies on the fundamental tenet that exposure-related behavior will vary from one individual to another within an exposed population. This variability can be described by a distribution called the probability density function. In a similar fashion, the

uncertainty associated with imprecise measurements can also be described by distributions. MCA is built upon this approach of using probability density functions to characterize the variability in exposure-related behaviors as well as the stochastic uncertainty. Such a composite probability density function provides risk managers with information necessary for regulatory decision-making.

ChemRisk®, on behalf of General Electric (GE), intends to conduct the risk assessments for the Housatonic River site and the other GE sites in Pittsfield in a manner consistent with the latest EPA guidance on exposure and risk assessment. To that end, and to the extent that high quality data distributions are available and applicable, we propose to use probabilistic methods in the exposure assessment portion of the risk assessment in order to characterize the range of potential risks associated with the Housatonic River and other areas. The Massachusetts Contingency Plan (MCP) explicitly allows the use of probabilistic techniques in risk assessments, and Massachusetts DEP personnel have indicated that they will accept such analyses once they have made final their risk assessment guidance.

This technical memorandum provides an overview of the Monte Carlo methodology, a description of the evolution of EPA guidance on exposure assessment, and a discussion of the way that Monte Carlo analysis can be used to quantify and analyze variability and uncertainty in the risk assessment process. It also describes the way in which we intend to use Monte Carlo analysis in the risk assessments for the Housatonic River and other GE sites, and identifies the exposure parameters for which we intend to use distributional data.

Monte Carlo Methodology

As explained by Harris and Burmaster (1992), Monte Carlo analysis is not a new technique; it was developed by physicists more than 50 years ago and has been used in the fields of nuclear engineering, health physics and environmental chemistry for some time. MCA can be applied to any equation where at least a portion of the equation's variables can be described with probability density functions. It is used to provide a range of solutions to the equation which takes into account the uncertainties and variabilities associated with each parameter. MCA operates by repeatedly calculating the equation using values selected from the parameter distributions. The result of each of the calculations is saved. Once completed, the results of all of the calculations are

plotted and statistical summaries are produced. A probability distribution of these collective results can also be derived.

A growing use of MCA is in estimating the Lifetime Average Daily Dose (LADD) that an individual receives from a source of environmental contamination. It allows all possible solutions to an exposure equation to be calculated, resulting in a probability distribution of potential exposure. From this probability distribution, the typical (50th percentile), high-end (e.g., 90th percentile, 95th percentile), or any other percentile of exposure can be selected from the distribution of estimated exposures across the exposed population for use in regulatory decision-making.

MCA is a computationally intensive technique. Often the equation must be iterated thousands of times before the distribution of the results is well defined. Because of this limitation, MCA was not a feasible tool for exposure analysis before the advent of computers. With the widespread availability of powerful desktop computers, Monte Carlo simulations involving thousands of solutions to the exposure equation can be generated within a short period of time.

EPA Guidance on Exposure Assessment

As risk assessment methods have improved, EPA has repeatedly revised its guidance on the conduct of exposure assessment. While early risk assessment guidance used a worst-case approach for estimating exposure, EPA recognized that these worst-case analyses resulted in unrealistic estimates of risk. Therefore, EPA revised its guidance by developing a reasonable worst-case approach. More recently, EPA has recommended that a multiple risk descriptor approach be used to estimate risks (EPA, 1992b,c; 1995).

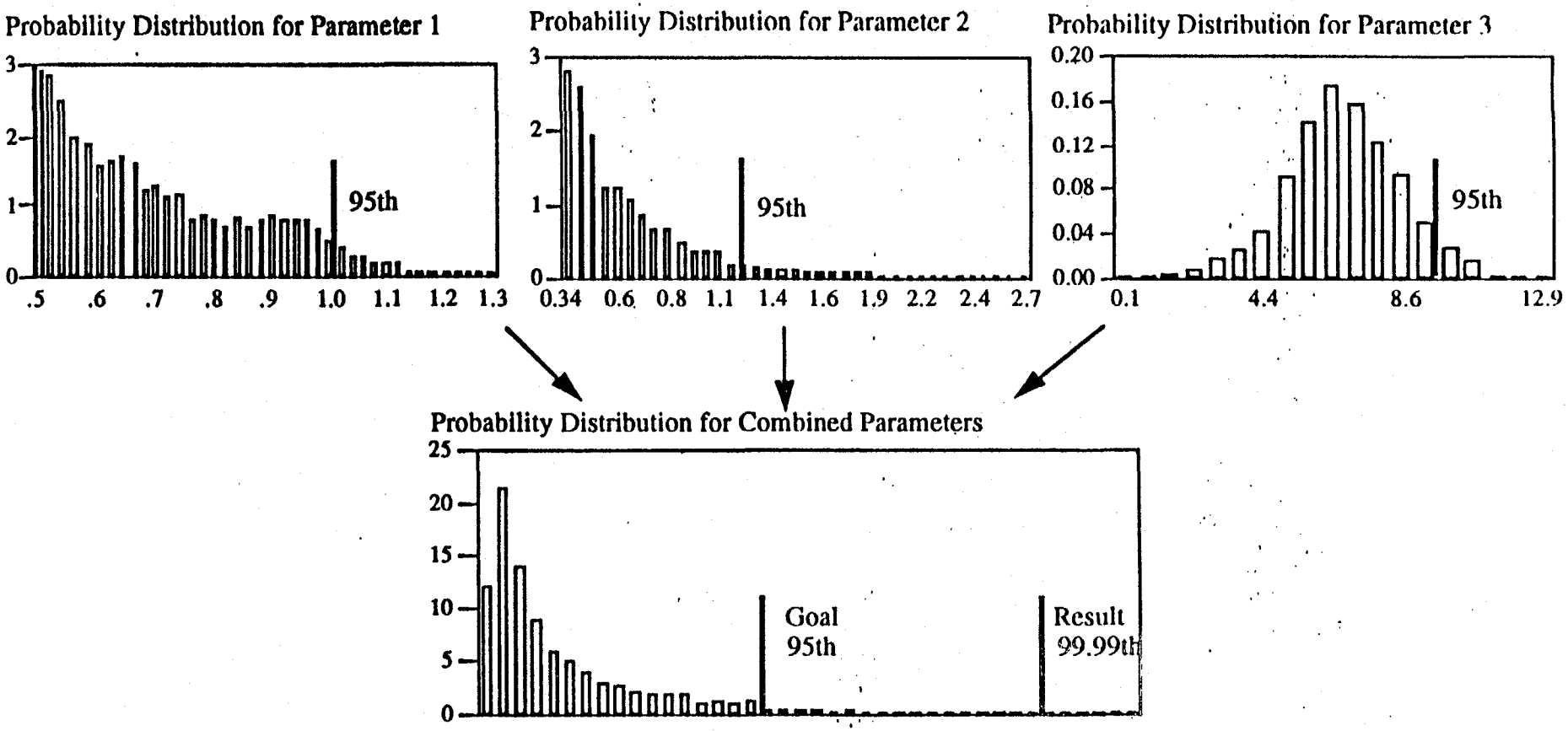
The goal of most risk analyses is to determine whether an activity, such as consumption of contaminated drinking water or contact with contaminated soil, results in an unacceptable risk. The early method of dealing with the variability and uncertainty in estimates of doses received from such activities was to adopt exposure assumptions that were "worst case" and estimate exposures for the maximum exposed individual (MEI). These assumptions guaranteed that the final estimates of exposure and risk would safeguard all individuals. It often resulted, however, in the selection of values that were not only much higher than those that would be expected in the general population, but were also wholly unrealistic (Keenan et al., 1994).

Up until the late 1980s, many EPA offices routinely used worst-case exposure assumptions in their risk analyses. Such assessments were inefficient as regulatory tools and were limited in their ability to serve as a yardstick by which alternative risk management options could be chosen (Goldstein, 1989; Finkel, 1990). Critics both within and outside the Agency demonstrated that the worst-case approach greatly overestimated risk and resulted in needless regulation or remediation (EPA, 1989a; Goldstein, 1989; Graham, 1990).

In 1989, EPA introduced the concept of Reasonable Maximum Exposure (RME) to risk assessment, in both the Exposure Factors Handbook (EPA, 1989b) and the Risk Assessment Guidance for Superfund Sites (EPA, 1989c). Rather than assessing a worst-case exposure scenario, an RME analysis used more reasonable but still conservative factors so that the resultant point estimate of exposure was more realistic than that generated by the worst case approach. However, this point estimate approach still requires that the variability among the population being studied be reduced to a single value to be used for each exposure parameter. Often these values are selected through the use of summary statistics without proper consideration of the full shape of the distribution for that parameter and the target population. An upper-bound estimate is often used as the point estimate. This approach describes exposure of anywhere between 0.01 and 1 percent of the population. For example, if the 95th percentile of each of three parameters are combined in an exposure estimate, the result of that calculation will be the 99.99th percentile of exposure, thereby describing exposure of 0.01 percent of the population (Figure 1). This *de facto* focus on the tiny minority of the population in exposure assessment translates into a narrowly focused risk estimate, and is inconsistent with the definition of RME.

In addition, EPA (1989c) also specified that risk assessments should contain a separate discussion of the "uncertainty" in the exposure and risk estimates. This section was intended to improve upon the worst-case approach; however, in practice this requirement resulted in uncertainty analyses that were qualitative in nature and which were disregarded by most risk managers because they provided little useful interpretation of the exposure and risk findings. While EPA (1989c) acknowledged that probabilistic techniques such as MCA could be used to quantify uncertainty, it recommended that "these analyses be used...only as a part of the uncertainty analysis (and not as a basis for the reasonable maximum exposure)".

Fig. 1. The Effect of Combining 95th Percentiles of Multiple Exposure Parameters on Estimates of Exposure



Subsequent to the development of RME exposure policy, a number of articles on the use of MCA as a technique to evaluate variability and uncertainty in exposure assessment appeared in the peer-reviewed literature (Finkel, 1990; McKone and Bogen, 1991; Burmaster and von Stackelberg, 1991; Harris and Burmaster, 1992; Thompson et al., 1992; Cullen, 1994; Slob, 1994). These authors maintain that the use of worst-case or reasonable worst-case estimates results in a substantial compounding of the conservatism, and thus in exposure and risk estimates that are generally overstated and which offer poor guidance for risk assessors and risk managers. It is not appropriate to routinely introduce this form of conservatism when adequate data are available for developing a reasonable or likely value. Instead, by incorporating a distribution of values into the analysis, risk assessors can better take account of the variability and uncertainty in exposure assessments.

In 1992, EPA revised its policies for performing exposure and risk assessments. This policy revision was announced by EPA in a memorandum dated February 26, 1992 (EPA, 1992c) and described in detail in EPA's *Guidelines for Exposure Assessment* published on May 29, 1992 (EPA, 1992b). EPA has recently issued updated *Guidance for Risk Characterization* (EPA, 1995), which updates and clarifies certain aspects of the 1992 guidelines. EPA's current policy identifies the need for a full and complete presentation of risk. It states that numerical risk assessments should always be accompanied by a full characterization of the uncertainties, limitations, and assumptions in the risk assessment. These guidelines specifically endorse the use of MCA in exposure assessment provided appropriate data are available (EPA, 1992b, pages 22919, 22927; EPA, 1992c, page 24; EPA, 1995, page 14). The guidelines replace the concept of the MEI and the RME 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 HEE is intended to reflect the doses received by the small but definable "high end" of the population. The primary objective in estimating HEE is that it is a realistic estimate of a potential high-end exposure and is not the result of a theoretical worst-case analysis.

The current guidelines (EPA, 1992b; 1995) also require a separate consideration of variability and uncertainty. As mentioned previously, variability reflects those differences in an exposure parameter from one individual to another. Uncertainty reflects the imprecision in an estimated parameter that occurs as either the result of a lack of information about the individual or our

inability to obtain precise measurements. It is very difficult to account for the enormous variability in a deterministic (point estimate) risk assessment. By simulating entire distributions of exposure parameters, probabilistic methods, like MCA, are more able to characterize this variability. Since the goal of the risk assessment is to generate realistic estimates of risk, probabilistic methods are necessary to adequately distinguish between *possible* combinations of variables and *plausible* combinations of variables.

In summary, EPA's most recent risk assessment guidance allows and endorses the use of Monte Carlo techniques to estimate exposure in risk assessments (not simply to estimate uncertainties, although MCA is useful for that purpose as well). This policy was initially announced in the 1992 exposure assessment guidelines (EPA, 1992b,c). Subsequently, in its draft document on *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." While EPA noted that the distributional data used in such analyses should be site-specific if possible, it indicated that "data on human behavioral characteristics could be obtained from survey information based on populations distant from the site, if comparability can be established" (EPA, 1994). In its most recent risk characterization guidance (EPA, 1995), EPA stated explicitly (page 14) that: "If sufficient information about the variability in chemical concentrations, activity patterns, or other factors are available, the distribution may be estimated through the use of appropriate modeling (e.g., Monte Carlo simulation or parametric statistical methods)." EPA made clear in that document that it was discussing the use of such probabilistic techniques to estimate variability of *exposure* in the population, and that such techniques may *also* be applied, as a separate step, to estimate uncertainty in the estimates (EPA, 1995, page 15).

Benefits of Using MCA

There are a number of benefits in using MCA. These include avoiding overestimates, developing exposure descriptors such as the HEE, considering site-specific demographics, and providing a basis for modeling long-term exposures. The most immediate benefit of MCA is that it avoids the use of multiplicative conservatism in exposure assessment that leads to the overestimates of exposure and risk presented in Figure 1. McKone and Bogen (1991) have demonstrated that the use of worst-case estimates for exposure parameters could result in estimates of risk that are several hundreds or thousands of times higher than those resulting from actual exposures. The

probability density function of the LADDs generated by a MCA represents the actual range of doses that results from the variability in the exposure parameters. Values taken from the upper portion of the probability density function of the LADDs (such as the 90th or 95th percentile) represent a more accurate estimation of high-end exposures within a given population.

For example, by means of point estimate and MCA analyses, Keenan et al. (1993) estimated the dose rates for recreational anglers exposed to a contaminant through the consumption of fish. The point estimate analysis of exposure used "default, upper bound" values for each of the exposure parameters. The results of the point estimate evaluation were compared to the estimates of the high-end exposed (HEE) angler using the results of the Monte Carlo simulation which used distributional data from a survey of recreational anglers for the key exposure parameters. The HEE was assumed to be the 95th percentile of dose. As seen in Table 1, the EPA default values for fish consumption rate and exposure duration exceeded the 90th percentiles of the relevant distributions, and the fish consumption rate exceeded the 95th percentile of consumption from the survey. The resulting risk estimate for the point estimate analysis was 1.8×10^{-5}. However, the Monte Carlo simulation resulted in risk estimates for the typical and HEE scenarios of 2.7×10^{-8} and 7.2×10^{-7}, respectively; 666 and 25 times less than the risk estimate developed by means of the point estimate approach. In fact, the point estimate analysis resulted in a risk estimate that exceeded the 99th percentile of risk in the Monte Carlo analysis. This demonstrates a clear difference between the two approaches, the results of which could eventually lead to risk management decisions based on analyses which are more conservative than actually intended.

The second benefit of MCA is that it is an excellent method for developing the risk descriptors required under the new exposure guidelines. The EPA guidelines provide considerable guidance on how to use the output of MCA to establish the HEE for the exposed population (EPA, 1992b;1995).

The third benefit of MCA is its ability to consider differences within the population potentially at risk. Under the traditional approach to assessing long-term exposures, the use of conservative point estimates makes it difficult to consider time-dependent and site-specific variability within the exposed population. This is because consideration of these factors can only be accomplished by separating out population groups, segmenting exposures over time, and summing exposures for each group. By incorporating the entire shape of the distributions pertaining to these populations,

Table 1. Comparison of Exposure Parameter Values and Risk Estimates

Exposure Parameter	50th percentile from Angler Survey Distribution	90th percentile from Angler Survey Distribution	95th percentile from Angler Survey Distribution	EPA Default Value
Fish Consumption rate g/day	0.99	6.1	12	30
Exposure duration (years)	9	26	33	30
Lifetime Risk	2.7×10^{-8}	3.5×20^{-7}	7.2×10^{-7}	1.8×10^{-5}

and modeling changes over time, MCA allows the complete range of values within the target population to be used in the exposure assessment.

For example, if one is evaluating risks of chemical exposure through contaminated drinking water, it is necessary to select a water ingestion rate as input into the exposure equation. The Agency default value for ingestion of drinking water has been conservatively set at two liters per day. EPA has acknowledged (EPA, 1989b) and many authors have shown that liquid consumption is generally less than two liters per day and that much of what is consumed is not actually tapwater (Evans, 1941; Bourne and Kidder, 1953; Walker et al., 1957; Wolf, 1958; McNall and Schlegal, 1968; Randall, 1973; NAS, 1974; Pike and Brown, 1975; NAS, 1977; Guyton, 1988). In reality, rates of tapwater ingestion are highly variable. Ershow and Cantor (1989) have shown that for the northeast region of the United States, adult tapwater ingestion rates range from 0.098 to 3.5 l/day and that 90 percent of the adult population consumes less than 2 l/day. MCA allows the risk assessor to preserve this natural variability in the exposure assessment phase by not forcing the risk assessor to pick a single value for the parameter. As a result, it allows all of the relevant ingestion rates and their probabilities of occurrence to be included in the exposure assessment, resulting in the full range of potential risks that could occur through this exposure pathway.

In addition, MCA can be used to improve exposure estimates through the development of simulation models of long-term exposure. Traditional exposure assessments develop estimates of LADDs assuming that an individual performs an action (e.g., drinking water, eating fish, living in a single home) at a constant rate for the entire duration of his or her exposure. It is also assumed that the individuals are exposed to a single concentration for the entire exposure duration and that their body weight remains unchanged during that time. In reality, individuals change throughout their lives; behaviors that are reasonable for one age group are not reasonable for another. In order to properly account for such changes, exposure assessments must model the doses received during different portions of an individual's life and then sum the doses to estimate the long-term dose received.

Implementation of MCA at GE Pittsfield Sites

Like many techniques, applications of MCA are only as good as the data on which they are based. Therefore, selecting the distributions for the exposure parameters in the MCA must be performed

carefully. Distributions must be selected to reflect long-term variation, or else the exposure equation should be modified to incorporate such data. The variation should also reflect the actual demographics of the exposed population. Fortunately, a large amount of data on the distribution of many exposure parameters can be found in a number of recent publications.

EPA Region I has expressed concern over which exposure parameters are most appropriate for distributional data. To this end, ChemRisk has identified the exposure parameters that will likely be used as part of the risk assessments for GE Pittsfield sites, including the Housatonic River (Table 2). It is our opinion that sound distributional data are available and appropriate for these parameters. It is beyond the scope of this memorandum to provide the actual distributions for these parameters. We propose to present full distributions for pre-approval by the Agencies at the time of submittal of the Supplemental HEA Proposal.

Distributions for a number of parameters, such as body weights, dermal bioavailability, inhalation rates, fish consumption rates, vegetable consumption rates, and milk ingestion rates are correlated with other parameters. For example, an individual's body weight will not be randomly selected from the full range of body weights but rather will be selected from the distributions that are applicable to his/her age. Each consumption rate will vary with age and gender. Dermal bioavailability will vary depending on the organic carbon content of the soil.

While many of the distributions will remain unchanged from scenario to scenario, some will vary depending upon the scenario. For example, dermal bioavailability is dependent upon the organic carbon content in the soil and thus will vary from scenario to scenario, depending upon the organic carbon contents of the soils that are relevant to a given scenario (e.g., residential properties, recreational properties, agricultural properties, etc.). Inhalation rate is an example of a distribution that may vary not only from scenario to scenario, but within a scenario; the distribution of rates for the residential gardener will be different from those rates used to evaluate indoor residential exposures.

Distributions are not recommended for several exposure parameters. In some cases distributional data are unavailable, while for other parameters, DEP or Region I have specifically indicated that they will only accept point estimates. Among these parameters are exposure frequency, area-

Table 2. Exposure Parameters Appropriate for Distributional Data

Common Parameters Across Pathways	Pathway-Specific Parameters
body weight	soil ingestion rate (incidental soil/sediment ingestion)
age and gender	skin surface area (dermal contact)
exposure duration	soil-skin adherence (dermal contact)
	dermal bioavailability (dermal contact)
	organic carbon content of soil (dermal contact, vegetable consumption)
	inhalation rate (inhalation)
	consumption rates (consumption of fish, vegetables, milk, etc.)
	homegrown fraction (consumption of vegetables, milk)

weighted soil concentrations, and the concentration of respirable particulates in ambient air. In addition, distributions will not be used for toxicity values.

In summary, distributional data will be used to characterize several of the exposure parameters for which adequate distributions are available. For the remaining exposure parameters, point estimates will be used. These data will then be used to generate a distribution of intakes through Monte Carlo Analysis for the exposure scenarios identified. These intake distributions, in turn, will be used in conjunction with the appropriate toxicity values (point estimates) to generate a distribution of risks. From these distributions, it will be possible to readily identify the appropriate percentile estimate of exposure to be considered (e.g., the 95th percentile, as specified in the MCP, 310 CMR 40.0993(4)&(5)(c)) and the risk level associated with that percentile of exposure.

We should also note that, in addition to developing distributions of intake through MCA, ChemRisk will calculate point estimates of intake for all exposure scenarios using point estimates for all exposure values. These point estimates will be used in a conventional risk assessment approach to calculate point estimates of risk, for comparison to the results of the assessment using MCA.

Use of MCA in Deriving Media Protection Standards

MCA can also be successfully used to develop Media Protection Standards (MPS) for a site. To complete such an analysis, it is necessary to rewrite the exposure equation so that it is being solved for the chemical concentration in the medium of concern. For example, the following equation might be used to estimate incremental carcinogenic risk as a result of ingestion of contaminated drinking water:

$$\text{Risk} = \frac{C \times IR \times EF \times ED}{AT \times BW} \times CSF$$

where:

C	=	Concentration in drinking water (mg/liter)
IR	=	Water ingestion rate (liter/day)
EF	=	Exposure frequency (days/year)
ED	=	Exposure duration (years)
AT	=	Averaging time (days)

BW = Body weight (kg)

CSF = Cancer slope factor $(mg/kg\text{-}day)^{-1}$

In order to solve for the media protection standard, the equation would be rewritten as follows:

$$C = \frac{Risk \times AT \times BW}{IR \times EF \times ED \times CSF}$$

To calculate potential MPS through MCA, the same distributions used in the forward calculation to estimate incremental risks would be used in the MCA along with a target single-point risk level. Because the Massachusetts Contingency Plan specifies target risk levels of 1×10^{-5} for carcinogenic risks and a Hazard Index of 1.0 for non-carcinogenic risks, those are the single-point risk levels that would be selected for the Pittsfield sites for carcinogenic and non-carcinogenic risks, respectively. The MCA is then rerun to develop a distribution of media-specific (e.g., soil, water, etc.) concentrations at that risk level from which risk managers can select a MPS.

This resulting distribution of media-specific concentrations represents potential MPS that are associated with different percentages of the exposed populations at the target risk level. The *n*th percentile of the media concentration distribution corresponds to risks that lie somewhere between zero and the target risk level for (100-*n*) percent of the exposed population. For example, the 5th percentile of the resulting media concentration distribution represents that media concentration at or below which 95 percent of the potentially exposed population would have an estimated risk no greater than the target risk level. Thus, based on the media concentration distribution results, risk managers can decide what percentage of the potentially exposed population should have risks that lie somewhere between zero and the target risk level. For example, if the risk manager decided to select as an MPS a media concentration that would be protective of 95 percent of the potentially exposed population, the 5th percentile value from the media concentration distribution would be selected.

Summary

Monte Carlo analysis has become increasingly valuable and important in the process of health risk assessment, moving from a tool for quantitative uncertainty analysis to a tool for predicting the variability and uncertainty in exposure assessment and identifying typical and high-end exposure estimates. The increase in importance has, in some respects, paralleled the increasing availability and improved user interface of computer hardware and software required for statistical simulations. The scientific literature is replete with risk assessments using MCA in addition to review papers on the appropriate selection of exposure parameter distributions. These resources greatly simplify the process of applying MCA to risk assessment and result in more realistic estimates of high-end exposure rather than theoretical, worst-case analyses. In accordance with the new EPA *Guidance for Risk Characterization* (EPA, 1995), MCA eliminates the need for decisions concerning the "degree of conservatism" to be made by risk assessors because it is not necessary to select single values for parameters. Rather, by including all possible values into the exposure equation and providing a distributional output of potential risks, MCA allows risk managers the opportunity to consider relative risks and the sizes of the potentially impacted populations, along with other factors, in making their risk management decisions.

MCA has been used at a number of EPA sites (Table 3). We urge EPA Region I to endorse the use of Monte Carlo analysis as an exposure assessment tool for risk assessment, in accordance with current EPA guidance. We believe that the use of Monte Carlo analysis to complete the human health risk assessment at the Housatonic River site and other GE sites in Pittsfield will result in improved estimates of risks and provide a better basis for risk management decisions for the sites.

Table 3. Partial List of EPA Sites Where Monte Carlo Analysis Has Been Used

EPA Region	Site	Work Performed
Region II	Hudson River	PCB Reassessment RI/FS. Final Phase 2 Work Plan and Sampling Plan
Region II	Marathon Battery	RI/FS
Region III	Halby Chemical	Remedial alternatives selected and ROD signed based on results of Monte Carlo assessment. 1991
Region III	American Color and Chemical Corp.	RCRA site. Accepted by EPA
Region IV	American Creosote Works	Remedial alternatives selected and ROD signed based on results of Monte Carlo assessment. 1989
Region VIII	Sharon Steel/Midvale Tailings Site	Feasibility Study. Submitted to EPA, 1990
Region VIII	Rocky Mountain Arsenal	Preliminary Draft Risk Characterization Integrated Endangerment Assessment Report. 1992
Region IX	Stringfellow	Final Workplan for Health Risk Assessment. Approved by EPA

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