Comparative Risk Framework
Methodology and Case Study

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Portions of this document were authored by the National Risk Management Research Laboratory.

FOREWORD

This Science Advisory Board Review Draft describes a framework methodology for comparative risks and provides an application of the methodology for a hypothetical drinking water treatment system. The effort was sponsored by the U.S. Environmental Protection Agency's (EPA) National Center for Environmental Assessment-Cincinnati Division (NCEA-Cin). Since its formation in1979, NCEA-Cin has been conducting and supporting risk assessment research in the area of drinking water. Exposure through drinking water to pathogenic microorganisms as well as disinfectants and disinfectant byproducts may pose risks to human health such as gastrointestinal illness and related sequellae, cancer, as well as reproductive and developmental impacts. The methodology presented herein offers a way to analyze disparate health risks using a common health metric.

The document was strengthened through collaboration with members of U.S. EPA's National Risk Management Research Laboratory, Water Supply and Water Resources Division and the U.S. Agency of Toxic Substances and Disease Registry. Joshua Cohen, Ph.D. of Gradient Corporation was responsible for the development of much of the case study and many key concepts in the document. Dr. Cohen wrote the SAS computer codes and executed the analysis. NCEA-Cin acquired Gradient Corporation's services through a contract with TN and Associates, Inc. The authors would also like to acknowledge the efforts of Bette Zwayer and Patricia Daunt (NCEA-Cin) and Patricia Wilder of International Consultants Inc. in the preparation of the document.

The document has evolved through a series of peer-review efforts. The document was initially cleared by NCEA-Cin in 1996 after the reviews of Daniel Guth of NCEA-RTP and Margaret Chu of NCEA-Wash. A Workshop entitled Comparing Risks from Disinfectant Byproducts and Microbes in Drinking Water was held in May of 1997 (see list of Workshop Participants). This document was internally reviewed again by Randall Bruins, Ph.D. in May of 1998. The document was externally peer-reviewed through a contract under the project officership of Marilyn Brower (see list of External Peer-Reviewers). James Koopman, MD MPH of the University of Michigan, Department of Epidemiology and Frank A. Sonnenberg, MD of the University of Medicine and Dentistry of New Jersey-Robert Wood Johnson Medical School also provided external review of the document in June of 1998.

The authors would also like to thank Sam Hayes of U.S. EPA's National Risk Management Research Laboratory, Water Supply and Water Resources Division, Donna Tucker (U.S. EPA NCEA-Cin) and Ruth Durham (U.S. EPA NCEA-Cin) for their assistance with the document.

The Safe Drinking Water Act Amendment of 1986 required the U.S. EPA to set standards and establish guidelines for residual disinfectant levels in drinking water and to set maximum contaminant levels (MCLs) for disinfectant byproducts. Subsequent regulations were promulgated or proposed by U.S. EPA to provided the needed balance between controlling risks from exposure to pathogenic organisms in water and from exposure to byproducts of water disinfection. This document was produced in support of the above legislation and U.S. EPA regulations.

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LIST OF ABBREVIATIONS

BBDR	Biologically based dose response
CBA	Cost-benefit analysis
CEA	Cost-effectiveness analysis
CUA	Cost-utility analysis
DALY	Disability adjusted life years
DBP	Disinfectant byproduct
DBP RAM	Disinfectant byproduct risk assessment model
DCA	Dichloroacetic acid
D/DBP	Disinfectant / disinfectant byproduct
ESWTR	Enhanced Surface Water Treatment Rule
GI	Gastrointestinal
GIS	Geographic information system
HAA	Haloacetic acid
HAN	Haloacetonitrile
HAV	Hepatitis A virus
IARC	International Agency for Research on Cancer
ICR	Information Collection Rule
MCL	Maximum contaminant level
MCLG	Maximum contaminant level goal
NHEERL	National Health and Environmental Effects Research Laboratory
QALY	Quality Adjusted Life Years
QSAR	Quantitative Structure Activity Relationship
RfD	Reference dose
SAB	Science Advisory Board of the U.S. EPA
SDWAA	Safe Drinking Water Act Amendment
SWTR	Surface Water Treatment Rule
TCA	Trichloroacetic acid
TCE	Trichloroethylene
TCR	Total Coliform Rule
THM	Trihalomethane
TTHM	Total trihalomethanes
TOC	Total organic carbon
YPLL	Years of potential life lost

EXECUTIVE SUMMARY

The disinfection and treatment of drinking water was instituted as a primary public health intervention that has greatly decreased the morbidity and mortality from water-borne microbial diseases such as typhoid and cholera. Although this practice has been highly effective, waterborne outbreaks of cryptosporidiosis, giardiasis, Norwalk virus, verotoxin-producing *Escherichia coli*, and other agents continue to occur when water supplies become contaminated and water treatment processes are inadequate. Chlorine, in combination with a variety of additional treatment processes, has been the most widely applied disinfectant and has been used in the United States since 1908. More recently, other disinfectants have also been used, such as ozone, chloramine and chlorine dioxide. Trihalomethanes, haloacetic acids, bromate and other chemicals are now known to be produced during the disinfection process and are considered to be potentially hazardous disinfection byproducts (DBPs) of this proven intervention.

In response to these health issues, rules and regulations have been established or proposed under the 1986 Safe Drinking Water Act (SDWA) and the 1996 Safe Drinking Water Act Amendments (SDWAA) to ensure that disinfection protection be maintained in drinking water distribution systems (Vasconcelos et al., 1996; Clark et al., 1996). The regulations also require that a detectable disinfectant residual level be maintained throughout the system in most cases and that the risks from exposures to disinfectants and DBPs be controlled to the levels mandated under the SDWAA.

This balancing of microbial efficacy with the control of DBP levels in the drinking water has emerged as a classic example of a risk trade-off that entails not only concerns for human

health across disparate health risks, but also decisions relative to the financial costs of changing or improving drinking water treatment systems. Research is needed on how aspects of the treatment process can be selectively changed to minimize the formation of potentially hazardous DBPs without compromising the efficacy of microbial treatment. The changes in existing drinking water treatment systems affect the costs of providing water to the customer, both in dollars and in type and number of health events that potentially could occur in those exposures. The problem is further complicated by many unknowns, uncertainties, and data gaps surrounding the health effects information for both DBPs and microbes.

Although both epidemiologic and toxicologic studies of the health effects associated with exposures to some of the better-studied DBPs have demonstrated concerns for adverse reproductive and developmental effects as well as for cancer, there are still many unknowns. For example, there is a need for continued information development characterizing the types and amounts and mixtures of DBPs formed by different disinfection/treatment train combinations and source water characteristics. Complementary epidemiologic and animal research is also needed to characterize any potential health risks, including the nature and likelihood of occurrence of any DBP-induced adverse health events.

Similar to the DBPs, existing information is sparse regarding the frequency of occurrence of potential waterborne pathogens. Analytical techniques are unavailable for reliably identifying and quantifying viable and infectious pathogens, particularly *Cryptosporidium*. Research is ongoing to quantify the amounts of pathogens in the source water and to define human dose-reponse relationships, but better data are needed to define the host susceptibility and immunity, agent virulence, and the impact of environmental determinants on the spectrum of outcomes

associated with human exposures to pathogens. Data collected during acute waterborne disease epidemics has contributed to the understanding of the dynamics of many outbreak situations, but also points to the lack of basic information regarding the endemic occurrence of many waterborne diseases.

Despite the substantial data gaps and uncertainties which still exist for all the different aspects of this problem, regulatory schedules dictate decision-making by risk managers in the absence of complete and often key information regarding selection of drinking water treatment options best suited to provide the most comprehensive protection to the public.

Because drinking water treatment is a primary public health intervention designed to accomplish specific infectious disease reduction goals, decisions to change one or more of the steps in this practice must consider all the consequences of those decisions. Similar to a medical pharmaceutical treatment, a proposed alternative therapy must demonstrate that it is at least as effective as the currently accepted standard treatment, and that it poses no unacceptable side-effects that would outweigh the benefits achieved by the intervention. During the past years several efforts have been made to develop systematic approaches to assessing a wide range of public health and medical interventions in this type of interdependent framework. In public health and medicine, comparisons of alternative therapies and interventions often take the form of cost-effectiveness analyses (CEA), which can be designed to provide a direct comparison of qualitatively disparate health outcomes (Haddix et al., 1996; Gold et al., 1996).

The purpose of a CEA is to systematically and quantitatively assess the expected outcomes and resource costs of alternative interventions, in a way which facilitates decision making by different stakeholders. Cost-effectiveness analyses of public health interventions

typically rely on information from a wide range of sources, including epidemiology, clinical microbiology, clinical trials, and intervention studies, to estimate the expected health outcomes of a series of alternative programs, policies or practices. The approach can be expanded to include information from other disciplines (e.g., engineering and risk assessment) regarding the expected impact of alternative strategies. This is then combined with an economic analysis of the costs of the intervention to provide decision makers and others with an estimate of the combined impact of the alternatives.

A perceived impediment to approaching the drinking water chemical and microbial risk problem this way has been the need to express all the health outcomes of interest with a common measure, so that valid comparisons can be made across the different health risks. Methods are available, however, to compare the qualitatively different risks of a case of cancer to a case of diarrhea. Expression of health risks in directly comparable ways can be accomplished by calculating the risks in terms of disease mortality and incidence rates, which are then converted into indicators of life lengthening or life shortening such as lives or life-years gained or lost. This approach would result in health outcomes that are expressed in natural units such as cases of cancer caused or averted. In CEA using natural units for health outcomes, the net cost of the intervention is compared directly to the disease events averted, e.g. costs per cancer, death, or injury. Alternately, disease mortality and incidence rates can be adjusted (i.e., weighted) by subjective quality of life estimates to generate measures such as the Quality Adjusted Life Year (QALYs) (Putnam and Graham, 1993). The weighting factors reflect some social valuation of the outcome characteristics which includes losses in the length of life from mortality and losses of quality of life from morbidity associated with a particular condition. This approach would express

health outcome costs as the number of life-years lost, adjusted for any change in quality associated with the health outcomes linked to each intervention. In a CEA using these QALY measures, the net cost of the intervention is compared to the number of QALYs gained or lost.

A CEA designed to compare alternative interventions to a baseline is called an incremental analysis. An incremental analysis considers the *additional* cost of an intervention compared to the baseline, and the *additional* benefits associated with the intervention compared to the baseline. The resulting cost-effectiveness ratio (cost per QALY or cost per case averted) reflect this incremental benefit and cost compared to the baseline, rather than the total costs and benefits associated with the intervention.

Traditional risk assessment activities have followed the four step paradigm, originally laid out by NAS (1983): hazard identification, dose-response assessment, exposure assessment, and risk characterization. This information is translated into an overall conclusion about the likelihood of an adverse health effect occurring due to the presence of a potential hazard (NAS, 1983; NRC, 1994). Risk assessments have been used to estimate plausible levels of risk that might result from exposure to environmental pollutants. These assessments are frequently used to guide regulatory decisions regarding the level of exposure that results in 'acceptable' health risks, with risk numbers that are calculated by design to be conservatively protective. Historically, risks have been identified, described and managed on a single chemical basis, in isolation of other exposures and risks that may exist. While this use of risk assessment serves as a starting point, additional approaches are needed to help decision makers determine how to best address the identified hazards. This is particularly true when the alternative strategies or interventions for reducing a health risk may carry costs or health risks of their own. As described above, the

situation of controlling DBPs while maintaining adequate protection from waterborne pathogens involves a potential risk tradeoff that requires a 'comparative risk' approach wherein the different health risks are analyzed and managed interdependently. The use of the QALY (and other) outcome measures in the cost-effectivenss evaluation of public health and medical interventions suggests their potential usefulness for evaluating environmental health interventions such as drinking water treatment decisions. This document proposes that these methods be combined with traditional health risk assessment information and applied to the drinking water comparative risk problem.

Figures ES-1 and ES-2 present the essence of the proposed framework and methodology, the integration of CEA as applied to public health interventions with the 1983 NAS Risk Assessment Paradigm. Figure ES-1 displays an overview of the basic comparative risk assessment framework. First, traditional risk assessments would be conducted, considering the microbial and DBP concentrations in finished water, tap water intake rates, and dose-response assessments for the microbial and chemical agents of concern. Next, to compare these chemical and microbial risks, the effects or consequences described in the risk characterization must be translated or expressed in terms of measurable human health conditions, such as cases of cancer and infection and illness from infectious diseases. The range of potential human health conditions can then be converted into a common health metric. In this framework, QALYs are used to capture changes in the length and quality of life associated with the different health conditions. In addition, the different health conditions can also result in economic costs associated with medical treatment and lost productivity.

Figure ES-1. Comparative Risk Assessment Framework Overview

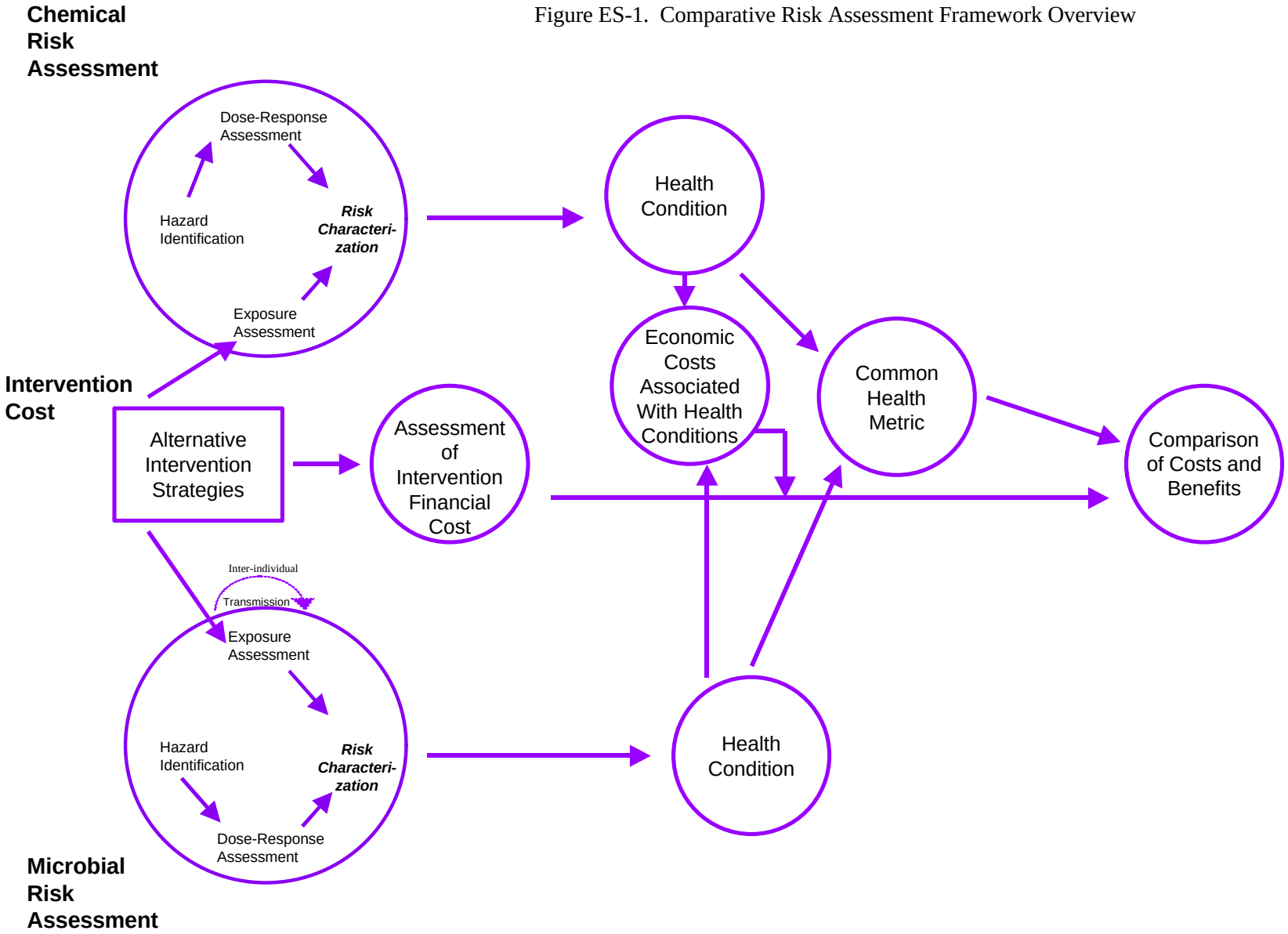
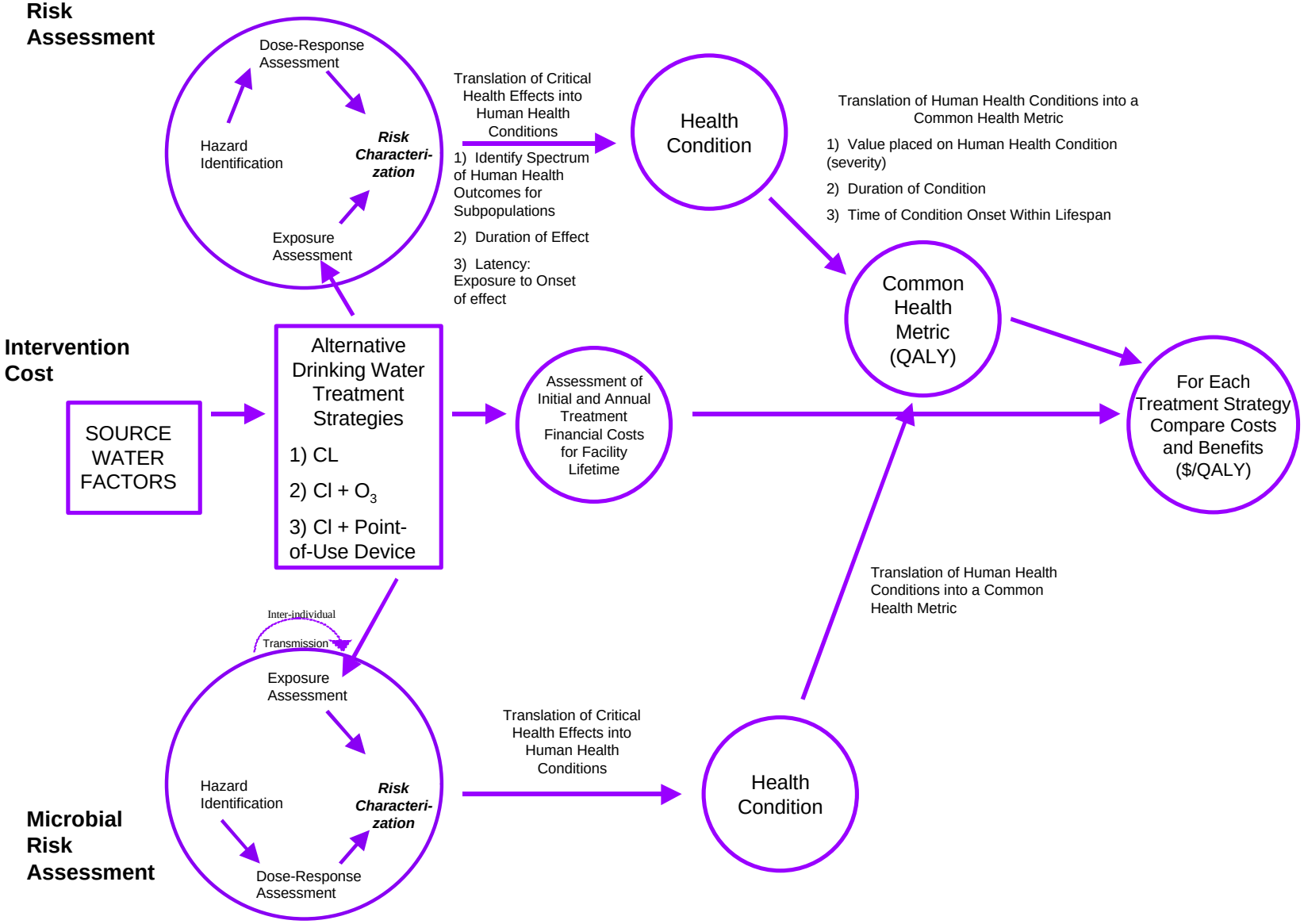


Figure ES-2. Issues Addressed in Comparative Risk Assessment Framework



The comparative risk framework assesses microbial and chemical risks in relation to specific drinking water treatment alternatives. As a result, an analysis must consider the estimated impact of baseline and alternative strategies on the different risks under consideration. In this case, treatments affect contaminant concentrations, exposures, and ultimately changes in expected health outcomes. In addition to impacting the different health risks, the alternative treatment strategies also require different resource expenditures for implementation. In the final stage of the framework, alternative strategies are compared by assessing their expected impact on health (QALYs) and economic outcomes. Figure ES-2 provides additional detailed information for specific application of this methodology to the drinking water treatment problem.

This framework provides a systematic approach to assessing the expected impact of specific treatment alternatives on microbial and chemical risks, and compares these disparate risks to the costs associated with the alternatives. The cost-effectiveness methodology differs from traditional risk assessments in that it is constructed as a predictive model and not as a protective one. The analysis uses central tendency estimates and distributions to describe input parameters instead of high-end, conservative values that are meant to be protective (and are useful in many risk management situations). This perspective is taken so that the end product describes the most complete picture of the results that includes both best estimates and a scientific evaluation of the extremes; thus the amount of information that is provided for the end user is optimal.

In order to demonstrate the utility of the proposed framework methodology, a case study is presented for a hypothetical water distribution system. Three treatment options are evaluated in terms of their impact on microbial risks (GI illnesses and mortality), their impact on DBP-induced risks (cancer, reproductive toxicity, and developmental toxicity), and their financial costs.

Through the development of a reasonable set of assumptions regarding the hypothetical drinking water treatment facility and the population it serves, the case study shows that site-specific and facility-specific data can be input to the framework to develop a reasonable comparison of treatment intervention options. The case study highlights critical areas where pertinent research could potentially change outcomes of the analysis, assuming that the inputs represent, in a reasonable way, some locations and treatment options under consideration in the U.S. The case study shows:

- A logical analysis that directly links each treatment technology to the health outcomes of interest;
- The major determinants of that outcome and the uncertainties inherent in them;
- That data currently exist in the scientific literature, permitting such an analysis to be undertaken with appropriate caveats.

While the CEA framework is conceptually a holistic concept, the application of the framework presented in the case study has limitations. The constraints of the case study include:

- Comparison of only 2 alternative drinking water treatment technologies and no comparison of changes in the technologic applications (e.g., changes in the levels of chlorination)
- Limitations in the development of input data distributions for conducting an uncertainty analysis
- Constraints concerning the current scientific measurement and the temporal distribution of concentrations of D/DBPs in treated drinking water from a single treatment system. Additionally, there has been no attempt to include the effects of distributional effects on estimated D/DBP concentrations.
- Limitations in the understanding of the relationship between health effects and D/DBP exposures in drinking waters inherent in the risk assessments of these agents both collectively and individually.
- Limitations in the current scientific understanding of the distribution of pathogenic organisms in source waters, the efficacy of treatment, and the relationship between

exposure concentrations of these organisms and disease in both healthy and immuno-compromised individuals.

- Limitations in the current scientific understanding of sequelae of more moderate disease states.

- The Case Study does not evaluate all sensitive subpopulations

- The Case Study does not evaluate outbreak scenarios which may result from perturbation(s) of drinking water treatment plants or point-of-use devices. Additionally, secondary spread of infection from an infected to a non-infected member of the population is not evaluated.

Figures ES-3 and ES-4 depict in detail the different treatment processes being compared. Specifically, the baseline treatment technology in Figure ES-3 (a standard treatment train of coagulation, sedimentation, sand filtration and chlorine disinfection) is compared to the baseline treatment technology augmented by either of two supplemental technologies. The first supplemental technology, which benefits all tap water consumers, is the addition of ozone pretreatment to the baseline treatment train (Figure ES-4). This treatment increases the fraction of pathogens inactivated, and decreases the concentration of many DBPs. The second supplemental technology is the installation of point-of-use water filters in the homes of individuals with compromised immune systems.

Health consequences, which are also referred to as the “health costs” associated with a treatment technology, are the health effects resulting from either the presence of infectious agents or DBPs in drinking water. Health effect costs depend on three factors: the tap water consumption rate, the incremental probability of an adverse health effect associated with each liter of water consumed, and the cost (measured in lost QALYs) associated with each health

event. A response addition model is used to calculate the incremental mixtures risk of DBP-induced disease for the known components, summing across chemicals, as the product of a slope factor (representing the potency of each DBP compound), the concentration of each DBP in tap water, and the tap water consumption rate. These health risk numbers are based on laboratory animal data.

Pathogens considered in this analysis are limited to *Cryptosporidium* under the assumption that the technologies evaluated are not thought to have a differential impact on the concentrations of other infectious agents. Health risks posed by exposure to *Cryptosporidium* in drinking water are modeled by defining four disease states (i.e., infection, mild illness given infection, moderate to severe illness given mild illness, death given moderate to severe illness). The probability of becoming infected is assumed to depend on the number of oocysts consumed during a 12 week period, the assumed minimum duration between infections by this pathogen. The infection dose-response function and the values of conditional probabilities of being in the different clinical states depend on one's immune system status; in the case study, a surrogate group, persons with Acquired Immune Deficiency Syndrome (AIDS), is used to represent this sensitive subpopulation. Information from the 1993 outbreak in Wisconsin was used to construct a population-specific distribution of AIDS cases, based on the estimated number of persons living with AIDS at that time in the defined geographic area.

DBP concentrations in the finished drinking water for each of the treatment trains in Figures ES-3 and ES-4 were estimated in large part from data published by Miltner et al. (1990). Those data, based on a study in which Ohio River water was treated in a pilot plant and then subjected to a simulated distribution system, are derived from empirical samples of the

concentrations (ug/L) in water following both chlorination only, and chlorination with ozone pretreatment. Concentration estimates were made for individual DBPs for each of the treatment trains and for the amount of unidentified Total Organic Halide (TOX) in the water. Because bromate is an important by-product of ozonation that has been identified since 1990, estimates were made of the formation of bromate following ozone pretreatment for use in calculating DBP risks. These estimates were made using data from more recent results from two additional studies in which raw Ohio River water was ozonated in the same pilot plant contactor employed in the Miltner et al. study.

Financial costs considered by the case study are limited to the direct costs of implementing the technologies evaluated. These costs consist of the capital costs necessary for installing the technology, and the ongoing operational costs. Other costs, such as medical treatment costs and the lost productivity costs stemming from morbidity and mortality, could also be included in a more expanded analysis. In addition to other limitations as noted, the case study addresses only conditions in which the technologies (treatment plants or in-home filters) are performing as designed (i.e., it is assumed that no outbreaks of waterborne microbial disease occur within the 20 years of plant operation considered in the case study).

The case study characterizes risks associated with pathogens and DBP exposure by quantifying discrete health events (e.g., numbers of cases of cancer, mild gastrointestinal illness, mortality, etc.) and by converting them to a common metric (QALY) useful in comparing and combining their impacts. By estimating the financial costs (dollars) for each treatment option, cost-effectiveness (CE) ratios (dollars/QALY) were calculated, and can be compared across treatment options.

For this case study, central tendency estimates, distributions or ranges for the model parameters were generated from data that vary widely in quality and certainty. Predictive models, expert judgment, or assumptions were used when empirical data were unavailable, and the associated uncertainty was characterized. The CEA was performed using a simulation procedure that accounts for the variability and uncertainty that is described by the parameter distributions. This simulation produces a distribution of CE ratios that represent the possible outcomes for the CE ratios, given the input parameter distributions. Thus, comparisons can be made across the treatment options of several CEA outcomes that include: the actual estimated numbers of health events; the lost QALYs for each of the health outcomes; and the CE ratios.

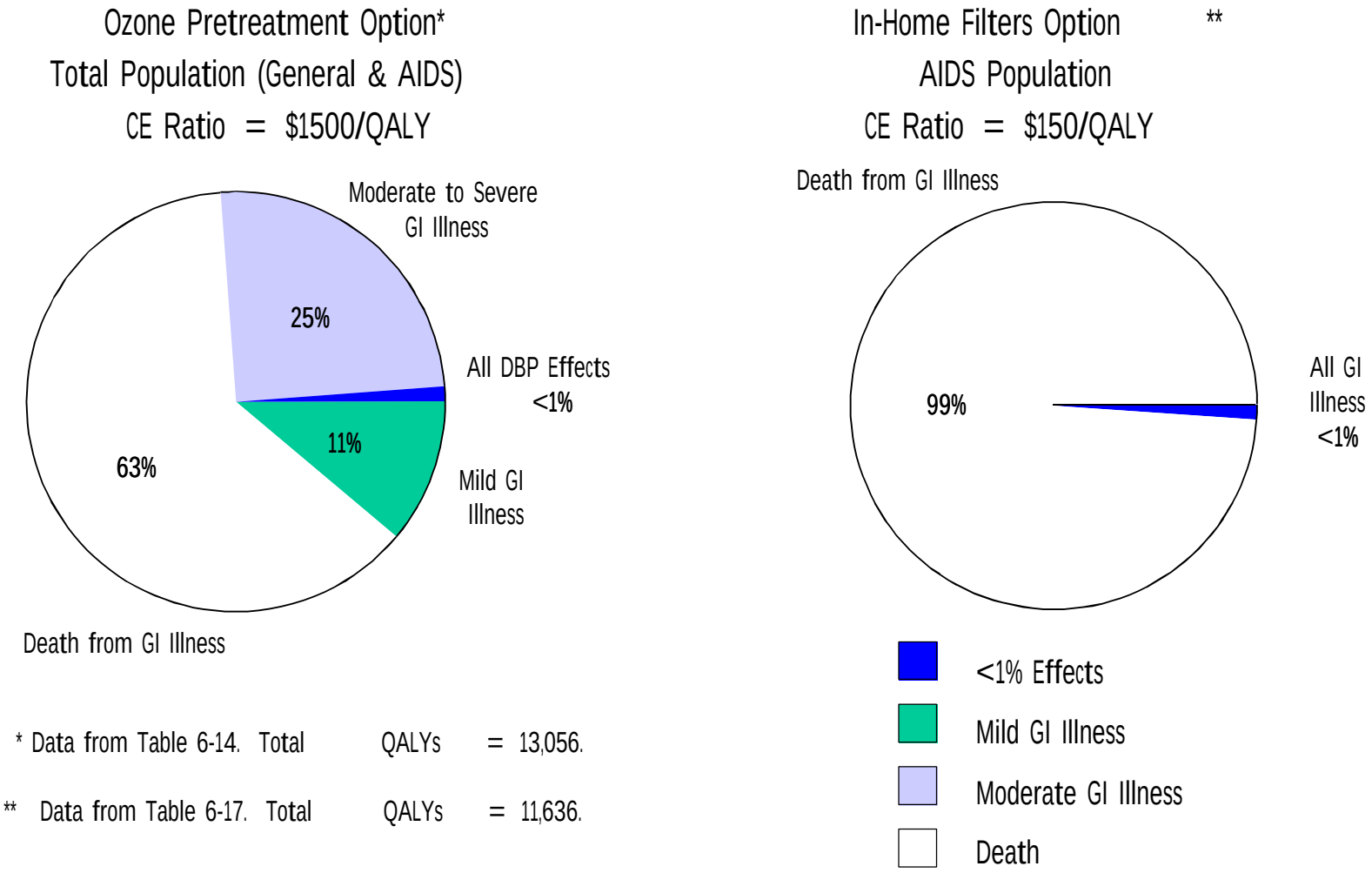
The case demonstrated the following findings:

- For both the baseline treatment option and the ozone pretreatment supplements, the impact of microbial-mediated illness and death overwhelm the health effects associated with DBP chemicals. Overall, the QALY costs of *morbidity* from combined microbial and chemical-related effects were substantially higher than the QALY costs for *mortality* for both the baseline treatment option and the ozone pretreatment option. Within treatment options, the QALY cost for microbial illness exceeded those for chemically-related effects by more than three orders of magnitude. The QALY cost for mortality for microbial illness for either treatment train far exceeded the QALY cost for cancer-related deaths, estimated for both the general population and the AIDs population. For a given treatment train, the QALY costs were also higher for microbe-related health effects than for DBP-related health effects for both populations.

- Capital operational costs incurred by the ozone pretreatment technology are substantial in absolute terms. Nonetheless, the case study results that show the incremental gains of this technology over the baseline treatment option yield substantial health benefits per dollar invested. For the total populations (the AIDs subpopulation and the general population together), the CE ratio compares favorably with ranges in the literature that are suggested to be cost-effective (Daplan and Bush, 1982). While the establishment of a ozone pretreatment facility would require an initial financial outlay, the treatment option would also reduce the total QALY cost associated with anticipated levels of risk for simultaneous exposures to both microbes and DBPs, although nearly all the benefits, as measured in terms of QALYs, stem from the former.

FIGURE ES-5

Average Change from Baseline in QALYs By Health Effects



* Data from Table 6-14. Total QALYs = 13,056.

** Data from Table 6-17. Total QALYs = 11,636.

- For the comparison of the baseline treatment option and the in-home filter technology, the impact of microbial-mediated illness and death are far greater than the health effects associated with DBP chemicals. The bulk of the benefits (measured in terms of QALYs) reflect a reduction in *mortality* from microbial induced illness, with a much smaller (although not insignificant) value for reduced *morbidity*. Differences between the ozone pretreatment technology and the in-home filters in terms of their impact on DBP-induced health effects are inconsequential. On the other hand, it was assumed that home filters completely eliminate microbial morbidity and mortality, whereas ozone filtration reduces these risks. The resulting gain in QALY costs comes at a substantial per capita technology cost, but the CE ratios for the in-home filtration technology fall well within ranges in the literature that are suggested to be cost-effective (Daplan and Bush, 1982).

- It is clear from the sensitivity analyses that most of the uncertainty stems from the lack of data available to accurately estimate parameters related to *Cryptosporidium*: concentrations of viable oocysts in the source water, removal efficacy of the treatments, infectivity rates, and conditional probabilities related to contracting mild illness, contracting moderate to severe illness, or dying. This is an extremely important point, because microbial morbidity and mortality drive the results of the case study, while the risks associated with health endpoints related to DBP exposure are essentially inconsequential.

The current case study provides an example of how the framework methodology can simultaneously assess the cost effectiveness of different drinking water treatment options based on their impact on several disparate health effects. It is intended to be a learning tool to help develop improved methodology to identify important health risk factors, recognize data gaps, and choose directions for investigations of other treatment options. The case study is not intended to provide definitive answers; discussions of the results are intended to illustrate the type of inferences that can be drawn from this kind of analysis, while acknowledging that changes to the specific assumptions used in the study could conceivably change the findings. Because the case study was performed for a hypothetical, single treatment plant, the results cannot be generalized to represent results for all similar plants at a regional or a national level. The present investigation is also

considered a demonstration, and not a definitive assessment, because it does not address all of the important issues surrounding this problem.

The benefits of this methodology should be apparent from the standpoint of the local water purveyor who must evaluate treatment options. This methodology may be useful at the local level for the evaluation of treatment options needed for compliance with new regulations under the SDWA and its amendments. For most public water supplies serving populations over 10,000, there are new requirements to filter and/or disinfect the water. These options have different technology costs, but also differ in terms of their efficacy for removal of microbes (particularly *Cryptosporidium*) and in terms of DBP formation and resulting concentrations. CEA methodology could be helpful in the assessment of these financial costs and the wide range of health impacts.

To reduce the uncertainty and increase the level of confidence in choosing among treatment options, the local purveyor must carefully evaluate source water quality, specifically identifying contaminants that may predispose the formation of DBPs and anticipated microbial concentrations. Additional efforts on the part of local purveyors should include an assessment of the population to be serviced and the consideration of specifically susceptible subpopulations. The results of a CEA may aid decisions makers in local governments to more carefully weigh the expected health outcomes against anticipated capital outlay.

Benefits of this methodology can also be seen from the viewpoint of risk assessors and managers at the national level who must develop data and draft regulations. From the perspective of the national risk manager, this methodology can be used to identify assumptions that most affect analysis results. Stage 1 of the negotiated rule-making by EPA and industry consists of the

implementation of the Information Collection Rule (ICR) for the collection of occurrence and treatment data, and the promulgation in 1998 of the Disinfectant/Disinfectant By-Products (D/DBPs) rule and the Interim Enhanced Surface Water Treatment rule (IESWTR), which would further reduce exposures to specific D/DBPs and enhance protection from pathogens, especially *Cryptosporidium*. The methodology set forth in this document can help provide a sound scientific basis for determining whether to go beyond the November 1998 Stage 1 DBP rule to lower DBP limits. This methodology can also be tailored to determine and evaluate the effect of changing variables within a treatment process such as the amount of disinfectant used, length of contact time, or changing the order in which disinfectants or filtration procedures are applied. The ICR will generate empirical data on the microbial and DBP concentrations that occur from specific treatment trains with detailed information on the source water characteristics; these date will be useful in future CEA studies.

From the present case study, it is apparent that microbial risks have the most affect on the overall risk of morbidity and mortality associated with these treatment options under the conditions assumed for this analysis. All else being equal, risk managers might most logically consider the option that results in the lowest level of microbial outflow. However, the sensitivity analysis indicates that microbial risk assumptions, including infectivity and morbidity, are largely responsible for the uncertainty of the case study results. It follows that further investigation of microbial parameters should include the effectiveness of disinfection strategies, the infectivity parameters for microbes to be investigated, and factors that may influence secondary transmission among the affected population. The lack of an adequate method to identify and quantify viable *Cryptosporidium* oocysts is largely responsible for the uncertainties for these parameters. Nation-

wide variations in geography, rainfall, and land use and variation in the size of treatment facilities, local economic conditions, and serviced-population size and characteristics indicate that assumptions made about treatment needs may vary substantially across localities, even among those that are closely located. When generalized to larger regions, careful assumptions must be made about parameters such as qualitative and quantitative differences in microbial content and bromide levels in the source waters. This case study suggests that research into alternative forms of disinfection should focus on the degree to which alternatives control microbial risks, although DBP formation may be important in some circumstances.

EPA believes that the proposed CEA approach to this public health intervention will assist the EPA in determining the balance between adequate water treatment to control and minimize microbial risk without creating an unacceptably high level of countervailing risks from DBPs. The framework methodology approach as presented here is intended to support and strengthen traditional and existing risk assessment and risk management activities.

FIGURE ES-3

Schematic of Conventional Water Treatment Train

FIGURE ES-4

Schematic of Conventional Water Treatment Train with Pre-Ozonation