1. INTRODUCTION

1.1. BACKGROUND

Risk analysis is an evolving field and analysts continually seek to develop better methods by which risks are assessed and risk management and regulatory policy decisions are made regarding both public health and environmental quality. The challenges to risk assessors include the establishment of methods for assessing human and ecological risks in ways that contend with the complex nature of environmental issues, allow for comparison of widely different risks, clearly identify the uncertainties in the existing knowledge, and consider available options for risk mangers, as well as communicate the risks to decisions makers and the public (NRC, 1996).

The U.S. EPA traditionally uses a four step approach, known as the risk assessment paradigm, to assess risks posed by pollutants, whose presence is generally considered not to be beneficial to human health (NAS, 1983). The risk assessment paradigm concludes with the risk characterization step. In this step, the results of the previous paradigm components are evaluated and integrated to form an overall conclusion about the likelihood of an adverse health effect occurring due to the presence of a potential hazard. This approach is used to estimate plausible levels of risk that might result from exposure to environmental pollutants and to guide regulatory decisions that are designed to reduce or limit such exposures.

1.2. PUBLIC DRINKING WATER

In 1908, the United States began treating public drinking water to prevent the outbreak of various waterborne diseases. While a dramatic reduction in the incidence of waterborne

diseases was quickly recognized as a results of this primary public health intervention and prevention measure, it was not until the 1970's that potential human risks from exposure to chemical disinfectants and disinfectant byproducts (DBP) were first recognized. Long term exposure to DBPs has been associated with human cancer and adverse reproductive and developmental effects (Bull and Kopfler, 1991; U.S. EPA, 1998).

Rules and regulations have been established or proposed under the 1986 and 1996 Safe Drinking Water Act Amendments (SDWAAs) to ensure that disinfection protection be maintained in drinking water distribution systems (Vasconcelos et al., 1996; Clark et al., 1996). They also require that a detectable disinfectant residual level be maintained throughout the system in most cases and that the risks from exposures to disinfectant and disinfectant byproducts (D/DBPs) be controlled to the levels mandated under the SDWAA. Additional background materials are provided in Chapter 2 of this document.

1.3. PROBLEM STATEMENT

The challenge of providing safe drinking water includes balancing the disparate risks of exposure to disinfection byproducts and microbial pathogens. Public drinking waters include microbial pathogens that may cause intestinal illnesses and possible sequelae and chemical disinfectants and byproducts that may cause cancer, developmental and reproductive effects. Because the chemical disinfectants are added to reduce exposures to the pathogens, and the addition of these disinfectants results in the formation of byproducts, these human health effects are interdependent and stem from consumption of the same drinking water. The use of the NAS paradigm alone is inappropriate for this type of risk assessment because it does not address the interdependency of the risks and its use may lead to inappropriate risk management and regulatory

policy conclusions. By viewing these different health outcomes as interdependent instead of as unrelated entities, they can be evaluated simultaneously in the proposed Comparative Risk Framework Methodology (CRFM). The CRFM augments the NAS paradigm with principals of cost effectiveness analysis as described in Haddix et al., 1996 and Gold et al., 1996.

1.4. DOCUMENT GOALS

The primary goal of this document is to advance a methodology capable of evaluating the interdependent and disparate health outcomes and financial costs of alternative treatment systems. This evaluation is effected through a comparison of multiple health outcomes using a common metric, and consideration of treatment system costs for different drinking water treatment systems. The method augments the 1983 NAS paradigm with a cost effectiveness analysis framework. This methodological approach organizes a systematic process that can simultaneously evaluate the health benefits of the public health interventions under study, the risks from any side effects that might result, and the relative costs of implementing the interventions. The CRFM advanced can also evaluate differences in the effects of different treatment systems on the health of various subpopulations. The method can then be applied to provide a more sound scientific basis for drinking water regulation. The document objectives are presented in Chapter 3 and the CRFM is presented in Chapter 4.

The secondary goal of this document is to highlight the usefulness of the methodology through a case study presented in Chapters 5-7. The case study applies the methodology from the perspective of a drinking water treatment system purveyor to a hypothetical but plausible site in the United States. The purveyor considers the benefits and costs of three drinking water treatment alternatives: 1) a conventional chlorination-based treatment train (Figure 1-1), 2) a

conventional chlorination-based treatment train preceded by a pre-ozonation step (Figure 1-2), and 3) a conventional chlorination-based treatment train coupled with the installation of a point-of-use device in the homes of immunocompromised members of the population served by the system. The application of the method highlights data limitations and uncertainties in the information needed for such an assessment and characterizes the overall importance of the limitations and uncertainties in light of the case study results (Chapter 8). The case study employs Monte Carlo techniques and demonstrates the use of sensitivity analysis to examine the impact of uncertainty on the results. The structure allows for a clear understanding of important data gaps. Finally, the case study illustrates the computation of results characterizing the impact of the alternatives on various subpopulations.

1.5. INTENDED AUDIENCE

The primary audience for the cost-effectiveness analysis methodology is the individuals and groups that make decisions concerning the treatment of public waters and the public health community. Other individuals or groups may be interested in the methodology advanced, particularly for application to other public health or environmental interventions. Finally, individuals and their representatives may be interested in the analysis presented in the case study; in particular they may be interested in how different members of the population fare under the different treatment regimens evaluated.

FIGURE 1-1

Schematic of Conventional Water Treatment Train

FIGURE 1-2

Schematic of Conventional Water Treatment Train with Pre-Ozonation

2. BACKGROUND

2.1. HISTORY OF DRINKING WATER HEALTH ISSUES

The disinfection of public water supplies began in the United States in 1908 as a public health measure for the prevention of waterborne diseases such as cholera, typhoid, and dysentery. Although this practice has virtually eliminated waterborne cholera and typhoid in the United States, 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. In the 1980's, for example, 291 waterborne disease outbreaks were reported in the United States (Craun, 1993). The continued occurrence of waterborne disease outbreaks and endemic waterborne disease demonstrates that microbial contamination still poses a serious public health risk.

Giardia, *Entamoeba* and *Cryptosporidium* are currently the primary protozoa of concern in U.S. drinking water (Rose, 1993). However, waterborne *Entamoeba* outbreaks are rare in the United States and none have been known to occur since 1971 (Rose, 1993). *Giardia* has frequently been implicated in waterborne disease outbreaks, (see Appendix A-2) but most cases are asymptomatic and are rarely fatal (Rose, 1993), and several effective therapeutic agents are available for treatment. *Cryptosporidium* can cause severe protracted illness and death in those with compromised immune systems (Flanigan et al. 1992; McGowan et al. 1993). There are currently no effective therapeutic agents to treat cryptosporidiosis. Additionally, *Cryptosporidium* oocysts are more resistant to chlorine disinfection and are smaller than *Giardia*

cysts. Thus, *Cryptosporidium* oocysts are more likely to pass through water treatment disinfection and filtration processes.

The largest recorded outbreak of waterborne cryptosporidiosis in the United States occurred during March-April 1993. An estimated 403,000 people who lived in and visited the 5-county area of greater Milwaukee, Wisconsin experienced a watery diarrheal disease due to *Cryptosporidium parvum* infection (MacKenzie et al., 1994). The spread of *C. parvum* in water obtained from Lake Michigan was traced to one of two municipal water treatment facilities serving the area (Fox and Lytle, 1996) Immunosuppression was the only risk factor associated with the post-outbreak illness when people who had diarrhea during the outbreak were excluded from the analysis conducted by Fox and Lytle. Hoxie et al. (1997) reported that 54 cryptosporidial-related deaths among the residents of the Milwaukee area occurred within the 2 years following the waterborne outbreak. AIDS was the underlying cause of death in 46 (85%) of these.

Chemical disinfection is a component of drinking water treatment systems; these systems are designed to prevent, remove, and inactivate microbial contaminants. Chlorination is the most widely used and most cost-effective method of chemical disinfection of drinking water in the United States and throughout the world. Other disinfectants include ozone, chloramine or chlorine dioxide alone or in combination with chlorine.

While the benefits of water disinfection were well known, it was not until the 1974 identification of chloroform (a product of the reaction between chlorine and naturally occurring organic matter) in disinfected drinking water that it was recognized there may be risks associated with the D/DBPs as well. A number of other disinfectant byproducts (DBPs) including

trihalomethanes (THMs), haloacetic acids (HAAs), haloacetonitriles, haloketones, and aldehydes have since been identified. There is evidence, in single-chemical animal studies at high DBP dose levels, of carcinogenicity, reproductive effects, developmental effects, and other toxic effects, particularly in the kidney and liver (Bull and Kopfler, 1991; NTP, 1985, 1986, 1989; Smith et al., 1989). There is also evidence of mutagenicity from exposure to extracts of finished drinking water in *in vitro* studies (Kool et al., 1981; Loper et al., 1978; Nestmann et al., 1982), but general toxic effects have not been observed in research animals exposed to similar concentrations in finished drinking water (Bull et al., 1982; Kavlock et al., 1979). Epidemiologic studies investigating exposure of humans to chlorinated drinking water have suggested associations with bladder cancer and possibly other cancers (Cantor et al., 1985, 1997; Morris, 1992; McGeehin et al., 1993; King and Marrett, 1996; Freedman et al., 1997). Additionally, other researches found limited evidence of reproductive and developmental effects (Bove et al., 1995; Kramer et al., 1992; Swan et al., 1998; Waller et al., 1998).

2.2. REGULATORY REQUIREMENTS

The passage of the Safe Drinking Water Act (SDWA) in 1974, mandated that the U.S. Environmental Protection Agency identify and regulate drinking water contaminants that may have adverse health effects and which are either known or anticipated to occur in public drinking water supplies. The SDWA also required that most public water supplies serving populations over 10,000 filter and/or disinfect their water. Rules and regulations have been established or proposed under the 1986 and 1996 Safe Drinking Water Act Amendments (SDWAAs) to ensure that disinfection protection be maintained in drinking water distribution systems (Vasconcelos et al., 1996; Clark et al., 1996). They also require that a detectable disinfectant residual level be

maintained throughout the distribution system in most cases and that the risks from exposures to D/DBP be controlled to the levels mandated under the SDWAA.

Several regulations are currently in place that attempt to control for exposures to DBPs and pathogens in drinking water. The Interim Total Trihalomethane Rule (TTHM) (1979) and Total Coliform Rule (1989) requires that systems achieve trihalomethane concentrations less than 0.10mg/l (milligrams per liter) and be below acceptable limits for coliform. The Surface Water Treatment Rule (SWTR) (1989) requires that systems achieve at least a three and four order of magnitude removal or inactivation of *Giardia* and viruses, respectively. Because of concerns that the TTHM rule only addressed one class of DBPs and that the SWTR and Coliform Rule may not be adequate to protect from exposures to *Cryptosporidium,* EPA initiated a negotiated rule-making in 1992. The intention of this negotiated rule-making was to evaluate the need for additional controls of DBPs and pathogens in drinking water and to identify critical research needs for addressing cost effective optimization of disinfection while minimizing pathogenic and DBP risks. This process in conjunction with the reauthorization of the SDWA in 1996 resulted in the development of a two stage rule-making process.

Stage 1 of the negotiated rule-making includes: implementing the Information Collection Rule (ICR) for the collection of occurrence and treatment data; promulgating the Disinfectant/Disinfectant By-Products (D/DBPs) rule in 1998 and; establishing the Interim Enhanced Surface Water Treatment rule (IESWTR), to further reduce exposures to specific D/DBPs and pathogens, especially *Cryptosporidium*.

A sound scientific base is essential to determine the need to go beyond the November 1998 Stage 1 DBP rule (e.g., 80 μg/L for Trihalomethanes [THMs]; 60 µg/L for 5 haloacetic

acids [HAAs]; 10 µg/L for bromate). The stage 2 DBP rule will rely on additional information on health risks, occurrence and treatment technologies and on a comprehensive analysis of the risk trade-offs between microbial and chemical health risks.

3. DOCUMENT OBJECTIVES

The purpose of this document is to describe and demonstrate through a limited case study, an adaptable framework that is capable of appropriately comparing risks related to both drinking water disinfectants/disinfectant byproducts and infectious microbiologic agents, and which also considers the financial costs of potentially reducing these risks. The framework advanced in this document augments the risk assessment paradigm developed by the National Academy of Sciences in 1983 (NAS, 1983). It broadens risk assessment methods and approaches utilized by EPA by combining these with accepted techniques for assessing the impacts of other types of public health interventions. The document frames the problem as a cost effectiveness analysis which compares public health risks for different potential audiences.

Specifically this document was written:

- To introduce and explain the concept of the Cost Effectiveness Analysis (CEA), as applied to a public health intervention;
- To demonstrate the utility of the CEA as a way to evaluate the risks, benefits, social costs and financial costs of the different drinking water treatment technologies;
- To construct a holistic analytical framework to perform a CEA that is capable of evaluating the public health impacts of different drinking water treatment technologies;
- To create a limited case study of the CEA framework using two alternative choices of drinking water treatment technologies. The example will show:
    1. A logical analysis that directly links each treatment technology to the health outcomes of interest;
    2. The identification of assumptions having the greatest impact on the results of the analysis, and the extent to which the analysis results are uncertain;

3. That data currently exist in the scientific literature, permitting such an analysis to be undertaken with appropriate caveats.

- To compare in the case study one of the public drinking water treatment technologies (i.e., the baseline treatment technology) with a point-of-use device (i.e., an in-home filter) and show the benefits of an incremental treatment add-on targeted toward a sensitive subpopulation, the immunocompromised.

- To list key research needs.

While other parties may be interested in the methodologic approach or its application in the case study, the intended audiences for this document are individuals and groups who make decisions concerning the treatment of public drinking waters and the public health community.

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

- Comparison of only two alternative drinking water treatment technologies and no comparison of gradations of application (e.g., changes in the levels of chlorination)

- Limitations of available input data to develop 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 characterize the impact of the water distribution system on estimated D/DBP concentrations.

- Limitations in the understanding of the relationship between health effects and D/DBP exposures through 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 drinking water treatment systems, and the relationship between exposure concentrations of these organisms in drinking water and disease in both healthy and immunocompromised individuals.

- Limitations in the current scientific understanding of the factors leading to more severe sequelae of moderate microbial disease states.
- Limited number of subpopulations considered in the case study.
- The case study does not evaluate all sensitive subpopulations
- The case study does not evaluate outbreak scenarios which may result from perturbation(s) or critical failures 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.

The case study demonstrates the utility of the proposed framework. Through the development of a reasonable set of assumptions regarding a hypothetical drinking water treatment facility and population it serves, the case study shows that site-specific and facility-specific data could be input to the framework to develop a reasonable comparison of treatment intervention options for a community served by a drinking water treatment system. The case study highlights critical areas where pertinent research could potentially change outcomes of the framework, assuming that the inputs represent, in a reasonable way, some locations and treatment options under consideration in the United States.

Chapter 4 of this document describes the concept of the CEA, as applied to a public health intervention. It shows how the process of CEA can simultaneously evaluate the benefits of the intervention in question, risks of both the public health risk and the side effects of the treatment, and the implementation costs for the intervention. Chapters 5 and 6 constitute the Case Study, which compares (1) the use of two alternative hypothetical yet plausible drinking water treatment plants for a hypothetical population and (2) the baseline treatment plant with a point-of-use device targeted to the immunocompromised subpopulation within the hypothetical population. Chapter 5 discusses the drinking water treatment scenario under consideration and the inputs to the case

study. Chapter 6 presents the analysis and results of the inputs. Equation 6-2 calculates the cost of each treatment option through consideration of all of the health outcomes considered in the analysis. Conceptually, this cost is the product of two components: the number of health events caused (which corresponds to "risk"), and the value placed on avoiding each of those events (which corresponds to "severity"). Those health events potentially related to D/DBP exposure include the following: cancer illness, cancer death, birth defects resulting from developmental toxicity, infertility resulting from reproductive toxicity. Those health events related to exposures to *Cryptosporidium* in drinking water include the following: mild illness resulting from infection and death resulting from infection. The results of the case study are discussed and interpreted in Chapter 7. Chapter 8 presents a list of research needs, and Chapter 9 lists the references cited. Appendix A presents materials that support and provide additional background to the inputs of the case study (Chapter 5). Appendix B presents the computer code used in the case study (Chapter 6). Appendix C defines selected terms used in the document.