BEFORE THE ILLINOIS POLLUTION CONTROL BOARD

IN THE MATTER OF:	)	
	)	
WATER QUALITY STANDARDS AND	)	R08-9
EFFLUENT LIMITATIONS FOR THE	)	(Rulemaking - Water)
CHICAGO AREA WATERWAY SYSTEM	)	
AND THE LOWER DES PLAINES RIVER:	)	
PROPOSED AMENDMENTS TO 35 Ill.	)	
Adm. Code Parts 301, 302, 303 and 304	)	

NOTICE OF FILING

To: ALL COUNSEL OF RECORD
(Service List Attached)

PLEASE TAKE NOTICE that on the 10th day of April, 2009, I electronically filed with the Office of the Clerk of the Illinois Pollution Control Board, **Metropolitan Water Reclamation District of Greater Chicago's Responses to EPA's Technical Review Comments Regarding the Report entitled: "Dry and Wet Weather Risk Assessment of Human Health Impacts of Disinfection vs. No Disinfection of the Chicago Area Waterways System," dated April 2008.**

Dated: April 10, 2009.

METROPOLITAN WATER RECLAMATION DISTRICT OF GREATER CHICAGO

By: /s/ David T. Ballard
One of Its Attorneys

Fredric P. Andes
David T. Ballard
BARNES & THORNBURG LLP
One North Wacker Drive. Suite 4400
Chicago, Illinois 60606
(312) 357-1313

PROOF OF SERVICE

The undersigned, a non-attorney, certifies, under penalties of perjury pursuant to 735 ILCS 5/1-109, that I caused a copy of the forgoing, **Notice of Filing of Metropolitan Water Reclamation District of Greater Chicago's Responses to EPA's Technical Review Comments Regarding the Report entitled: "Dry and Wet Weather Risk Assessment of Human Health Impacts of Disinfection vs. No Disinfection of the Chicago Area Waterways System," dated April 2008**, to be served via First Class Mail, postage prepaid, from One North Wacker Drive, Chicago, Illinois, on the 10th day of April, 2009, upon the attorneys of record on the attached Service List.

/s/ Barbara E. Szynalik
Barbara E. Szynalik

[This filing submitted on recycled paper as defined in 35 Ill. Adm. Code 101.202]

SERVICE LIST
R08-9 (Rulemaking - Water)

Richard J. Kissel
Roy M. Harsch
Drinker, Biddle, Gardner, Carton
Suite 3700
191 N. Wacker Drive
Chicago, IL 60606-1698

Claire A. Manning
Brown, Hay & Stephens LLP
700 First Mercantile Bank Building
205 South Fifth St., P.O. Box 2459
Springfield, IL 62705-2459

Deborah J. Williams, Assistant Counsel
Stefanie N. Diers, Assistant Counsel
IEPA
Division of Legal Counsel
1021 North Grand Avenue East
P.O. Box 19276
Springfield, IL 62794-9276

Katherine D. Hodge
Monica T. Rios
Matthew C. Read
Hodge Dwyer & Driver
3150 Roland Avenue
P.O. Box 5776
Springfield, IL 62705-5776

Kevin G. Desharnais
Thomas W. Dimond
Thomas V. Skinner
Mayer, Brown LLP
71 South Wacker Drive
Chicago, IL 60606-4637

Jerry Paulsen
Cindy Skrukrud
McHenry County Defenders
132 Cass Street
Woodstock, IL 60098

Robert VanGyseghem
City of Geneva
1800 South Street
Geneva, IL 60134-2203

Lisa Frede
Chemical Industry Council of Illinois
Suite 100
1400 E. Touhy Ave.
Des Plaines, IL 60019-3338

Matthew J. Dunn, Chief
Office of the Attorney General
Environmental Bureau North
Suite 1800
69 West Washington Street
Chicago, IL 60602

James L. Daugherty, District Manager
Thorn Creek Basin Sanitary District
700 West End Avenue
Chicago Heights, IL 60411

Bernard Sawyer
Thomas Granao
Metropolitan Water Reclamation District
6001 W. Pershing Road
Cicero, IL 60804

Tracy Elzemeyer, General Counsel
American Water Company Central Region
727 Craig Road
St. Louis, MO 63141

Keith I. Harley
Elizabeth Schenkier
Chicago Legal Clinic, Inc.
4th Floor
205 West Monroe Street
Chicago, IL 60606

W.C. Blanton
Blackwell Sanders LLP
Suite 1000
4801 Main Street
Kansas City, MO 64112

Traci Barkley
Prarie Rivers Networks
Suite 6
1902 Fox Drive
Champaign, IL 61820

James Huff, Vice President
Huff & Huff, Inc.
Suite 3300
915 Harger Road
Oak Brook, IL 60523

Cathy Hudzik
City of Chicago - Mayor's Office of
Intergovernmental Affairs
City Hall - Room 406
121 N. LaSalle Street
Chicago, IL 60602

Irwin Polls
Ecological Monitoring and Assessment
3206 Maple Leaf Drive
Glenview, IL 60025

Marc Miller, Senior Policy Advisor
Jamie S. Caston, Policy Advisor
Office of Lt. Governor Pat Quinn
Room 414 State House
Springfield, IL 62706

Frederick D. Keady, P.E., President
Vermilion Coal Company
1979 Johns Drive
Glenview, IL 60025

James E. Eggen
Director of Public Works & Utilities
City of Joliet, Department of Public
Works & Utilities
921 E. Washington Street
Joliet, IL 60431

Ann Alexander, Sr. Attorney
Natural Resources Defense Council
Floor 23
2 N. Riverside Plaza
Chicago, IL 60606

Beth Steinhorn
2021 Timberbrook
Springfield, IL 62702

Dr. Thomas J. Murphy
DePaul University
2325 N. Clifton Street
Chicago, IL 60614

Vicky McKinley
Evanston Environment Board
223 Grey Avenue
Evanston, IL 60202

Kenneth W. Liss
Andrews Environmental Engineering
3300 Ginger Creek Drive
Springfield, IL 62711

[This filing submitted on recycled paper as defined in 35 Ill. Adm. Code 101.202]

Albert Ettinger, Senior Staff Attorney
Jessica Dexter
Environmental Law & Policy Center
Suite 1300
35 E. Wacker Drive
Chicago, IL 60601

Bob Carter
Bloomington Normal Water
Reclamation District
P.O. Box 3307
Bloomington, IL 61702-3307

Tom Muth
Fox Metro Water Reclamation District
682 State Route 31
Oswego, IL 60543

Kay Anderson
American Bottoms RWTF
One American Bottoms Road
Sauget, IL 62201

Jack Darin
Sierra Club
Illinois Chapter
Suite 1500
70 E. Lake Street
Chicago, IL 60601-7447

Kristy A. N. Bulleit
Brent Fewell
Hunton & Williams LLC
1900 K Street, NW
Washington, DC 20006

Marie Tipsord, Hearing Officer
John Therriault, Assistant Clerk
Illinois Pollution Control Board
100 W. Randolph Street
Suite 11-500
Chicago, IL 60601

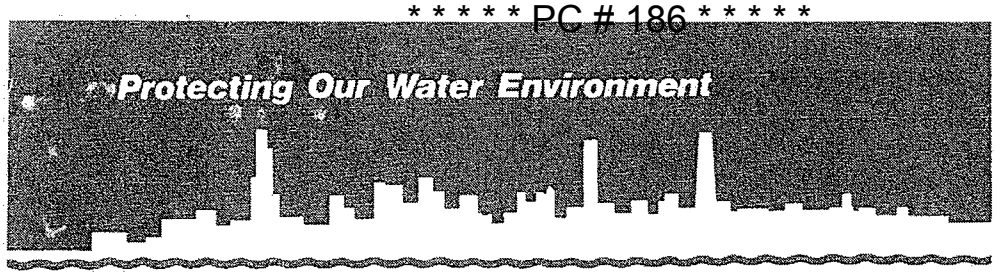
Lyman C. Welch
Manager, Water Quality Programs
Alliance for the Great Lakes
17 N. State St., Suite 1390
Chicago, IL 60602

Stacy Meyers-Glen
Openlands
Suite 1650
25 East Washington
Chicago, Illinois 60602

Mark Schultz
Regional Environmental Coordinator
Navy Facilities and Engineering Command
201 Decatur Avenue
Building 1A
Great Lakes, IL 60088-2801

CHDS01 532756v1

[This filing submitted on recycled paper as defined in 35 Ill. Adm. Code 101.202]



Metropolitan Water Reclamation District of Greater Chicago
100 EAST ERIE STREET CHICAGO, ILLINOIS 60611-3154 312·751·5600

Louis Kollias, P.E., BCEE
Director of Research and Development
312·751·5190

March 13, 2009

Mr. Andrew Tschampa
Acting Chief Water Quality Branch
United States Environmental Protection Agency
Region V
77 West Jackson Boulevard
Chicago, Illinois 60604-3590

Subject: Response to EPA Review of Dry and Wet Weather Risk Assessment of Human Health Impacts of Disinfection vs. No Disinfection of the Chicago Area Waterway System

We wish to express our sincere appreciation for the time, effort and expertise that EPA brought forward by reviewing the dry and wet weather risk assessment of the Chicago Area Waterway System (CAWS) report. The review comments brought forth were sent to Geosyntec Consultants (Geosyntec) for a detailed and thorough assessment of the comments. Responses to the technical comments were received from Geosyntec in a letter dated March 11, 2009. Attached are the letter and the response document that describes how each comment was addressed in the final report.

Geosyntec found a number of the comments valuable in providing guidance to strengthen the presentation of the science in the report. These comments prove valuable in our efforts to publish the research in peer-reviewed journals. We concur with the EPA's comment that quantitative microbial risk assessment is an area of research where the ground is not as well tread as that in chemical risk assessment. We are confident that the risk assessment performed by Geosyntec represents the best effort the current state of the science can provide. There are inherent uncertainties and assumptions in microbial risk assessment methodology; and, therefore, the District has undertaken a companion epidemiological (Chicago Health Environmental Exposure & Recreation Study [CHEERS]) assessment of the health risk to incidental contact recreating population on the CAWS which is necessary to complete and verify the results of the quantitative microbial risk assessment study. To date, no study has validated any quantitative microbial health risk study. The CHEERS will be the first study to bridge the science of microbial risk assessment with direct public health assessment for secondary contact recreation.

Subject: Response to EPA Review of Dry and Wet Weather Risk Assessment of Human Health Impacts of Disinfection vs. No Disinfection of the Chicago Area Waterway System

We believe the responses presented by Geosyntec provide clarification on the comments noted by the reviewer. If you have any questions regarding the enclosed letter, please call me at (312) 751-5190.

Very truly yours,

Louis Kollias

Louis Kollias,
Director
Monitoring and Research

LK:GR:ss
Enclosure
cc w/enc.: Marcia Willhite, Illinois EPA
Ephraim King, USEPA Office of Water Washington D.C.
cc w/o enc.: Chriso Petropoulou, Geosyntec Consultants Chicago
Lanyon/Feldman/Hill/Granato/O'Connor/Rijal/Glymph

Geosyntec consultants

134 N LaSalle St
Suite 300
Chicago, IL 60602

PH 312-658-0500
FAX 312-658-0576

www.geosyntec.com

Via E-Mail and U.S. Mail

11 March 2009

Dr. Thomas C. Granato
Assistant Director of Research & Development
Metropolitan Water Reclamation District of Greater Chicago
6001 W. Pershing Road
Cicero, Illinois 60804-4112

Subject: **Responses to EPA's Technical Review Comments Regarding the Report entitled: "Dry and Wet Weather Risk Assessment of Human Health Impacts of Disinfection Vs. No Disinfection of the Chicago Area Waterways System," dated April 2008**

Dear Dr. Granato:

Geosyntec Consultants (Geosyntec) is enclosing responses to EPA's technical review comments regarding the subject report (see Enclosure). The responses follow the corresponding EPA comment(s). In addition, the responses refer to EPA's Technical Review Comments Regarding the Interim Phase I Report, dated November 2006, "Dry Weather Risk Assessment of Human Health Impacts of Disinfection Vs. No Disinfection of the Chicago Area Waterways System", which are included as an attachment to the Enclosure.

If you have any questions or comments regarding the enclosed report please call me at (312) 658-0500.

Very truly yours,

Chriso Petropoulou

Chriso Petropoulou, Ph.D., P.E., BCEE
Associate

Enclosure

ENCLOSURE

Responses to EPA's Technical Review Comments Regarding the Report, entitled: "Dry and Wet Weather Risk Assessment of Human Health Impacts of Disinfection Vs. No Disinfection of the Chicago Area Waterways System," April 2008.

EPA Review of Dry and Wet Weather Risk Assessment of Human Health Impacts of Disinfection vs. No Disinfection of the Chicago Area Waterways System

This document provides EPA's comments on MWRDGC's Dry and Wet Weather Risk Assessment. We praise MWRDGC for their willingness to undertake the effort and expense associated with the data collection and analysis in this report. We understand that quantitative microbial risk assessment is an area of risk assessment where the ground is not as well tread as that in chemical risk assessment and appreciate MWRDGC's challenge in developing the report. The work that MWRDGC is doing in the area of risks from exposure to fecal contamination from secondary contact recreation is of interest to EPA and we believe it is critically important to ensure that it is accurate, transparent and scientifically defensible. We have provided numerous comments to help MWRDGC improve the report so that it can achieve those goals and would like to offer to discuss and answer any questions you may have regarding our comments.

This Agency review is summarized into two main parts; a process-oriented section under "General Comments"; and, a technical evaluation under "Technical Comments."

General Comments

Risk Assessment versus Risk Management and Policy getting

This report confuses the purposes of risk assessment with risk management and policy setting (e.g., see p. *xiv*, "Microbial Risk Assessment Objectives" pp. *xxix - xxx*, "Wastewater Disinfection" and "Microbial Risk Assessment"). The lack of clear delineation between these various functions severely hampers the importance of transparency in the risk assessment process. In this case, the goal of a microbial risk assessment is to estimate the potential for human disease associated with exposure to waterborne pathogens or a medium in which the microbes occur. This risk estimate should be derived in a transparent fashion and be scientifically defensible. As stated in the ILSI *Revised Framework for Microbial Risk Assessment* (ILSI, 2000) in regards to transparency: "methods and assumptions should be clearly stated and understandable to the intended audience..." and the "audience should be able to evaluate the adequacy of the data and methods from the provided information."

Response: The text in the last sentence of the above paragraph infers that the 2008 Geosyntec report does not meet the ILSI requirements regarding transparency: "methods and assumptions should be clearly stated and understandable to the intended audience..." and the "audience should be able to evaluate the adequacy of the data and methods from the provided information."

However, a review of the 2007 Interim Geosyntec Report conducted by the US EPA Office of Research and Development for US EPA Region 5, Office of Water, states the following (see Attachment A): "The general approach described for the QMRA also seems appropriate. The authors do a thorough job of explaining and justifying their selections of dose-response functions and their parameters. Generally, citations from peer reviewed literature are provided to support their decisions."

Therefore, it appears that some EPA reviewers believe that the QMRA provides transparency while others disagree. In order for Geosyntec and MWRDG to address the EPA comments, we need to receive consistent and specific comments that we can address.

However, the stated main objective of the MWRDGC dry and wet weather risk assessment "was to evaluate the human health impact of continuing the current practice of not disinfecting the effluents from the District's" wastewater treatment plants (p. xiv, Executive Summary). This objective is

clearly a policy and/or risk management decision that should be informed by the risk assessment. While the risk assessment process should be iterative in nature and requires input from risk managers even in the initial problem formulation phase, it should not be used to simply justify, a policy decision. As such, this risk assessment appears compromised in its function and purpose and the report's conclusions appear suspect.

Response: The stated objective was formulated in MWRDGC's Request for Proposal, dated January 2005 with input from various stakeholders, including the Illinois Environmental Protection Agency. The risk assessment did not include any objectives to justify a policy decision. The study objective was formulated to evaluate, estimate and compare recreational health risks in the Chicago Area Waterway System with and without effluent disinfection. The same objective was stated in the 2007 Interim Dry Weather Report and the EPA reviewers of the subject report did not express any concern about the objective (see Attachment A).

Need for Clear Problem Formulation

Another major criticism of this report is the lack of a coherent problem formulation and development of a transparent conceptual model. This criticism was identified upon review of the dry weather risk assessment and was never satisfactorily addressed. The problem formulation is iterative in nature and of critical importance in the risk assessment process and should include input from both risk managers and assessors.

Response: The reviewer's assertion that the QMRA lacks a transparent conceptual model and a thorough uncertainty/variability analysis is incorrect. Section 5.2 of the report presents the conceptual exposure model of the recreational use of the waterway. Section 5.4.7 of the report discusses Sensitivity and Uncertainty analysis. Tables 5-16 and 5-17 present pertinent results. The iterative problem formulation process was not within the scope of work of the Geosyntec QMRA.

Additionally, a sampling schematic would be helpful to track the various sample methods, as well as, a table and corresponding justification for the parameters chosen in the risk assessment. Having both would greatly improve transparency.

Response: Figures 2-1 and 2-2 presents the sampling locations during the dry and wet weather samples. Table 2-2 presents the dry and wet weather samples. Table 2-1 presents a summary of the pathogenic microorganisms selected for the microbial risk assessment and rationale for their selection. Section 2.3.2 discusses in detail the sample collection equipment, materials and procedures and Section 2.4.1 presents the microbial methods of analysis. Furthermore, Tables 5-1 though 5-8 summarize all parameters chosen for the microbial risk assessment. Geosyntec believes that adequate schematics and tables were provided in the report and all the information used in the QMRA is clearly and transparently presented.

Additionally, as stated in the report, roughly 70% of the annual flows into the waterways are from undisinfected sewage treatment plant discharges. This number would most likely be higher in dry weather and lower during wet weather (i.e., the contribution of precipitation to the waterways versus the volume of undisinfected effluents). Conversely, approximately 30% of the annual flows into the waterways are unspecific (e.g., urban runoff CSO overflows, direct precipitation, etc.). This significant component is mostly ignored by the risk assessment other than to make a qualitative attempt to discuss pseudomonads. The approximately 230 CSOs on the waterways were not covered, nor sampled during wet weather events (Region 5, verbal communication). This component could have been identified and discussed had a coherent problem formulation, including a transparent and

clear conceptual model, been employed in the risk assessment process.

Response: On the contrary, risks were developed using waterway data that accounts for all sources to the waterways. Section 2.2.2 of the report discusses the Wet Weather Objective of the Microbial Risk Assessment. One of the wet weather objectives of the microbial risk assessment was to evaluate the impact of combined sewer overflows (CSOs) on the microbial quality of the Chicago Area Waterway System (CAWS). The purpose of microbial sampling during both dry and wet weather was to measure the microbial concentrations in the CAWS, where recreational activities take place. During wet weather, the CAWS receives microbial loads due to surface runoff, storm drains, overland runoff, land use activities (such as agriculture and construction), erosion, and habitat destruction and CSOs, including discharges from three major pumping stations (North Branch, near the North Side WRP; Racine Avenue, near the Stickney WRP; and 125th Street, near the Calumet WRP). During wet weather sampling, samples were collected very near the pumping stations at locations determined by the sampling boat captain to be safe. Because of the turbulent flow conditions induced from the pumping station discharges, it was not possible to sample at the exact point of discharge. Table 2-3 in the report presents the CSO volumes discharged during wet weather sampling. The pumping stations contribute relatively large volume of CSOs in the waterway. Therefore, the sampling performed near the pumping stations during the wet weather sampling events has accounted for the contribution of CSOs on the microbial quality of the CAWS.

Need for Peer Review

For the report and its conclusions to be considered "scientifically defensible," we strongly recommend that it be subject to the same type of external peer review that you are conducting for your secondary contact epidemiological study (CHEERS). We feel the process of an objective peer review (including incorporating changes in order to address peer review comments) would allow MWRDGC to strengthen the validity of the report and its conclusions.

Response: The QMRA study was conducted by experts using EPA-approved methods and state-of the science techniques. The results of the study are scientifically defensible. As indicated earlier, the EPA reviewers' general comment on the 2007 Interim Dry Weather Report acknowledged that world-renowned experts were consulted to conduct the QMRA. The reviewers further commented that the general approach described for the QMRA was appropriate and the authors did a thorough job of explaining and justifying the selections of dose-response functions and their parameters with citations from peer reviewed literature (see Attachment A). EPA's review comments on the Interim Dry Weather Report and responses submitted by the project team referencing the sections of the Final Report where the changes were incorporated are provided in the Attachment A. MWRDGC is pursuing peer review of the findings of the study by publishing the results in peer-reviewed scientific journals.

In addition, it is unclear whether the subcontractors on the Geosyntec team (as listed in the Executive Summary) have reviewed the final report and would agree with the use and interpretation of data they provided. They should be given this opportunity or a more accurate description of their contribution to the report should be provided.

Response: The Geosyntec Team, which includes Geosyntec Consultants (Geosyntec) and its subcontractors: Patterson Environmental Consultants (PEC); Cecil Lue-Hing & Associates (CLHA); Dr. Charles Gerba of the University of Arizona (UA); Hoosier Microbiological Laboratory, Inc. (HML); and Clancy Environmental Consultants, Inc. (CEC) worked seamlessly to perform the Microbial Risk Assessment study and to prepare the report. The roles

of each team member were defined at the proposal stage of the project. Also, these roles are described in the 2005 and 2006 Sampling and Analysis and Quality Assurance Project Plans, which are referenced in the April 2008 report. Geosyntec had overall responsibility for the management of the project and for performing the microbial risk assessment. At the onset of the study, Dr. Gerba provided on-site training to the District personnel on sample collection procedures. The subcontractor laboratories used for this study are very reputable and have assisted in the development of EPA-approved methods. The laboratories analyzed the microbial samples and submitted laboratory reports summarizing the analytical results that were included in the Final Report Appendices and formed the database for the QMRA. CEC analyzed the Cryptosporidium and Giardia samples and provided pertinent laboratory reports. HML analyzed the bacteria and culturable virus samples and provided pertinent analytical reports. The Environmental Virology Laboratory, Department of Soil, Water and Environmental Science at the University of Arizona that performed the analysis of adenovirus and norovirus for this study under the direction of Dr. Gerba. However, it was not the role of the three subcontractor laboratories to review the Final Report. The project had three peer reviewers: Drs. Charles P. Gerba, Cecil Lue-Hing and James W. Patterson, served in the senior scientific advisory committee for the project and provided direction and peer review on every aspect of the work performed.

Purpose of Disinfection Chapter

> The "Disinfection" section (Chapter 4) of this report serves only to obfuscate the purpose of this risk assessment. While the discussion of disinfection efficacy, indicator organisms and pathogens was relatively accurate, it seems tangential to the actual purpose of estimating the potential for human disease associated with exposure to waterborne pathogens or a medium in which the microbes occur.

***Response:** The main objective of the Microbial Risk Assessment Study was to evaluate the human health impact of continuing the current practice of not disinfecting the effluents from the District's North Side, Stickney and Calumet water reclamation plants versus initiating disinfection of the effluent at these three plants. This objective was formulated in the MWRDGC Request for Proposal (RFP) for this study. Therefore, the Geosyntec Team performed a desk-top study of peer-review technical literature on wastewater pathogen and indicator disinfection and summarized the findings in Section 4 of the report. Disinfection effectiveness of chlorination/dechlorination, ultraviolet oxidation and ozonation was summarized, because these are the technologies currently evaluated by MWRDGC for the North Side, Stickney and Calumet facilities. The range of disinfection effectiveness reported for each selected pathogen for the QMRA study was used to estimate the expected pathogen removal, under the disinfection scenario.*

> Also of superficial relevance to this human health risk assessment is the discussion of potential risks from disinfection byproduct (DBP) formation and exposure. The authors state that human health effects associated DBPs tend to be chronic in nature and therefore the development of a risk assessment for exposure to chemical constituents, including DBPs, is far more complex than the microbial risk assessment. First, even less is known about the chronic effects on human health from single and/or repeated exposures to pathogens. However, data have shown that chronic fatigue syndrome can be linked to chronic infection by enteroviruses (Kerr, 2008, *J. Clin. Pathol,* 61:1-2; Chia, 200S, *J. Clin. Pathol* 61:43-48).

***Response:** This study addresses microbial risks only and it does not address chemical risks*

quantitatively or qualitatively. The point of the statement in the report was to acknowledge the chemical risks of disinfection by-products. The text on page 91, Paragraph 3 of the report states that: "Risk assessments of wastewater disinfection should consider microbial and chemical quality. The health effects of disinfectants are generally evaluated by epidemiological studies and/or toxicological studies using laboratory animals." The quantification of chemical risks due to disinfection by-products was outside the scope of work of this study. Also, the chronic effects of pathogens on human health were not evaluated in this study.

Second, a properly conducted microbial risk assessment, including all of the components necessary to develop a transparent and scientifically defensible evaluation, can be as complex a procedure as the development of a chronic toxicity human health risk assessment.

Response: Geosyntec believes that the QMRA study was conducted properly and includes all of the necessary components.

There are differences in the structure and approach between a chemical and microbial risk assessment, but either can range from simple (e.g., in the case of a qualitative or screening level deterministic point estimate assessment) to complex (e.g., in the case of a probabilistic risk estimation that includes the dynamic nature of prior immunity and secondary pathogen spread). That the authors felt that this microbial risk assessment lacked needed complexity only underscores the need for a proper problem formulation, conceptual model, and thorough uncertainty/variability analysis. Indeed, it is important to account for system variability that can lead to changes in exposure and microbial risk because short periods of exposure to high pathogens levels can result in greater risk *(Clean Water: What is Acceptable Microbial Risk?* Amen Soc. Microbiol., 2007).

Response: The reviewers comment makes unsubstantiated assertions about what the authors felt. Geosyntec does not feel that this QMRA lacked needed complexity. There is no statement in the report describing such feelings. Also, the reviewer's assertion that the QMRA lacks a conceptual model and a thorough uncertainty/variability is incorrect. Section 5.2 of the report presents the conceptual exposure model of the recreational use of the waterway. Section 5.4.7 of the report discusses Sensitivity and Uncertainty analysis. Tables 5-16 and 5-17 present pertinent results.

General Issues in Chapter 5

The use of an outdated risk assessment model (e.g., Chapter 5) further hampers transparency and confidence in this report's conclusions. See the ILSI "Revised Framework for Microbial Risk Assessment" enclosed with this review (ILSI, 2000).

Response: Geosyntec used the same risk assessment as in the reference provided in the reviewer's comment. Dr. Gerba in our team contributed in the development of the ILSI model and he confirmed that the model used in the QMRA study is identical to the ILSI model.

Chapter 5 also contains numerous inaccurate statements and broad sweeping statements based on assumptions with little or no justification. For example, gastrointestinal illness is the principal adverse outcome associated with exposure to *fecally contaminated* (i.e., human and or animal waste) waters, not just water containing microbes (note: all ambient waters arid many drinking waters contain microbes). To date, rates of gastrointestinal illnesses have been most strongly correlated with indicators of fecal contamination in

epidemiology studies conducted on predominantly POTW-impacted (note: with disinfection) waters, hence the general acceptance of this category of illness as the 'principal adverse outcome'. The pathogens of concern vary by fecal source, but many can cause gastrointestinal illnesses of varying severity.

Response: This comment makes many broad and unsubstantiated claims. Text in Section 5.1 refers to microbial contaminated water, not just water containing microbes as the reviewer claims. The text in Section 5.1 of the report refers to microbial pathogens that can contaminate the water and cause gastrointestinal illness. Text in Section 5.1 also states that fecal-oral transmission associated with gastrointestinal illness is the primary effect evaluated in this study.

The authors also state that there is correlation between different pathogens. This uncorroborated statement is an inaccurate broad conclusion. Which human pathogens are present in a waterbody is determined by the source(s) of those pathogens and degree of treatment those pathogens undergo during their fate and transport. For example, *Pseudomonas* sp. tends to occur in urban runoff in high numbers (EPA, 1977, *Microbes in Urban Stormwater;* Pitt, 2002, *Stormwater Effects Handbook,* chapt. 3), but is only one of the pathogens of concern from this particular source. Indeed, the authors do not attempt to justify or explain how they compare risk with the different pathogens and potential disease endpoints in mixed source waters (i.e., are less variably-occurring pathogens with potentially lower relative illness severity equal to or different from variably occurring human and zoonotic pathogens with potentially higher relative illness severity). Given that ~30% of the average annual inputs into the waterways can be from non-POTW sources, more results and discussion is needed on this topic.

Response: We concur with the reviewer's comment about Pseudomonas occurring in urban runoff in high numbers. The results of the QMRA study indicate that the sources of Pseudomonas aeruginosa during wet weather are sources other than the WRP effluents. However, we disagree with the remaining comment. The QMRA study accounted for the effect of wet weather by collecting and analyzing samples from the CAWS during wet weather events. Sections 3.1, 3.2 and 3.3 of the report discuss the wet weather bacteria, protozoa and virus results in detail. In addition, a comparison between dry and wet weather results is provided.

The sometimes-controversial issue of what constitutes the secondary contact portion of the designated recreational use underpins this risk assessment. The report attempts to characterize secondary contact activities (e.g., wading) in contrast to what can be normally considered primary contact recreation (e.g., swimming). All 'high' risk secondary contact activities were combined into the 'canoeing' category or as the report describes, "low contact boating". These activities include: canoeing, kayaking, sculling, and jetskiing. Additionally, while observed occurring during the UAA survey, wading and swimming activities were not included at all in this assessment. We recommend more appropriate categorization for some of the activities in the "low contact boating" category (e.g., kayaking, sculling) as we believe they may carry a higher degree of likely incidental or accidental ingestion than canoeing (i.e., closer to that of primary contact). These activities would then be assigned greater consumption values based on the higher exposure. While one can debate the differences between the consumption values, hence the exposure, for the

various activities in the 'high' risk 'canoeing' group, it is important that the analysis reflect the full range of exposures for such activities and not underestimate them.

Response: Exposure was divided into 3 exposure categories; high medium and low exposure groups. Representative activities were ascribed to each of these categories; canoeing, fishing and boating. For each exposure category, input distributions were developed for use in the QMRA. The QMRA accounted for the full range of expected exposures for all activities in this category by using exposure duration and ingestion distributions, which are discussed in detail in Section 5.2 of the report. Kayaking and sculling were evaluated as high exposure activities. The input range for the high exposure "canoeing" group includes the potential for ingestion that ranges from minimal contact with the CAWS to exposure levels that are similar to those used for swimming ingestion levels. Therefore, we believe that the high exposure category (i.e., canoeing) adequately captures the potential for higher incidental intake of water while recreating.

Stylistic Comments

A couple of stylistic issues hamper the transparency of the report. First, the executive summary is rather long and the presentation of the results does not occur until page *xxiv*. An effective executive summary states the bottom line up front. Additionally, typically an effective executive summary is much shorter in length. Second, having the various tables and figures embedded in the chapters when they are referenced would facilitate comprehension of the report as a whole. This is even more important when the report is only viewed in the electronic (-pdf) format. Given the current state of desktop publishing and the relative ease inserting the tables and figure in the text that these software packages allow, EPA would suggest making this change prior to submitting this report to an external peer review.

Response: The style of the report follows a typical Geosyntec format. The same style was used for the Interim Dry Weather Report and the EPA reviewers of that report did not have any concerns about the style of the report.

Technical Comments

Synopsis of major comments:

- Variability of concentration of pathogens in water appear not to have been adequately addressed in the risk assessment nor was sensitivity analysis of that key variable reported.

Response: This comment is misleading and inaccurate. Section 5.4.1 of the report discusses the bootstrapping method that was used in the QMRA. Bootstrapping is a widely accepted and extensively used procedure in statistical analysis and represents a process of selecting a random input from a dataset. This technique is useful in Monte Carlo analysis when the exact distributional form of an input variable is either unknown or unable to be represented with a continuous distribution. Bootstrap samples are random selections from the empirical data with replacement. Bootstrap methods provide robust estimates of variability in Monte Carlo assessments as the probabilities associated with drawing extremes in the distribution is mimicked by the presence of extreme values in the empirical data.

Assumptions are not provided. For example, the report should provide a table that clearly lays out, for each pathogen assessed, the assumptions and descriptive parameters used.

Response: Section 5.3 and Tables 5-5 through 5-7 in the report present each pathogen assessed, the assumptions and descriptive parameters used.

- It is not appropriate to combine the wet and dry weather analyses, as that will underestimate the risk from the wet weather events.

Response: It appears that in this comment EPA implies that the dry and wet weather results were arbitrarily combined, which is incorrect. The dry and wet weather results were integrated to simulate the climatic conditions expected within a recreational season, based on actual weather and pumping station discharge occurrence data as described in Section 5.4.4 of the report and Table 5-8. To represent risks from recreational exposure across the entire recreational season, the input pathogen concentrations used in the risk assessment should account for the probability of encountering pathogen concentrations related to different weather conditions. The proportion of days under each weather condition in a recreational year was developed from historical records of CSO and rainfall records. The input distribution used in the simulations for selecting weather specific pathogen concentrations is shown in Table 5-8. A conservative assumption was made in this analysis that recreational use and weather conditions are not correlated. Common experience would suggest this is not the case as people tend to spend less time recreating during rain events. The assumption in the QMRA was that recreational use may resume shortly after rain events when waterway concentrations are still strongly influenced by the preceding weather patterns.

- Based on information presented in the report, it is difficult to get a clear picture regarding the quality of the data (e.g., assumptions not provided, no description of method recovery, no probability density functions (PDFs) used to describe viability nor if viability data was used in the estimates of pathogen concentrations, inappropriate number of significant figures).

Response: The reviewer's assertion that there is no description on method recovery is inaccurate. Where appropriate, method recovery was discussed. For example, Section 2.4.3 of the report presents the quality control (QC) data of all microbial results, including Cryptosporidium and Giardia QC data. The following QC samples were analyzed for Cryptosporidium and Giardia: Matrix spike (MS), ongoing precision and recovery (OPR), and method blanks.

The reviewer's assertion that no recovery data is presented nor corrected for is inaccurate. Section 2.4.3 of the report summarizes the recovery rates of the MS and OPR samples. MS results were within the acceptance criteria specified in EPA Method 1623. In addition, all recoveries were well within the acceptance criteria specified for OPR samples in Method 1623. No oocysts or cysts were detected in method blanks analyzed indicating no contamination in the spiking or sample processing procedures.

EPA Method 1623 does not allow the use of MS recovery results to adjust the samples. Text in Section 2.4.3 of the report states that the MS sample results were not used to adjust Cryptosporidium and Giardia recoveries at any sampling location.

PDFs were not used for viability because a very small percentage of samples had viable Giardia cysts. The average viability was used to adjust the detactable concentrations of Giardia in the samples.

- Report does not provide information on the duration of the wet weather discharges (events). This is critical in understanding the exposure to recreators, in essence,

what is the time to return to 'background' conditions versus when recreation may resume?

Response: Table 2-3 in the QMRA provide both, the pumping station discharge volumes in millions of gallons and the duration of the discharges. In addition, Section 5.4.3 and Figure 5-7 and Section 5.4.4 and Table 5-8 discuss the integration of dry and wet weather data in the QMRA. The assumption in the QMRA was conservative in that recreational use may resume shortly after rain events when waterway concentrations are still strongly influenced by the preceding weather patterns.

Data regarding the removal of pathogens through secondary treatment appears to differ from published data — no discussion presented to explain this.

Response: It is not clear what this comment refers to. The removal efficiency of pathogens through the secondary treatment was not assessed in this study. Specifically, no influent untreated wastewater samples were collected. Therefore, the reviewer's assertion is unsubstantiated and false. The QMRA microbial concentrations are based on an extensive microbial characterization of the District's final effluents. The QMRA results indicate that the pathogens are generally lower than that observed in several other sewage discharges reported in the literature. The analytical microbiological results reflect the actual concentrations measured in the WRP effluents.

This report (as provided on MWRDGC's website) is missing Appendices B-D and, therefore, we could not view the analytical data that serve as the basis for much of the analysis.

Response: Mr. Louis Kollias, Director of Research and Development of the Metropolitan Water Reclamation District of Greater Chicago, provided a copy of the April 2008 Geosyntec report, entitled: "Dry and Wet Weather Risk Assessment of Human Health Impacts of Disinfection Vs. Non-Disinfection of the Chicago Area Waterways System," to Mr. Allen Melcer, Water Quality Branch, EPA Region 5. In his transmittal letter, Mr. Kollias specifically acknowledged that the raw data can be made available upon request. To this date, MWRDGC has not received a request from EPA for the raw data.

General

In describing the results of a quantitative microbial risk assessment there are two key issues: 1) characterizing the estimated risk(s) against some benchmark or relative measure, and 2) identifying uncertainties where possible so as to better inform those interpreting the results. This report uses a draft benchmark risk for recreational water use of 14 illness per 1000 exposed recreators - which is neither adopted nor policy of the U.S. EPA. That value was discussed in an EPA draft guidance document that was never formerly issued. EPA's current criteria are based on 8 cases of highly credible gastroenteritis per 1000 for freshwaters, and 19 cases per 1000 for marine waters. None of the targeted thresholds/benchmarks are presented with statistically-derived confidence intervals or ranges that reflect the uncertainties associated with their values, including the values reported in the final study.

Response: Table 5-10 of the report presents a summary of various EPA acceptable swimming-associated gastroenteritis rates per 1,000 swimmers. Because EPA does not currently have microbial water quality criteria for secondary contact recreation, Geosyntec considered all historical criteria. Footnotes to Table 5-10 provided clarifications and citations of the sources of the information presented. The rate of acceptable swimming-associated gastroenteritis of

14 illnesses per 1,000 swimmers was a limit that EPA proposed in May 2002. Table 5-9 in the report summarizes the total expected illnesses under dry, wet and combined dry and wet weather events. Although the designated uses of the CAWS do not include swimming and other primary contact activities, the results in Table 5-9 indicate that the total expected illnesses of recreational users in the CAWS are below EPA's current criteria of 8 illness of highly credible gastroenteritis per 1000 swimmers.

In addition, the reviewer's assertion that "none of the targeted thresholds/benchmarks are presented with statistically-derived confidence intervals or ranges that reflect the uncertainties associated with their values" is incorrect. Section 5.4.7 of the report discusses the sensitivity and uncertainty analysis that was performed on the microbial risk assessment results. Results of the sensitivity evaluation are presented on Table 5-16. Table 5-17 presents an alternative sensitivity evaluation.

> Whether the waters are natural or not is not considered relevant when determining if the human exposure from recreation presents unacceptable risks. Given that 70 % of the annual flows in the CWS are from discharges of secondary treated municipal wastewater effluent from the District's WRPs (this review has assumed largely from Calumet, North Side and Stickney) - focus should have been given to the performance of these wastewater facilities with respect to frequency and duration of unacceptably high pathogen loads (which could have been back-calculated from the target 'acceptable' risk level). That is, what is the duration of the wet weather discharges?

Response: Geosyntec agrees with the reviewer's comment that whether the waters are natural or not is not considered relevant when determining human exposure from recreation. In fact, for the QMRA study, dry and wet weather surface water samples were collected from the CAWS, that receives contributions of both: (1) discharges of secondary treated municipal wastewater effluent from the District's WRPs at the North Side, Stickney and Calumet; and (2) wet weather inputs. Therefore, the QMRA study accounted for the issues discussed in the reviewer's comment.

Table 2-3 in the report presents the CSO volumes discharged (in millions of gallons) during wet weather sampling and the duration of the discharges. The pumping stations contribute relatively large volumes of CSOs in the waterway for relatively long periods of time. Therefore, the sampling performed near the pumping stations during the wet weather sampling events has accounted for the contribution of CSOs on the microbial quality of the CAWS. Also, during wet weather, additional sampling locations were used to include the entire stretch of each waterway segment in the sampling program as illustrated in Figure 2-2.

> The range of microorganisms studied seems appropriate, yet the number of pathogen samples appears unacceptably low (detects in only a few of 10-12 samples per WRP, of a total of 50 wet and 75 dry weather samples collected) to simply take mean estimates, rather than predict probability density functions (PDFs) of pathogen concentrations and their uncertainties. Further, the use of geometric means in the report is useful to provide an estimate of the central tendency of microbial concentrations, but loses information about uncertainties that could have been achieved by describing concentrations as PDFs and Monte Carlo sampling to estimate infection risks. Lastly, it would seem inappropriate to combine wet and dry weather pathogen sample results due to the few detects collected, if a goal was to describe risks under dry versus wet conditions.

Response: Geosyntec concurs with the reviewer's comment that the range of microorganisms studied seems appropriate. However, the reviewer's assertion that the number of pathogens

appears unacceptably low, is vague and unsubstantiated. The sampling results reflect the actual concentrations measured in the CAWS and the WRP effluents. The analysis of 125 samples (75 dry weather and 50 wet weather samples) provides a very robust database of microbial pathogens and indicators.

Text in Section 5.4.1 of the report discusses the bootstrapping method that was used in the QMRA. Bootstrapping is a widely accepted and extensively used procedure in statistical analysis and represents a process of selecting a random input from a dataset. This technique is useful in Monte Carlo analysis when the exact distributional form of an input variable is either unknown or unable to be represented with a continuous distribution. Bootstrap samples are random selections from the empirical data with replacement. Bootstrap methods provide robust estimates of variability in Monte Carlo assessments as the probabilities associated with drawing extremes in the distribution is mimicked by the presence of extreme values in the empirical data. Geosyntec believes that the bootsrapping technique captured the variability in the concentration of pathogens.

Geosyntec disagrees with the reviewer's comment that "it would seem inappropriate to combine wet and dry weather pathogen sample results due to the few detects collected, if a goal was to describe risks under dry versus wet conditions." Table 5-9 in the report summarizes the total expected illnesses under dry, wet and combined dry and wet weather events. Therefore, dry and wet weather risks were estimated and reported in the QMRA study. In addition, combined dry and wet weather risks were estimated to represent the entire recreational season that includes both dry and wet weather events. It appears that in this comment EPA implies that the dry and wet weather results were arbitrarily combined, which is incorrect. The dry and wet weather results were integrated to simulate the climatic conditions within a recreational season, based on actual weather and pumping station discharge occurrence data as described in Section 5.4.4 of the report and Table 5-8. To represent risks from recreational exposure across the entire recreational season, the input pathogen concentrations used in the risk assessment should account for the probability of encountering pathogen concentrations related to different weather conditions. The proportion of days under each weather condition in a recreational year (April through November) was developed from historical records of CSO and rainfall records. The input distribution used in the simulations for selecting weather specific pathogen concentrations is shown in Table 5-8 of the report. A conservative assumption was made in this analysis that recreational use and weather conditions are not correlated. Common experience would suggest this is not the case as people tend to spend less time recreating during rain events. The assumption in the QMRA was that recreational use may resume shortly after rain events when waterway concentrations are still strongly influenced by the preceding weather patterns.

As stated in the executive summary, the four main objectives of the wet weather QMRA were, in summary:

1. Evaluation of wet weather impact on outfall microbial quality
2. Evaluation of CSOs impact on CWS
3. Health risk from CWS under wet weather conditions
4. Risk reduction from disinfecting WRP wet weather effluent

Points where at least parts of these main objectives are not met are discussed below.

Statistical Analyses

The merging of pathogens data for dry and wet weather may be inappropriate, depending on the question being addressed. Comments such as (page xxi) that 'The *Salmonella* spp. dry weather results had statistically insignificant detections and therefore an ANOVA analysis of both the dry and wet weather results was not performed' are not really satisfactory, as a non-detect means that the concentration was below a certain concentration, which could have been compared against the distribution of detects under wet weather conditions.

Response: It appears that in this comment EPA implies that the dry and wet weather results were merged, which is incorrect. The dry and wet weather results were integrated to simulate the climatic conditions within a recreational season, based on actual weather and pumping station discharge occurrence data as described in Section 5.4.4 of the report and Table 5-8.

Statistical estimates may be biased in cases where an ANOVA is conducted with highly censored datasets. Salmonella spp. was detected in only 13% of the dry weather samples and therefore an ANOVA analysis of the results was not performed. However, the geometric mean values for the Salmonella spp. censored datasets (i.e., datasets containing below detection results) were computed using a maximum likelihood method. Salmonella spp. concentration data with censoring greater than 80% were considered statistically insignificant, and therefore no geometric mean values were computed (see Table 3-2a in the report). The April 2008 Report presents all Salmonella spp. results. Although, the ANOVA statistical test was not performed because of the reasons outlined above, a direct comparison of the results can be performed by any reviewer of the report.

One related factor that appears to be missing is the waterway recovery time, how long after a wet event does it take the recreational water bodies to reach 'baseline' conditions? This raises the question as to how dry and wet weather samples periods were defined -which does not appear to be reported?

Response: Section 2.3.2, Page 17 of the report discusses wet weather sampling protocol. In addition, Section 5.4.3 of the Report discusses the integration of dry and wet weather results in the QMRA. Figure 5-4 presents an illustration of the attenuation of pathogen concentrations between wet and dry sampling events that was used to derive estimates of the pathogen concentrations between wet and dry weather events. Section 5.4.3 of the report discusses the estimation and incorporation of the estimates of microbial concentrations between wet and dry weather in the microbial risk assessment.

Information regarding the analysis of pathogen samples is not sufficient. Section 3 provides adequate details of the raw data collected, but Section 4 summary concentration tables/figures appear not to indicate the sample sizes involved. In Section 3, the actual numbers of positive samples used to estimate concentration was really too low to give meaningful values as simple means. Given all the data available, far better estimates of means and their uncertainties could have been achieved, which could have been carried through to the QMRA results.

Response: The reviewer incorrectly assumes that geometric mean pathogen concentrations were used in the QMRA. As discussed in Section 5.4.1 of the report the bootstrapping method was used in the QMRA. Bootstrap methods provide robust estimates of variability in Monte Carlo assessments as the probabilities associated with drawing extremes in the distribution is mimicked by the presence of extreme values in the empirical data.

Section 4 is a summary of information presented in peer review literature regarding disinfection of pathogens in wastewater samples. Disinfection efficiency data is summarized and available pertinent information is presented in the text and table footnotes. Such information includes the types of tests (bench- or pilot-scale) or reagents, and reagent dosages.

Parasitic Protozoa

Some of the low positive rates for pathogens were (from page xxi):

Dry Weather:

North Side: *Giardia* outfall (5/5), upstream (4/10), downstream (? /10)

Cryptosporidium outfall (3/5), upstream (1/10), downstream (6/10)

Stickney: *Giardia* outfall *(515),* upstream (4/10), downstream (8/10)

Cryptosporidium outfall (3/5), upstream (1/10), downstream (3/10)

Calumet: *Giardia* outfall (4/5), upstream (0/10), downstream (4/10)

Cryptosporidium outfall (1/5), upstream (1/10), downstream (4/10)

There appear to be some translation errors or missing data, for example, in Table 3-3a there are only five up and downstream samples reported, but in the executive summary (p xxi) positives are reported out of 10 samples? Presumably there was data collected for dry weather in addition to 2005 data reported in Table 3-3? However, as Appendix C was not included with the report (nor for that matter Appendices B-D) it was not possible to check against the original data provided by CEC.

***Response:** The reviewer miscounted the number of samples in Table 3-3a; the table clearly indicates that samples at the North Side outfall and waterway segment were collected on 5 different dates (events): 7/28/05; 8/4/05; 8/18/05; 8/25/05; 9/01/05. During <u>each</u> event, 2 upstream (surface and 1-meter depth) and 2 downstream samples (surface and 1-meter depth) were collected. Therefore, a total of 10 upstream and 10 downstream samples were collected at each waterway. The reviewer's statement/question: "Presumably there was data collected for dry weather in addition to 2005 data reported in Table 3-3?" is false. <u>All data collected was reported.</u>*

Mr. Louis Kollias, Director of Research and Development of the Metropolitan Water Reclamation District of Greater Chicago, provided a copy of the April 2008 Geosyntec report, entitled: "Dry and Wet Weather Risk Assessment of Human Health Impacts of Disinfection Vs. Non-Disinfection of the Chicago Area Waterways System," to Mr. Allen Melcer, Water Quality Branch, EPA Region 5. In his transmittal letter, Mr. Kollias specifically acknowledged that the raw data can be made available upon request. To this date, MWRDGC has not received a request from EPA for the raw data.

Nonetheless, secondary-treated sewage effluent will always have some *Giardia* and *Cryptosporidium* in it, and based on the 20-liter samples being processed it in unlikely to have non-detects if recoveries were >50%; this raises a major concern in that no recovery nor corrections for recoveries were reported when estimating pathogen risks. Similarly, for the environmental waters assayed for parasitic protozoa (typically 18.9 liters assayed according to Section 3), no recovery data is presented nor corrected for.

Response: Section 2.4.3 of the report presents the quality control (QC) data of all microbial results, including Cryptosporidium and Giardia QC data. The following QC samples were analyzed for Cryptosporidium and Giardia: Matrix Spike, ongoing precision and recovery (OPR), and method blanks.

The reviewer's assertion that no recovery data is presented nor corrected for is inaccurate and false. Section 2.4.3 of the report summarizes the recovery rates of the MS and OPR samples. MS results were within the acceptance criteria specified in EPA Method 1623. In addition, all recoveries were well within the acceptance criteria specified for OPR samples in Method 1623. No oocysts or cysts were detected in method blanks analyzed indicating no contamination in the spiking or sample processing procedures.

EPA Method 1623 does not require or allow the use of MS recovery results to adjust the samples. Text in Section 2.4.3 of the report states that the MS sample results were not used to adjust Cryptosporidium and Giardia recoveries at any sampling location.

> Again, in the absence of the original data it is hard to make any more of a comment on the 'viability' testing of oocysts, other than to say that if only a few oocysts were examined, as indicated by the dry weather positive counts, it would not be appropriate to report two significant figures for the precision of the viability statistic reported, such as 21 % or 26 % when the error in such estimates is likely to be at least 50%. Also, with only three of 125 *Cryptosporidium* samples (75 dry weather and 50 wet weather) testing 'viable' (2.4 % as presented on page xxiv) it calls into question how sensitive the viability assay is with so few oocysts being assayed - another uncertainty not discussed.

Response: The reviewer mischaracterizes and misinterprets the results. Overall, this comment is inaccurate and incoherent. The report does not report the precision of viability. It reports the percentage of total cysts that are viable, based on propidium iodide (PI) staining. Section 3.2.3 of the report discusses the Giardia viability results.

Also, the reviewer mischaracterizes the Cryptosporidium results and refers to 3 of 125 samples testing 'viable.' In fact, the text on page xxiv refers to 'infectious foci' not 'viable' Cryptosporidium. Section 3.2.2 of the report discusses "Detection of Infectious Cryptosporidium Oocysts Using Cell Culture." The infectivity test for Cryptosporidium is completely different than the 'viability' test.

> In summary, with poor accuracy (and unreported) in parasitic protozoan viability and no reporting of recoveries, there is considerable uncertainty introduced into the datasets used which has not been expressed when using and reporting risks from these data.

Response: The reviewer's assertion that the accuracy is poor and unreported is inaccurate and false. Section 2.4.3 of the report summarizes the recovery rates of the MS and OPR samples. MS results were within the acceptance criteria specified in EPA Method 1623. In addition, all recoveries were well within the acceptance criteria specified for OPR samples in Method 1623.

Enteric viruses

> In the executive summary (p xxiv) under virus results, the terms 'enteric viruses, adenovirus and Calicivirus' are used, presumably 'enteric viruses' should read 'enteroviruses' here and elsewhere in the report when enteroviruses were indeed the target group (noting concerns if only cytopathicity was the endpoint in cell line assays).
>
> Based on Tables 3-4, enteric viruses were assayed from 100-L samples, but no protocol was

given. It is unclear if the full 100-L concentrate was used for each of the three virus groups assayed (i.e., 300-L collected for all virus assays), or if 100-L was split, so in essence a lesser volume equivalent of the concentrate was assayed for the three different virus groups? Given the way the data are presented, for example in Table 3-5, a <1 MPN/100 L implies that all 100 liters were assayed for each. However, since there is no protocol provided in the report (and Appendix D was not available), one cannot determine how the sample analysis was performed. The concern here is data correction bias that occurs when smaller volumes are assayed than what is reported, also no uncertainties were presented with the MPN values given in Table 3-5. This concern is a major issue for the Norovirus data, where the PCR assay claims (Tables 3-7, 3-8) to only have utilized some 0.2 liters of the original water sample, but is reported on a 100-L basis. The MPN in various tables (e.g. 3-6, 3-7) present results with three significant figures, far too many than what the assay can justify.

Response: Section 2.3.2.1 of the report discusses virus sampling. Text in Section 2.3.2.1 states that approximately 300-L of upstream and downstream samples were filtered at each location during dry and wet weather sampling. In addition, approximately 100-L samples were filtered at the outfall. The actual volumes collected were recorded in the sample collection forms in Appendices A-1 and A-2 of the report. Also, Appendices B-1 and B-2 and D-1 and D-2 of the report include the laboratory bench-scale forms that indicate the sample volumes analyzed for virus samples. Appendices B-1 and B-2 include the total culturable enteric virus results by Hoosier Microbiological Laboratory. Appendices D-1 and D-2 include the adenovirus and norovirus results by the University of Arizona. The reviewer's assertion that Appendix D was not available is incorrect. Mr. Louis Kollias, Director of Research and Development of the Metropolitan Water Reclamation District of Greater Chicago, provided a copy of the April 2008 Geosyntec report, entitled: "Dry and Wet Weather Risk Assessment of Human Health Impacts of Disinfection Vs. Non-Disinfection of the Chicago Area Waterways System," to Mr. Allen Melcer, Water Quality Branch, EPA Region 5. In his transmittal letter, Mr. Kollias specifically acknowledged that the raw data can be made available upon request. To this date, MWRDGC has not received a request from EPA for the raw data.

In addition, the reviewer's concern that only 0.2 Liters of sample was utilized for norovirus analysis is unjustified. The volume of 0.2 Liters of sample analyzed is significantly greater than EPA's estimated water ingestion volume for swimmers of 30ml and significantly greater of the incidental ingestion volumes for the recreational uses considered in this microbial risk assessment including, boating, canoeing and fishing (see Section 5.2.2 of the report, Exposure Inputs).

In the PCR assays used, as no method data was available, it is unknown what level of amplicon confirmation was used, e.g. was sequence confirmation undertaken, probing or none? For cell lines showing a cytopathic effect (e.g. PCL/PRF/5 for adenoviruses) on Table 3-6, footnote 1 states that only 31 of the 42 virus infected cell line samples were confirmed as adenoviruses by PCR. Hence, was the adenovirus MPN/100L adjusted on that percentage? It appears that the total MPN value was simply translated into adenovirus MPN without any adjustment given the same values presented in Tables 3-6 and 3-8 (and only 42/50 PCR confirmed in Table 3-8).

Response: The reviewer's comment is incorrect. First, there was no adjustment on the adenovirus concentration based on the ratio (31/42) of samples that were confirmed as adenoviruses by PCR. For the samples with PCR confirmation of adenoviruses, the total concentration of sample was assumed to be adenovirus, which is a conservative assumption for the risk assessment.

The summary enteric viruses data Tables 3-9 & 3-10 have far too many significant figures given the lack of precision in the assays used along with the data management issues associated with the actual volumes assayed versus the 100-L reported volume (sometimes four significant figures are reported, when 1-2 are all that can likely be justified). Overall, the outfall concentrations of enteric viruses reported appear low, particularly for a non-disinfected wastewater, compared to what has been published in the literature. Based on the *E. coli* & fecal coliform concentration data (Table 3-1), the wastewater seems to have only lost about 2 logs through treatment as expected from normal raw sewage. Hence, virus numbers seem to be some orders of magnitude less than expected for undisinfected effluents, which has potential significant ramifications for disinfection studies and risk assessments using this data.

Response: The virus analytical results under both dry and wet weather results and from two different laboratories (HML and UA) indicate that the virus concentrations are very low. The occurrence and concentration of protozoa, culturable viruses, adenoviruses and norovirus were generally equal to or lower than observed in other studies by Dr. Gerba and others on wastewater discharges and surface waters in general during dry weather conditions (Gerba, 2008; Rodriquez et al., 2008; Rose et al., 1988, 1991,1996). These studies involved both disinfected and non-disinfected treated wastewater, and streams into which they were discharged. Some of these studies were conducted in Europe where disinfection of treated wastewater discharges is usually not practiced. The culturable viruses were also lower than observed in a study of a recreational stream in Arizona conducted by Dr. Gerba's laboratory in which bathers were the only source (Rose at al., 1987). The Geosyntec Team, including Dr. Gerba, believes that the results are representative of the CAWS.

References to this response:

Gerba, C. P. 2008. Virus occurrence and survival in the environmental waters. In: Human Viruses in Water. A. Bosch, ed. pp. 91-108. Elsevier, Amsterdam.

Rodriquez, R. A., P. M. Gundy and C. P. Gerba. 2008. Comparison of BGM and PLC/PRC/5 cell lines for total culturable viral assay of treated sewage. Appl. Environ. Microbiol. 74:2583-2587.

Rose, J.B., R.L. Mullinax, S.N. Singh, M.V. Yates, and C. P. Gerba. 1987. Occurrence of rotaviruses and enteroviruses in recreational waters of Oak Creek, Arizona. Water Research 21:1375-1381.

Rose, J.B., C.P. Gerba and W. Jakubowski. 1991. Survey of potable water supplies for Cryptosporidium and Giardia. Environ. Sci. Technol. 25:1393-1400.

Rose, J. B., L. J. Dickson, S. R. Farrah and R. P. Carnahan. 1996. Removal of pathogenic and indicator microoganisms by full-scale water reclamation facility. Water Res. 30:2785-2797.

Smith, H. V. and A. M. Grimason. 2003. Giardia and Cryptosporidium. The Handbook of Water and Wastewater Microbiology. D. Mara and N. Horan. pp. 695-756. Elsevier, London.

Disinfection

The potential disinfection effects of ozonation, UV and chlorination given in Table ES-1 are generally lacking any ranges - so again minimal uncertainty has been assigned to these data. Furthermore, actual efficacy under operating conditions would be expected to increase the range in performances of these unit operations.

In summary, the disinfection chapter does not actually present operational data nor performance ranges required to undertake a sensitivity analysis or thorough risk assessment - hence it adds little to the document.

Response: The reviewer's comment is incorrect and provides an unjustified and unfair criticism of the disinfection section (Section 4) of the report. Section 4 is a summary of an exhaustive literature search and provides information presented in peer review literature regarding disinfection of pathogens in wastewater samples. Disinfection efficiency data is summarized and available pertinent information is presented in the text and table footnotes. Such information includes the types of tests (bench- or pilot-scale) or reagents, and reagent dosages. The information was used to derive a range of expected pathogen disinfection effectiveness using UV, chlorination/dechlorination and ozonation. No treatability studies were conducted as part of the QMRA study to determine site-specific disinfection effectiveness.

Microbial Risk Assessment

Given the above comments, it is clear that the intended microbial risk assessment was largely focused at what would be called a screening level largely using point mean estimates in a deterministic manner.

Response: The reviewer's comment is grossly inaccurate. The QMRA did not use mean estimates. Text in Section 5.4.1 of the report discusses the bootstrapping method that was used in the QMRA. Also a probabilistic, not a deterministic methodology using distributions of exposure parameters was used in the QMRA. Section 5.2 discusses the methodology used.

Yet there are some surprising attempts to incorporate some elements of a stochastic assessment, such as in the PDF describing ingestion rates (Table 5-4). No reference is provided to justify either the values presented in Table 5-4 nor the precision implied by the number of significant figures presented (generally three, sometimes four).

Response: The reviewers comment is false. The reviewer reluctantly acknowledges that QMRA has elements of a stochastic assessment, but calls them "surprising." It is not clear what that characterization refers too. The reviewer claims that there are no references for the information presented on Table 5-4. This statement is incorrect. Table 5-4 summarizes the information discussed in detail in Section 5.2.2, where multiple references are presented.

It is stated (bottom of page 130) that a one-dimensional probabilistic risk assessment was undertaken (i.e., taking on board variability, but not also uncertainty). However, as stated above, PDFs do not appear to have been utilized in describing pathogen concentration variations; indeed, it is unclear to this reviewer what all the assumptions are as they appear not to be listed. For example, (1) were median values or averages used? (2) what standard deviations and assumed distributional forms were used or each PDF or how were parameters fitted for each PDF? (3) how were viability estimates incorporated into the results? (4) if 'normal' pathogen loads in raw sewage were used and their dilution/removal was based on *E. coli* or other indicators in stream waters - how would that change the

estimated pathogen ranges? (5) what ranges were assessed in the sensitivity analyses and on what basis were they selected? and (6) how many iterations were undertaken in the Monte Carlo simulations? The only PDFs for input parameters appear to be ingestion volume (from Figure 5-2, which has no source identified as to where these numbers come from) and canoeist duration activity (Figure 5-3).

Response: The reviewer's comment is inaccurate. The QMRA did not use mean estimates. Text in Section 5.4.1 of the report discusses the bootstrapping method that was used in the MRA. Also a probabilistic, not a deterministic methodology using distributions of exposure parameters was used in the QMRA. Section 5.2 discusses the methodology used. Table 5-4 summarizes the information discussed in detail in Section 5.2.2, where multiple references are provided. Also, the reviewer is asking the number of iterations used. Section 5.4.5 of the report discusses the number of simulations used. Specifically, text on page 126, 1st Paragraph indicates that 1,000,000 iterations were performed.

Furthermore, there are various key questions not addressed in this assessment, such as:

- What were the risks during wet weather alone (to take a worst case scenario) given it was not noted how long it takes to return to 'baseline' conditions? Rather than using some mix (Figure 5-4) to estimate pathogen concentrations between wet and dry conditions, and not even using any variability of that in the assessment.

Response: Table 5-9 clearly presents the wet weather risks

- If method recovery was included for each of the pathogen groups, what would be the implications to the estimated risks?

Response: Method recovery correction is not required or allowed in the EPA-approved methods used for the analysis. Therefore, it is not scientifically defensible to derive speculative estimates that are not based on proven, validated methods.

- "What about sediment load of pathogens and resuspension of those to added risk?

Response: The sampling accounted for sediment re-suspension of pathogens. Section 2.3.1 of the report discusses sediment re-suspension due to barge traffic and sampling when these conditions occurred.

What levels of indicators could be predictive of 'safe' recreational waters.

Response: This assessment was outside the scope of the QMRA. The CHEERS (Chicago Health Environmental Exposure & Recreation Study) being conducted by the District will answer this comment.

ATTACHMENT A

Responses to EPA's Technical Review Comments Regarding the Interim Phase I Report, dated November 2007, "Dry Weather Risk Assessment of Human Health Impacts of Disinfection Vs. No Disinfection of the Chicago Area Waterways System"

Metropolitan Water Reclamation District of Greater Chicago
100 EAST ERIE STREET CHICAGO, ILLINOIS 60611-3154 312-751-5600

Louis Kollias, P.E., BCEE
Director of Research and Development
312-751-5190

FILE COPY

May 28, 2008

Mr. Allen Melcer
United States Environmental Protection Agency
Region V, Water Quality Branch
77 West Jackson Boulevard
Mail Code: WQ-16J
Chicago, IL 60604-3507

Dear Mr. Melcer:

Subject: Final Report Entitled "Dry and Wet Weather Risk Assessment of Human Health Impacts of Disinfection vs. No Disinfection of the Chicago Area Waterways System," and Response to Comments on Interim Draft Report

The Metropolitan Water Reclamation District of Greater Chicago (District) is pleased to provide you the final report entitled "Dry and Wet Weather Risk Assessment of Human Health Impacts of Disinfection vs. No Disinfection of the Chicago Area Waterways System (CAWS)." The report was prepared by the Geosyntec team which includes Geosyntec Consultants; Cecil Lue-Hing & Associates; Dr. Charles Gerba of the University of Arizona; Hoosier Microbiology Laboratory; and Dr. Jennifer Clancy of the Clancy Environmental Consultants Inc. The District is confident that the microbial risk assessment performed by the Geosyntec team represents the best effort the current state of the science can provide. The report acknowledges uncertainties that are inherent in any risk assessment methodology. To address these uncertainties and to validate the microbial risk assessment report, the District has embarked on a companion epidemiological study to ascertain health impacts of recreational use of the CAWS.

One paper copy of the report is enclosed. The raw data are not included in the final report and can be made available upon request. In addition, a copy of the final report is posted on the District website (www.mwrd.org) and for convenient access, click on "UAA Study" listed under "Public Interest," and then click on the eighth bullet. Also attached to this letter is a copy of the itemized responses to your comments dated March 20, 2007 on the Interim Draft Report. The comments were reviewed by the Geosyntec team and the responses to the comments presented reflect the changes made to the final document. We very much appreciate the reviewers' time and efforts and have found their comments useful in improving the quality of the final report.

Subject: Final Report Entitled "Dry and Wet Weather Risk Assessment of Human Health Impacts of Disinfection vs. No Disinfection of the Chicago Area Waterways System," and Response to Comments on Interim Draft Report

We would like to thank you all for your valuable contributions to this report. If there are any questions, please feel free to contact Dr. Thomas Granato, Assistant Director of Research and Development, Environmental Monitoring and Research Division, at (708) 588-4059 or e-mail Thomas.Granato@mwrd.org.

Very truly yours,

Louis Kollias

Louis Kollias
Director
Research and Development

LK:TG:GR:rag
Attachments
cc: R. Lanyon
F. Feldman
W. Stuba
T. Granato
G. Rijal

Geosyntec consultants

55 West Wacker Drive
Suite 1100
Chicago, IL 60601

PH 312-658-0500
FAX 312-658-0576

www.geosyntec.com

Via E-Mail and U.S. Mail

23 May 2008

Dr. Thomas C. Granato
Assistant Director of Research & Development
Metropolitan Water Reclamation District of Greater Chicago
6001 W. Pershing Road
Cicero, Illinois 60804-4112

Subject: **Responses to EPA's Technical Review Comments Regarding the Interim Phase I Report, dated November 2006, "Dry Weather Risk Assessment of Human Health Impacts of Disinfection Vs. No Disinfection of the Chicago Area Waterways System"**

Dear Dr. Granato:

Geosyntec Consultants (Geosyntec) is enclosing responses to EPA's technical review comments regarding the subject report. Geosyntec's responses refer to the April 2008 Final Report entitled, "Dry and Wet Weather Risk Assessment of Human Health Impacts of Disinfection Vs. No Disinfection of the Chicago Area Waterways System," (Final Report), which is incorporated to the responses by reference. The responses follow the corresponding EPA comment(s).

If you have any questions or comments regarding the enclosed report please call me at (312) 658-0500.

Very truly yours,

Chriso Petropoulou

Chriso Petropoulou, Ph.D., P.E., BCEE
Associate

Enclosure

ENCLOSURE

Responses to EPA's Technical Review Comments Regarding the Interim Phase I Report, dated November 2007, "Dry Weather Risk Assessment of Human Health Impacts of Disinfection Vs. No Disinfection of the Chicago Area Waterways System"

Dry Weather Risk Assessment of Human Health Impacts of Disinfection vs. No Disinfection of the Chicago Area Waterways System

Review conducted for: US EPA Region 5, Office of Water,
Review conducted by: US EPA Office of Water, Office of Science and Technology

NOTE: In an effort to avoid duplication, these points are in addition to comments sent by ORD already. OST/HECD agrees with ORD's comments.

Summary:

A Quantitative Microbial Risk Assessment (QMRA) of the Chicago Area Waterways (CAW) was conducted to evaluate the risk of illness posed to recreational users of the CAW with the current practice of not disinfecting the effluent at three wastewater treatment plants with discharges into the CAW. Using monitoring data for pathogenic microorganisms and integrating over dose response functions, exposure times and ingestion rates, the conclusion was made that the risk for gastrointestinal illness was well under the 8-10/1000 currently deemed "acceptable" by the US EPA 1986 Ambient Water Quality Criteria, and that there was therefore no need for additional disinfection to adequately protect public health

This QMRA was only done for the Phase I "dry" weather season, and does not present results for the wet season. So presumably any conclusions would be only applicable to the dry season until the wet season analysis is completed.

Response: We concur with the reviewer's comment. The Interim Report summarizes the dry weather microbial risk assessment results and any conclusions are only applicable to the dry season. However, the April 2008 Final Report entitled, "Dry and Wet Weather Risk Assessment of Human Health Impacts of Disinfection Vs. No Disinfection of the Chicago Area Waterways System," (Final Report) integrates both the dry and wet weather microbial risk assessment results in a comprehensive outcome.

Health and Ecological Criteria Division

- Introductory material biases risk assessment

A few statements made in the Introduction were either opinion or unsupported fact (e.g., page 2, paragraph 2: The year-round implementation of chlorination…..). There is no need to focus on chlorination, since there are alternatives available. No citations were given to support these upfront conclusions. Additionally, there is no mention of the benefits of disinfection of human sewage effluents, chlorinated or otherwise. Mentioning this in the introduction as it is serves only to bias the reader.

Response: The report includes the following citation for the statements made:

"Metropolitan Sanitary District of Greater Chicago (MSDGC), 1984, Wastewater Disinfection: A Review of Technical and Legal Aspects in Illinois. Department of Research and Development. Report No. 84-17. July."

However, the above-mentioned paragraph has been removed from the Introduction of the Final Report. In addition, a section has been added (Section 4) in the Final Report that provides a comprehensive overview of disinfection technologies, including: (1) chlorination/dechlorination, (2) ozonation, and (3) UV. Advantages and disadvantages of each technology are discussed, including disinfection effectiveness, and disinfection by-product formation.

Another example: page 3, paragraph 3, The CWS is not a coastal recreation water. This statement follows evidence for increased and encouraged use of the waterways for recreational activities. While the CWS is not, by definition, a coastal recreation water, it is a 'water of the United States' as defined by the Clean Water Act.

Response: We concur with the reviewer's comment. The subject sentence has been removed from the Final Report.

- Data presented are for dry weather only

The risk assessment's main conclusion that the risk for GI illness was well under EPA's recommended 1986 recreational AWQC is a bit premature given that no wet weather data was available at the time this report was published. Rain events can be a major driver for influx of microbes into a surface water body, so until the wet weather data is analyzed, any broad sweeping conclusions in this report should be taken in context.

Response: We concur with the reviewer's comment. The Interim Report summarizes the dry weather data only. However, the Final Report integrates both the dry and wet weather data in a comprehensive outcome in the microbial risk assessment.

- Enterococcus enumeration method: most appropriate?

The author's used EPA method 1106.2 to enumerate Enterococcus. Method 1600 is the recommended method to use for this purpose.

Response: At the time of the planning and implementation of the study, EPA Method 1106.2 was the EPA-approved method for Enterococcus.

- Risk assessment lacks necessary components

While this report contains a fair amount of 'upfront' material, there is a concern over the lack of a coherent problem formulation. This would include a listing of parameters evaluated in the assessment and why each parameter was chosen. A range of estimates with the rationale for picking one deterministic point over another would be helpful.

Response: The 2006 Interim Phase I Dry Weather Report has the information mentioned in the reviewer's comment. This information is also included in Section 5, of the Final Report. More specifically, Section 5.2 of the Final Report discusses in detail the parameters evaluated as part of the exposure assessment, including: (1) waterway use and receptor group categorization and (2) exposure inputs. The rationale for parameter selection is also provided. Also, the exposure input parameters used were based on distribution functions and not single deterministic point values. Section 5.2.2 of the Final Report discusses in detail the types of exposure input distributions that were used to develop estimates for the following parameters: (1) incidental water ingestion rates and (2) exposure duration. In addition, Section 5.3 of the

Final Report provides the basis and rationale for the selection of dose response parameters used in the microbial risk assessment analysis for each of the pathogens of concern, including: Enteric Virus, Calicivirus, Adenovirus, pathogenic E. coli (estimated), Pseudomonas aeruginosa, Salmonella, Cryptosporidium and Giardia.

Also, this impacts the lack of a sensitivity analysis mentioned by Tim Wade. In order for this report to impart confidence in its conclusions, an effort to spell out each parameter and the rationale behind that choice would be welcome (e.g., why choose the pathogens they did). Given the propensity for choosing assumptions that minimize risk at each step of the risk assessment, more credibility would be gained by also stating why those assumptions were chosen.

Response: Section 5.4.7 of the Final Report includes a detailed discussion regarding Sensitivity and Uncertainty Analysis. The sensitivity analysis was performed to identify the contribution of each input distribution to the variance of the resulting risk estimates. In addition, uncertainty factors and their impact in the risk estimates are clearly identified and discussed.

Also, for the sake of clarity: fecal coliforms, *E. coli* and Enterococci are NOT pathogens. All three are fecal pollution indicator organisms. They give no direct evidence of the presence of pathogens. While there are pathogenic strains of *E. coli*, these strains are not enumerated by the method used.

Response: We agree with the reviewer's comment about fecal coliforms, E. coli and Enterococci. The analytical results of these bacteria were only used to characterize the microbial quality of the waterway. The microbial risks of the waterway were estimated based on bacteria pathogens, viruses, and protozoa. Although strains of pathogenic E. coli were not determined during this study, we relied on results published in the technical literature and made conservative assumptions to estimate the percent the pathogenic E. coli as a percentage of the total E. coli detected. Section 5.3.4 of the Final Report includes a detailed discussion regarding the dose response of pathogenic E. coli (estimated), Pseudomonas aeruginosa, Salmonella, Enteric Virus, Calicivirus, Adenovirus, Cryptosporidium and Giardia.

- Indicator correlations are not appropriate

The authors state that they attempted to identify a correlation between fecal coliforms and other pathogen concentrations (page 33, paragraph 3). If this correlation could be discerned, then the historic fecal coliform concentration data could be extrapolated to generate concentration statistics for other pathogens. This is highly inappropriate and takes up a fair amount of the report. Fecal indicator bacteria, such as the fecal coliform group, only indicate the presence of fecal pollution. They do not indicate the presence of pathogens; that has always been an inference. Additionally, fecal indicator bacteria do not correlate with pathogen loads, only fecal pollution loads. Given the myriad of potential fecal pollution sources listed in the report, each with a different spatial and temporal influx to the waterways, the indicator to pathogen ratio would be quite variable and would be difficult to elicit based on five sample points over a six-week period.

One would expect a correlation between *E. coli* (as measured in this report) and fecal coliforms, since *E. coli* is a subset of the fecal coliform group. This would be different if one were enumerating the toxin-producing strains like *E. coli* O157:H7, which are not necessarily enumerated by the method used in this report. Also, the correlation of Enterococci and fecal coliforms would also be expected since both are of fecal origin and excreted by warm-blooded

animals. Given the source of these organisms here, it is no surprise that as the concentration of one increases, so does the other.

Response: ***We agree with the reviewer's comments that during dry weather there is poor correlation between indicator bacteria and pathogens. However, the ultimate purpose of the analysis was to determine correlations between pathogens and indicators under both dry and wet weather conditions in order to ascertain if the weather or any other factor can affect such correlations. The statistical correlations between bacteria pathogens and indicators have been removed from the body of the report and are included in Attachment A of the Final Report. The statistical analysis in Appendix A indicates that the correlation of bacteria in wet weather samples is statistically more significant compared to dry weather samples.***

- GI illness as the sole endpoint of risk

This is a major weakness in the risk assessment. On page 90, paragraph 1, the authors state that GI illness is the principal adverse outcome associated with exposure to microbiologically contaminated water. This is not necessarily true. As noted by ORD in their epidemiological studies, the greatest correlations are noted between fecal indicator concentrations and GI illness rates, but that does not mean that other endpoints and other metrics are not just as viable. Inhalation is another major route of infection, but is somewhat poorly correlated to fecal indicators (which are of GI origin). Pseudomonas and adenovirus were found, so the authors should have explored the inhalation route to properly examine the risk associated with recreating on this water. If there was a problem formulation, then the various routes of exposure could have been discussed and compartmented for risk analysis. Canoeists, boaters, jet skiers, etc. all are affected by this route of exposure. Also, respiratory illnesses can be easily transmitted to other persons.

Response: Section 5.1 of the Final Report describes in detail the Hazard Identification component of the microbial risk assessment study. As stated in this section, exposure to microbial contaminated water may result in both gastrointestinal and non-gastrointestinal illness. However, there are no known dose response models for the non-gastrointestinal exposure routes. The risk of gastrointestinal illness was selected as the sentinel effect for conducting the quantitative risk assessment. However, non-gastrointestinal illnesses were addressed qualitatively. Section 5.4.6 of the Final Report presents a qualitative assessment of the non-GI risks associated with Pseudomonas aeruginosa.

While I have no data at hand to properly discuss this point, there is a notable lack of discussion of the food intake route of exposure. Given the levels of fecal pollution in this waterbody and the fact the authors discuss increased fishing on the waterways, I wonder what the fish intake route would add to the overall risk. Is there evidence for pathogen concentration in fish tissues here? If this were a chemical contamination issue, these additional exposure pathways would be included in the toxicological analysis.

Response: Fish consumption was not part of this microbial risk assessment study. Pathogens present in the fish would most likely be destroyed during the cooking process. Also, fish consumption is typically regulated with fish advisories.

Overall, this risk assessment does not do an effective job at presenting the actual risk of exposure to undisinfected sewage effluent present in the CAWs. More transparency would aid the reader in the confidence of the conclusions.

Response: We believe that we have conducted a very comprehensive systematic study to characterize the microbial quality and associated risks of the CWS, under both dry and wet weather conditions. The samples were collected and analyzed during the recreational season, over a two-year period; dry weather samples were collected during the 2005 recreational season and wet weather samples were collected during the 2006 recreational season. This study focused on the detection of microorganisms typically present in the feces of humans and other warm-blooded animals as indicators of fecal pollution. Hence, a group of EPA-approved indicator microorganisms, such as E. coli, enterococci, and fecal coliform was selected for this study. In addition to the indicator microorganisms, pathogens representative of those present in the wastewater that are also of public health concern were selected. Overall, one hundred and twenty five (125) samples were collected and analyzed during the dry and wet weather events.

Risk assessment inputs were drawn extensively from site-specific data and were developed using state-of-the-science methodology to accurately represent recreational user exposure conditions and risks. Recreational survey studies were used to provide insight on the types and frequency of recreational exposure expected in the waterway. For quantitative risk analysis, the UAA study was used as the primary source for exposure use data for the CWS. Exposure parameters were developed as distributional parameters for each receptor scenario as inputs to the exposure model. These parameters include incidental ingestion rates and exposure duration. Selection of input distributions relied on literature derived sources, site-specific use information and professional judgment using conservative assumptions. Dose-response data was developed from regulatory documents, industry white papers and peer reviewed literature. Concentrations of pathogens in the waterway were selected for each simulation from the entire dataset of dry and wet weather samples collected. The proportion of dry and wet weather samples utilized were weighted to account for the proportion of dry and wet weather days in a typical Chicago recreational season.

Dry Weather Risk Assessment of Human Health Impacts of Disinfection vs. No Disinfection of the Chicago Area Waterways System

Review conducted for: US EPA Region 5, Office of Water,
Review conducted by: US EPA Office of Research and Development

Summary:

A Quantitative Microbial Risk Assessment (QMRA) of the Chicago Area Waterways (CAW) was conducted to evaluate the risk of illness posed to recreational users of the CAW with the current practice of not disinfecting the effluent at three wastewater treatment plants with discharges into the CAW. Using monitoring data for pathogenic microorganisms and integrating over dose response functions, exposure times and ingestion rates, the conclusion was made that the risk for gastrointestinal illness was well under the 8-10/1000 currently deemed "acceptable" by the US EPA 1986 Ambient Water Quality Criteria, and that there was therefore no need for additional disinfection to adequately protect public health

This QMRA was only done for the Phase I "dry" weather season, and does not present results for the wet season. So presumably any conclusions would be only applicable to the dry season until the wet season analysis is completed.

Response: We concur with the reviewer's comment. The Interim Report summarizes the dry weather microbial risk assessment results and any conclusions are only applicable to the dry season. However, the April 2008 Final Report entitled, "Dry and Wet Weather Risk Assessment of Human Health Impacts of Disinfection Vs. No Disinfection of the Chicago Area Waterways System," (Final Report) integrates both the dry and wet weather microbial risk assessment results in a comprehensive outcome.

National Health and Environmental Effects Research Laboratory (NHEERL):
Note: This lab's review does not assess in detail the adequacy of the microbial methods, QA procedures and sampling techniques.

Comments:

The QMRA was conducted by a consulting group, GeoSyntec Consultants, based in Chicago, with analytical assistance from Dr. Charles Gerba at University of Arizona, and Dr. Jennifer Clancey of Clancey Environmental, among others.

The microbial sampling and characterization seems thorough and adequate. World-renowned experts were consulted and retained to conduct the analyses for pathogenic microorganisms and details of the sampling scheme, rationale and methods are well described.

The general approach described for the QMRA also seems appropriate. The authors do a thorough job of explaining and justifying their selections of dose-response functions and their parameters. Generally, citations from peer reviewed literature are provided to support their decisions.

However, there are some fundamental problems in the application, presentation and interpretation of the results of the QMRA. These are detailed below:

- No justification was provided for the organisms measured or pathogens considered in the QMRA
- The risks presented are only for a few gastrointestinal pathogens. Risks were not presented for Hepatitis A, Shigella, Camplyobacter, to name a few. Therefore risks presented will be biased low.

Response: Section 2.1 of the Final Report presents the rationale for indicator and pathogenic microorganism selection. This study did not account for all pathogens that may be present in CWS recreational water. This study focused on the detection of microorganisms typically present in the feces of humans and other warm-blooded animals, as indicators of fecal pollution. Hence, a group of EPA-approved indicator microorganisms, such as E. coli, enterococci, and fecal coliform was selected. In addition, pathogens representative of those present in the wastewater that are also of public health concern were selected. Table 2-1 in Section 2.1 of the Final Report presents a summary of the microorganisms selected for this microbial risk assessment study and rationale for their selection. The rationale for selecting the pathogens for this microbial risk assessment study included the following criteria:

- ***The pathogens selected are associated with documented outbreaks of disease, including gastrointestinal and respiratory diseases and infections***
- ***There are EPA-approved methods or laboratory standard operating procedures (SOPs) available for the measurement of the selected pathogens.***

- Only gastrointestinal illness was considered

Since *Pseudomonas* and adenovirus were found, descriptions of non GI Illness should also be provided to present a clear picture of the actual risk associated with recreating in the CAW

Response: Section 5.1 of the Final Report describes in detail the Hazard Identification component of the microbial risk assessment study. As stated in this section, exposure to microbial contaminated water may result in both gastrointestinal and non-gastrointestinal illness. However, there are no known dose response models for the non-gastrointestinal exposure routes. The risk of gastrointestinal illness was selected as the sentinel effect for conducting the quantitative risk assessment. However, non-gastrointestinal illnesses were addressed qualitatively. Section 5.3.5 of the report discusses the dermal risks and eye and ear infections caused by Pseudomonas aeruginosa. Although Pseudomonas aeruginosa is not a pathogen that is linked to gastrointestinal illness, this pathogen has been linked to recreational illness outbreaks involving dermal (folliculitis), eye, and ear (otitis externia) infections. For this reason, the levels of Pseudomonas aeruginosa were evaluated under the sampling program for this risk assessment. However, quantitative evaluation of the risk for this pathogen is problematic. There are no published dose-response relationships for Pseudomonas aeruginosa. Without a clear dose-response relationship there is no way to establish the expected illness level associated with any particular waterway concentration. The

dermal pathway for estimating exposure to Pseudomonas aeruginosa is also problematic. Ear and eye infections associated with contact by Pseudomonas aeruginosa contaminated water are typically associated with full immersion activities. Since these types of activities are not permitted or designated uses of the CWS the incidence of ear and eye exposures are expected to be low and as the result of accidental or intentional misuse of the waterway. Pseudomonas related folliculitis commonly requires a break in the skin from a preexisting cut, open sore or scrape as an entry point for infection. Immunocompetent individuals without skin abrasions rarely develop folliculitis by exposure to intact skin. For these reasons, a quantitative evaluation of risks is not feasible.

Section 5.4.6 of the Final Report presents a qualitative assessment of the non-GI risks associated with Pseudomonas aeruginosa.

- Conservative assumptions were not made

In nearly every case, when simplifications and assumptions were made in such a way to ultimately minimize the estimated risk.

Response: We believe that conservative assumptions were made in estimating the microbial risks in the CWS. Section 5.4.7 of the Final Report discusses in detail the Sensitivity and Uncertainty Analysis of the Microbial Risk Assessment and provides the following examples:

- *Secondary transmission rates used are generally at the high end of those reported in the technical literature. Therefore, the assumptions on secondary transmission are conservative and the resulting secondary illness rates may be biased high.*
- *The measured pathogen concentrations under dry weather conditions are limited to sampling locations near the WRPs and they were used as representative concentrations of the entire waterway downstream of the WRP. Under dry weather conditions, these concentrations will be biased high relative to concentrations at locations more distant from the WRP.*
- *The measured concentrations of E. coli are assumed to represent the most virulent strain; the percentage of pathogenic E. coli was conservatively assumed to represent 2.7% of the total measured concentrations. For other organisms, such as adenovirus, all the organisms are assumed to represent the pathogenic strain leading to gastrointestinal illness. This assumption may overestimate the illness associated with exposure to these organisms.*
- *Virus concentrations measured by the assay systems may overestimate viral risk. Viral assays are not specific to the pathogenic virus in question and may detect less pathogenic viral strains.*
- *Recreational use may be inversely correlated with wet weather. CWS recreational use was assumed to occur randomly over the course of the recreational season. The majority of the illnesses were associated with wet*

weather events. If the frequency of exposure on wet weather days is lower than average then the resulting risk estimate may be biased high.

- *Some receptors with frequent use of the CWS may have lower sensitivity to some pathogens due to acquired immunity. Repeated exposure to pathogens in water is known to produce tolerance in individuals through immune related mechanisms. Dose-response parameters used in the assessment are generally derived from "naive" individuals and represent upper-end estimates of infectivity for the general population. Since repeated exposure to the waterway is likely for a significant subset of the recreational population, the risk of illness for these individuals is probably over-estimated by this risk assessment.*

For example, high Calicivirus measures were dismissed as an artifact and an outlier.

Response: Section 3.3.3 of the Final Report discusses all Calicivirus results in detail. During dry weather, norovirus was only detected in 5 samples or about 7% of the 75 samples. During the North Side dry weather sampling, only one outfall sample (1 of 25 samples [4%]) had a detectable norovirus concentration of 35,000 PCR MPN/100L (see Tables 3-7 and 3-9 in the Final Report). The greater concentration of Calicivirus or norovirus observed in this sample could be attributed to the fact that only duplicates per dilution in the MPN assay could be performed because of reassay difficulties reducing the precision of this analysis. In addition, of the five norovirus samples with MPN assays, this sample was the only one that had a positive result in the highest dilution. The combination of these factors could have resulted in the relatively high MPN value of this sample. As stated in the report, the high Calicivirus concentration in the subject sample is likely an artifact of these factors and it appears to be an outlier.

High infectivity parameters for adenovirus were dismissed because they usually cause respiratory illness.

Response: The reviewer's comment mischaracterizes how adenovirus microbial risks were estimated. Section 5.1 of the Final Report clearly states that some adenovirus strains are primarily associated with respiratory illness. However, fecal-oral transmission associated with gastrointestinal illness is the primary effect evaluated in this study. As a conservative assumption all detected adenovirus was assumed to contribute to gastrointestinal illness.

The lower infectivity of echovirus was considered instead of rotavirus.

Response: The reviewer's comment mischaracterizes the selection of the echovirus dose response as a surrogate for adenovirus. Section 5.3.3 of the Final Report states that several dose-response relationships are reported for adenovirus but none of these are specifically for Ad40 or Ad41, subtypes primarily associated with gastrointestinal illness. This will lead to an overestimate of the true risks for gastrointestinal illness. Therefore, the dose-response for echovirus 12 was selected as a surrogate for total

enteric viruses. This approach was recommended by Dr. Charles Gerba of the University of Arizona.

> The notable exception to this is secondary transmission where some apparent conservative assumptions were made, but since it is not clear how secondary transmission was modeled and since there was no sensitivity analysis conducted it is impossible to evaluate how these assumptions ultimately affected the results.

***Response:** Section 5.4.2 of the Final Report presents a detailed discussion on Disease Transmission Model, including secondary attack rates. As stated in the report the secondary attack rates for various organisms depend on the virulence of the organism in question, the amount of organisms an infected individual sheds, and the environmental stability of the organisms. Table 5-6 of the Final Report presents a summary of secondary attack rates used in this analysis. Footnotes to Table 5-6 indicate that the secondary transmission rates used in the microbial risk estimates are generally at the high end of those reported in the technical literature. Therefore, the assumptions on secondary transmission are conservative and the resulting secondary illness rates may be biased high.*

> There is also some question about the activities considered. Why wasn't full body jet skiing considered? Or other full body exposures even if they area rare and prohibited, would still result in risk of illness.

***Response:** As stated in the Introduction of the Final Report (see first paragraph on page 5), the UAA Stakeholders evaluating the CWS have agreed that swimming and other primary contact recreation should not be considered as a viable designated use for the CWS because of physical limitations due to the configuration of the embankments and safety hazards. It was not within the scope of work of the microbial risk assessment to evaluate health risks originating from undesignated uses of the CWS.*

- Inadequate reporting of risk assessment results and methods

> The actual risk assessment is brief and contains no graphs and few brief tables. It is unclear how microbial pathogen densities were estimated. Were distribution functions estimated based on the observed results, or were the potential values sampled from the actual results? Were only viable Cryptosporidium results considered? A table should be provided listing the details of all parameters and their ranges in used in the risk assessment. Furthermore, it is not clear how activities were randomly assigned, were they assigned based on their frequency of occurrence, or were they completely random? It is also not clear how secondary illness was modeled or incorporated into the estimate.

***Response:** Section 5.0 of the Final Report (pages 94-140) discusses the data used; assumptions made and detailed procedures involved in the risk assessment calculations, including: (1) hazard identification, (2) exposure assessment, (3) dose response assessment, and (4) risk*

characterization. In addition, Tables 5-1 to 5-17 and Figures 5-1 to 5-4 provide pertinent information that addresses the reviewer's comments.

Section 3.0 of the Final Report presents all the analytical results that were used in the microbial risk estimates in accordance with the procedures discussed in Section 5.4.3 of the report. Section 5.4.2 of the report discusses the disease transmission model, including secondary illness.

For cryptosporidium, the infectious concentrations determined by the EPA-approved method were used in the microbial risk assessment.

- Interval estimates were not reported

This is a major failing since only one estimate of the risk was reported. With the significant amount of assumptions and uncertainty, bounds on these estimates must be provided (95% bounds). Complete details of the Monte Carlo analysis should be provide so the distribution of risk can be visualized.

- No sensitivity analysis was provided

A sensitivity analysis should describe which assumptions most affected the risk estimates and how they affected the risk estimates. Since so many assumptions that were made were not necessarily conservative, this is a vital aspect to a risk assessment.

Response: Section 5.4.7 of the Final Report presents a sensitivity analysis of the contribution of each microbial risk input distribution to the variance of the resulting risk estimates.

- Variability and uncertainty were not discussed, evaluated or quantified

Each step of the risk assessment contains variability and uncertainty. Uncertainty could be considered in the dose-response parameters or in the microbial densities.

Response: Section 5.4.7 of the Final Report presents a sensitivity analysis of the contribution of each microbial risk input distribution to the variance of the resulting risk estimates. In addition, uncertainties associated with the risk estimates are also discussed in this section.

- Limitations were not discussed

One clear limitation is that only a few pathogens were considered and this methodology does not characterize the cumulative risk associated with all pathogens potentially present in an environment. Another clear limitation is the failure to discuss sensitive or susceptible limitations, illnesses other than GI and the potential for long term sequelae resulting from infection.

Response: Section 5.4.7 of the Final Report presents a discussion of all above-mentioned limitations. As stated in the text, this study did not account for all

pathogens that may be present in the CWS recreational water. However, the microorganisms that were selected for inclusion in the study include regulatory indicators and those that could be measured by EPA-approved methods that were judged most likely to produce gastrointestinal illness. In addition, Section 2.1 of the report includes a more complete rationale on pathogen selection.

Section 5.1 of the Final Report describes in detail the Hazard Identification component of the microbial risk assessment study. As stated in this section, exposure to microbial contaminated water may result in both gastrointestinal and non-gastrointestinal illness. However, there are no known dose response models for the non-gastrointestinal exposure routes. The risk of gastrointestinal illness was selected as the sentinel effect for conducting the quantitative risk assessment. However, non-gastrointestinal illnesses were only addressed qualitatively. Section 5.4.6 of the Final Report presents a qualitative assessment of the non-GI risks associated with Pseudomonas aeruginosa.

In summary, while the QMRA methodology is appropriate, many assumptions are questionable, important details are left out, there is no evaluation of the potential range of risks, and no sensitivity analysis. Therefore the QMRA does not provide sufficient information to support the assertion that there is minimal risk with the current state of no disinfection. These details should either be provided to support the claims made, or another, independent risk assessment should be conducted.

Response: The reviewer's comment makes a lot of assertions, but does not provide any specifics. Section 5.4.7 of the Final Report presents a sensitivity analysis of the contribution of each microbial risk input distribution to the variance of the resulting risk estimates. In addition, uncertainties associated with the risk estimates are also discussed in this section.

<u>*Additional specific comments:*</u>

Introduction:

Did all the consultants listed contribute? While Drs. Gerba and Clancy role was clear, that of Dr. Jack Colford was not. If Dr. Colford contributed specifically to this study, his role should be clearly defined.

Response: Dr. Colford was a member of our team and his role was to provide peer review of the final Dry and Wet Weather risk assessment report. However, due to other professional commitments he informed us in December 2007 that he was not available to provide these services for our report.

Page 2:

"..no outbreaks..traceable to treated wastewater..."

Statement is misleading because outbreaks are not a reliable health indicator due to problems with consistent and reliable detection. Furthermore, statements such as these require citation from peer reviewed literature or other outside sources to avoid the perception of bias.

Response: The report includes the following citation for the statements made:

"Metropolitan Sanitary District of Greater Chicago (MSDGC), 1984, Wastewater Disinfection: A Review of Technical and Legal Aspects in Illinois. Department of Research and Development. Report No. 84-17. July."

However, this statement was removed from the Final Report.

"The year round implementation of chlorination to disinfect the sewage treatment effluents has been reported to have adverse environmental effects"

The purpose of statements such as these is unclear and their presence in the introduction of a presumably unbiased risk assessment is concerning. While this may be true, citations from peer reviewed literature are necessary following statements such as these to avoid the perception of bias. Furthermore, benefits of chlorination should also be discussed if the downsides are going to be presented.

Response: The report includes the following citation for the statements made:

"Metropolitan Sanitary District of Greater Chicago (MSDGC), 1984, Wastewater Disinfection: A Review of Technical and Legal Aspects in Illinois. Department of Research and Development. Report No. 84-17. July."

However, this statement was removed from the Final Report.

In addition, a section has been added (Section 4) in the Final Report that provides a comprehensive overview of disinfection technologies, including: (1) chlorination/dechlorination, (2) ozonation, and (3) UV. Advantages and disadvantages of each technology are discussed, including disinfection effectiveness, and disinfection by-product formation.

Page 32:

If censoring is greater than 80%, all data are statistically insignificant? Even though there was 20% detection?

As discussed in Section 3.1.3 of the Final Report, semi-log box plots were created to graphically demonstrate the central tendencies and variability of the various bacteria datasets. The text states that no box plots were prepared for dry weather Salmonella results as most of these datasets were statistically insignificant (i.e., non-detect frequency >80%). As explained in the text these results were not excluded, but the geometric mean values (generated using the maximum likelihood method) are better indicators of this trend for significantly censored datasets. However, box plots of bacteria, including Salmonella were prepared for wet weather data that had a more robust data base of detectable results.

Page 33:

What is the point to the detailed analysis of the correlation of indicator organisms? These are not used in the risk assessment. Rather energy should have been spent on providing more details of the actual risk assessment.

Response: ***The ultimate purpose of the analysis was to determine correlations between pathogens and indicators under both dry and wet weather conditions in order to ascertain if the weather or any other factor can affect such correlations. To address the reviewer's comment, the statistical correlations between bacteria pathogens and indicators have been removed from the body of the report and are included in Attachment A of the Final Report. The statistical analysis in Appendix A indicates that the correlation of bacteria in wet weather samples is statistically more significant compared to the dry weather samples.***

Page 36:

Although the EC/FC differences in upstream vs. downstream samples were not statistically significant this could be a function of sample size—there is a consistent difference and there could be more sophisticated measures to assess this. The p-value should be reported, not simply stated as >0.05.

The difference in the EC:FC ratios with what the District obtained calls into question the representativeness of the data for the risk assessment.

Response: The lower EC/FC estimates in this study could be attributed to the fact that the District's analysis is based on a much larger database that includes several years of sampling of the waterway.

Page 41:

"While levels of potentially viable *Giardia* cysts may pose public health risk, it is important to note that not all viable organisms are capable of infection"

Seems to be a prejudicial statement. Not clear why this is important to note.

Response: ***This statement was taken verbatim from the Clancy Environmental Consultants, Inc. (CEC) analytical laboratory report. CEC was our expert laboratory for protozoa analysis. According to CEC this is a factual statement that is important to note. All CEC analytical reports are included in Appendices C-1 and C-2 of the Final Report.***

Page 42:

"The results indicate that a relatively small number of samples (23%) had detectable concentrations of enteric virus."

Relative to what? This could be an important contribution to pathogen exposure, but no information is provided to support the assertion that it is "relatively" small.

Response: "Relative" refers to the total number of samples.

Page 44:

Citations need to be provided for statements to the effect of that b/c the RT PCR does not provide infectivity information it impedes meaningful health risk evaluation. Certainly it puts bounds on the levels of potential risk (0% viable, to 100% viable). Other sources could be evaluated for viability of norovirus in wastewater.

Page 91:

Inhalation not considered important—need citations to support this anti-conservative simplification and assumption.

For canoeists, kayakers, this could be an important pathway

Response: Section 5.2 of the Final Report discusses exposure assessment pathways. The text clearly states that the most important exposure pathway is via incidental ingestion but other routes can also be important for some microorganisms, like exposure via inhalation, eye or dermal contact. The text also discusses the relative contribution to total intake by several pathways (incidental water ingestion, inhalation and dermal contact) to determine the relative contribution of each pathway to total exposure to microbiological organisms in surface water while recreating.

Page 92:

Activities such as water skiing, etc. were excluded because they are not allowed, but do they occur? Is the prohibition enforced? An accurate risk assessment would consider these activities if they occurred especially when evaluating the potential benefit of disinfection.

Jet Skis-classified as pleasure boating with minimal contact. This is problematic-also "the RA does not consider jet skis that result in immersion.

Response: As stated in the Introduction of the Final Report (see First Paragraph on page 5), the UAA Stakeholders evaluating the CWS have agreed that swimming and other primary contact recreation should not be considered as a viable designated use for the CWS because of physical limitations due to the configuration of the embankments and safety hazards. It was not within the scope of work of the microbial risk assessment to evaluate health risks originating from undesignated uses of the CWS.

Page 100:

Using echovirus (less infectious) instead of rotavirus (the most infectious) for the dose response relation, results in less conservative (fewer illness) estimates.

Response: Section 5.3.3 of the report discusses the Dose Response Assessment of Adenovirus. As stated in the report, several dose-response relationships are reported for adenovirus but none of these are specifically for Ad40 or Ad41, subtypes primarily associated with gastrointestinal illness. This will lead to an overestimate of the true risks for gastrointestinal illness. Therefore, the dose-response for echovirus 12 was

selected as a surrogate for total enteric viruses. This approach was recommended by Dr. Charles Gerba of the University of Arizona.

Page 101:

Was genetic immunity/susceptibility to norovirus infection considered?

Response: No special distribution was applied to account for genetic polymorphisms related to susceptibility. Similarly no adjustment was made to account for acquired or natural immunity. We do not believe that the additional uncertainty added by including these factors is warranted by the increase in accuracy of the results if these factors were considered. For example, we do not have data to indicate what percentage of the recreational population are repeat visitors and potentially more resistant by acquired immunity. Our analysis considers all receptors naïve and equally susceptible.

Page 102:

By using the more conservative GI model for adenovirus, total health effects are underestimated. Should also evaluate respiratory risks with the more infectious model. What is the justification for using the less infectious parameter?

Response: Section 5.3.3 of the Final Report discusses the Dose Response Assessment of Adenovirus. As stated in the report, several dose-response relationships are reported for adenovirus but none of these are specifically for Ad40 or Ad41, subtypes primarily associated with gastrointestinal illness. This will lead to an overestimate of the true risks for gastrointestinal illness. Therefore, the dose-response for echovirus 12 was selected as a surrogate for total enteric viruses. This approach was recommended by Dr. Charles Gerba of the University of Arizona.

Page 105:

Again the focus on GI results in a conservative estimate of overall risk

Response: Section 5.1 of the Final Report describes in detail the Hazard Identification component of the microbial risk assessment study. As stated in this section, exposure to microbial contaminated water may result in both gastrointestinal and non-gastrointestinal illness. However, there are no known dose response models for the non-gastrointestinal exposure routes. The risk of gastrointestinal illness was selected as the sentinel effect for conducting the quantitative risk assessment. However, non-gastrointestinal illnesses were addressed qualitatively.

Section 5.4.6 of the Final Report presents a qualitative assessment of the non-GI risks associated with Pseudomonas aeruginosa.

Page 111:

Since Monte Carlo analysis was used, why wasn't a risk distribution (e.g., 50th percentile, 90th percentile, etc) generated?

Response: To simplify the presentation of the results, the final exposure distributions were realized for a set of recreational receptors and the proportion of that population is reported. Specifically, for each of the one million individuals evaluated in the Monte Carlo analysis an exposure dose was computed and the probability of infection computed. At that point a random number was generated and compared to the probability of infection. If the random number was less than the probability then the individual was assumed to be infected and subsequent evaluation of the probability of illness given infection and secondary infection was computed. The advantage of this technique is the easy computation of the proportion of recreational users in the CWS that may become ill during recreational exposure.

Details on how secondary spread was modeled are not clear.

Response: Section 5.4.2 of the Final Report discusses the Disease transmission model, including secondary transmission. As stated in the report, to account for secondary transmission, a dynamic risk model was developed that considers secondary exposure through contact with CWS recreational users. Estimates of the infectivity and transmission rate as inputs for the dynamic model were derived from the primary literature for each of the microorganisms of interest. Because the number of individuals exposed through recreation on the CWS is a relatively small proportion of the total population of the Chicago metropolitan area, population levels of acquired immunity and illness by secondary transmission were not impacted. Therefore, the proposed dynamic model considers a steady-state level of immunity and estimates disease incidence only in the recreational receptor population and their immediate family. This approach addresses the important dynamic aspects of disease transmission from CWS exposure in the population most at risk.

Page 117:

How was recreation type selected in the simulation? Were they in proportion to the actual usage?

Response: Section 5.2.1 of the Final Report discusses Waterway Use Summary and Receptor Group Categorization. As stated in the report, several sources of information were reviewed to estimate recreational use and exposure to the CWS. Each of these studies provides insight on the types and frequency of recreational exposure expected in the waterway. For quantitative risk analysis, the Use Attainability Analysis (UAA) study was used as the primary source for exposure use data for the CWS. The purpose of the UAA is to "evaluate existing conditions, including waterway use practices and anticipated future uses to determine if use classification revisions are warranted" (Source: Camp Dresser and McKee, Inc. (CDM), 2007, Use Attainability Analysis of the Chicago Area Waterway System. August). The UAA surveys were conducted to evaluate the types of recreational use that are currently being exhibited on each of the

waterway segments. Based on the UAA, several recreational exposure scenarios were selected for evaluation in the risk assessment.

Page 134:

Risk assessment was only conducted for limited number of GI pathogens.

Response: This study did not account for all pathogens that may be present in the CWS recreational water. Section 2.1 of the Final Report includes a more complete rationale on pathogen selection. However, the pathogens that were selected for inclusion in the study include regulatory indicators and those that could be measured by EPA approved methods that were judged most likely to produce gastrointestinal illness. In addition, Section 5.1 of the Final Dry and Wet Weather Report, dated April 2008 describes in detail the Hazard Identification component of the microbial risk assessment study. As stated in this section, exposure to microbial contaminated water may result in both gastrointestinal and non-gastrointestinal illness. However, there are no known dose response models for the non-gastrointestinal exposure routes. The risk of gastrointestinal illness was selected as the sentinel effect for conducting the quantitative risk assessment. However, non-gastrointestinal illnesses were addressed qualitatively.

Section 5.4.6 of the Final Report presents a qualitative assessment of the non-GI risks associated with Pseudomonas aeruginosa.

National Center for Environmental Assessment (NCEA):
Note: this lab's comments are based on a cursory review only.

Comments

There are some serious surrogacy issues -- e.g., using rotavirus data for a norovirus dose-response is implausible.

Response: Section 5.3.3 of the Final Report discusses the Dose Response Assessment of Adenovirus. As stated in the report, several dose-response relationships are reported for adenovirus but none of these are specifically for Ad40 or Ad41, subtypes primarily associated with gastrointestinal illness. This will lead to an overestimate of the true risks for gastrointestinal illness. Therefore, the dose-response for echovirus 12 was selected as a surrogate for total enteric viruses. This approach was recommended by Dr. Charles Gerba of the University of Arizona.

Page 133:

Table 4-6 presents a summary of the secondary attack rates that appear quite high. Additional investigation of the original references are needed to get a better idea of whether or not the values posted are reasonable.

***Response:** Secondary transmission rates used are generally at the high end of those reported in the technical literature. Therefore, the assumptions on secondary transmission are conservative and the resulting secondary illness rates may be biased high.*

Page 115-116:

The discussion of the "disease transmission model" and secondary attack rates is very sketchy. The authors vaguely mention "dynamic models" (which do not seem to be provided anywhere in the document) and appear to be rather naive about the difficulty of parameterizing such models. They state that secondary attack rates depend on virulence, shedding rate, and environmental stability of the organisms. But probably human contact patterns, characteristics, and age groups are more important.

It does appear that this risk assessment has weaknesses that could potentially be meaningful

***Response:** Section 5.4.2 of the Final Report discusses the Disease Transmission Model, including secondary transmission. As stated in the report, to account for secondary transmission, a dynamic risk model was developed that considers secondary exposure through contact with CWS recreational users. Estimates of the infectivity and transmission rate as inputs for the dynamic model were derived from the primary literature for each of the microorganisms of interest. Because the number of individuals exposed through recreation on the CWS is a relatively small proportion of the total population of the Chicago metropolitan area, population levels of acquired immunity and illness by secondary transmission were not impacted. Therefore, the proposed dynamic model considers a steady-state level of immunity and estimates disease incidence only in the recreational receptor population and their immediate family. This approach addresses the important dynamic aspects of disease transmission from CWS exposure in the population most at risk.*

National Exposure Research Laboratory (NERL):

Comments

Since the overall goal of the study is to determine whether or not to disinfect the effluent why the protozoans were included in this study?

The chlorine concentrations that would be used would result in little or no inactivation of the G/C. However, CEC's summation of the protozoan results and interpretation and method limitations were quite reasonable.

The number of Giardia cysts is lower than some other reports for sewage; however, this may because there are only dry weather events in this portion of the study.

It should be more clearly emphasized that the number of Cryptosporidium oocysts from the samples were below the cell culture detection limit and even if all of the oocysts applied were infectious it is unlikely that a foci would develop.

The documents treatment of the parasite issue was really not adequate.

Response: We believe that the Final Report provides a comprehensive evaluation of the protozoa in the CWS. The following aspects of protozoa are discussed in the report:

1. *Section 3.2 discusses Protozoa Analytical Results including, infectious Cryptosporidium and Viable Giardia Cysts under both dry and wet weather conditions*
2. *Section 4.5.2 discusses wastewater protozoa disinfection effectiveness using UV, chlorination and ozonation*
3. *Sections 5.3.7 and 5.3.8 present dose-response models for cryptosporidium and giardia*

The risk assessment appears to be a standard boiler plate, which is only as good as the data used to form it.

Response: The use of probabilistic microbial risk assessment for estimation of illness in recreational users is the state-of-the-science approach for estimating risk. Inclusion of secondary infection risks within a limited recreational population, joint risk estimation for multiple pathogens, and realization of risks to estimate the proportion of users that are likely to become ill are novel techniques and represent the latest thinking on risk evaluation. The methods and results from this study have been the subject of 4 papers presented at National conferences and 3 peer manuscripts are currently in preparation for peer review stemming from this work.

This assessment uses input data that represent the highest quality and most extensive contemporaneous bacteria, virus and protozoa data for recreational water currently available. The fact that sampling was conducted over multiple years from numerous locations along the waterway in conditions that encompasses a range of weather conditions provides some assurance that support information on census figures, meteorological data, and recreational use are developed from highly reliable sources. While it is true that the results of a risk assessment are only as good as the input data used, the inputs for this study are arguably the best recreation use microbial risk databases ever assembled.