Protecting Our Water Environment

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December 30, 2010

Ms. Tinka G. Hyde
Director, Water Division
United States Environmental Protection Agency
Region 5, Water Quality Branch
77 West Jackson Boulevard
Mail Code: WQ-16J
Chicago, IL 60604-3507

Dear Ms. Hyde:

Subject: United States Environmental Protection Agency's Review of Geosyntec's Response to the United States Environmental Protection Agency's Comments on the Report entitled "Dry and Wet Weather Risk Assessment of Human Health Impacts of Disinfection Versus No Disinfection of the Chicago Area Waterway System"

The Metropolitan Water Reclamation District of Greater Chicago (District) acknowledges the receipt of your letter dated July 21, 2010, regarding the above subject matter.

Before responding to the specific United States Environmental Protection Agency (USEPA) comments, the District wishes to present a brief summary background on the subject project history which will provide clarification on the purpose of the study. The events leading to the study and the correspondence with USEPA and Illinois Environmental Protection Agency (IEPA) are summarized in Table 1. In September of 2002, the IEPA began conducting a Use Attainability Analysis Study (UAA) on the Chicago Area Waterway System (CAWS). The goal of the CAWS UAA was to review and evaluate established use classification and water quality criteria, make recommendations for appropriate changes, and gain regulatory and public input for the CAWS. One aspect of the UAA study was to determine whether the water quality standards for some and/or all parts of the CAWS are necessary to protect the incidental contact use designation. In March 2004, the IEPA suggested that the District address disinfection and water quality management alternative strategies. The key element in the alternative strategy was to retain the services of a consultant to perform a comparative risk assessment of the human health impacts of continuing with the current practice of no disinfection vs. initiating disinfection at the three large water reclamation plants (WRPs).

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To support the CAWS UAA, the District awarded the research contract to the Geosyntec Consultants team in June 2005 to conduct the risk assessment study. The study was originally planned to be completed in 2005; however, due to climatic conditions that year, only dry weather samples could be collected and the study had to be extended through 2006 to allow for wet weather data collection. The preliminary results of the dry weather study were summarized in an interim dry weather report in November 2006. The report was posted on the District website and copies were sent to IEPA and USEPA Region 5. In the meantime, Phase II (wet weather study) continued from June to October, 2006.

At the CAWS UAA Stakeholder Meeting on March 20, 2007, the District received two sets of similar comments on the Interim Dry Weather Draft Report: one from USEPA Office of Research and Development (R&D), and the other from Office of Water's Office of Science and Technology (S&T). At the meeting, Mr. Toby Frevert of the IEPA suggested that the District meet with USEPA staff to discuss and resolve these comments. As a result, a meeting was held on April 10, 2007 at the USEPA Region 5 office in Chicago, to clarify and discuss the issues raised by USEPA reviewers with the Geosyntec team. The meeting participants included: District staff; the Geosyntec team; USEPA Region 5 (in person); and staff from the USEPA office of S&T and R&D (via conference call). The meeting was particularly helpful in clarifying the reviewers' comments for the Geosyntec team (Drs. Petropoulou, Gerba and Tolson) and concurrence on the final report format to address USEPA concerns.

The Geosyntec team reviewed the comments and provided a response to USEPA concerns dated March 20, 2007 on the Interim Report, which was transmitted to USEPA and IEPA with the copy of the final report on May 28, 2008. The Geosyntec team submitted the final report document with multiple binders, with each binder focusing on the appendices (A1, A2, B1, B2, C1, C2) dealing with the report sections. The appendices provide documentation of microbial method and technical assessment of results. It was made clear in the letter that the appendices which included the raw data from laboratories for each of the sections were not included in the final report, and could be made available upon request. There were no requests made from USEPA for copies of the supporting appendices.

On July 31, 2008, the USEPA provided comments on the final report. The comments were forwarded to Geosyntec, who prepared the itemized responses, which were transmitted to USEPA on March 13, 2009. The Geosyntec responses emphasized that the study descriptions were sufficiently complete with proper illustrations and justification(s), such that the scientific foundation of the CAWS risk assessment study is understandable and well documented in the report. The risk assessment analysis contains very significant site specific data, including all of the important exposure ranges and distributions required for a sound scientific study. All of the USEPA comments and concerns were also discussed during the hearing proceedings before the Illinois Pollution Control Board (IPCB) held on September 9-10, 2008, at the Thompson Center,

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Chicago, Illinois. The entire proceeding documents are available at http://www.ipcb.state.il.us/documents.

On July 21, 2010, USEPA provided to the District another set of comments on GeoSyntec's March 2009 response to USEPA's July 2008 comments on the final GeoSyntec report. This letter and the attachments are the District's response to the July USEPA letter.

Several of the USEPA comments have stemmed from a misinterpretation or misunderstanding of the information provided in the final report. The information is in the report, but may not be in the format that the USEPA prefers. The Geosyntec team has provided clarification in their responses to the suggestions and comments. Many of the USEPA comments offered are generic statements without providing supporting data upon which the statement is made in the response. Without this supporting clarification, it is difficult to evaluate the merit and validity of USEPA comments to Geosyntec responses. However, a response to each USEPA comment has been provided in Enclosure 1: Dry and Wet Weather Risk Assessment, and Enclosure 2: Phase I Interim Report, even though some of the comments seem to be redundant (see attached). The responses to USEPA comments on Geosyntec responses are highlighted in bold.

Regarding the specific statements transmitted in the July 21, 2010, letter, we submit the following:

Statement: The risk characterization methodology used was unconventional in the field of quantitative microbial risk assessment.

Response: The microbial risk assessment approach used is based on previous research work by Drs. Haas, Gerba and Rose[1], and is consistent with the International Life Sciences Institute's (ILSI) risk assessment principles and methods (ILSI, 2000[2] and 2001[3]), which are state of the art methods.

Statement: A coherent problem formulation is lacking, as are an appropriate assessment of the input parameters (sensitivity analysis of each key parameter), appropriate statistical analyses, presentation of confidence intervals and formal peer review.

Response: The microbial risk assessment procedure involved a coherent problem formulation as described in the final risk assessment report. The "*Coherent Problem Formulation*" included in the final report covers the overall goals and objectives of the risk

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assessment study. In addition, the primary element of the CAWS risk assessment model described in Section 5 of the final report consists of a detailed review of the microbial hazard identification, exposure assessment, microbial dose response estimates, and probabilistic analytical computations to determine the illness rate. As indicated by Geosyntec prepared responses (see attached March 13, 2009 letter to Mr. Tschampa, which includes Geosyntec responses to USEPA comments), appropriate assessment of the input parameters and statistical analyses were evaluated to ensure that no health exposure risks were overlooked in the final assessment. Further, a report by Parkin (2008)[4] entitled "Foundations and Frameworks for Human Microbial Risk Assessments" which was submitted to USEPA found that problem formulation was not a common element in microbial risk assessments conducted in the United States or throughout the world. It cites USEPA's own 2003 report "Proceedings of the microbial risk assessment framework: Problem formulation workshop, July 28-29, 2003" which states that problem formulations do not always have the same components and are not conducted in a uniform manner.

Regarding the USEPA's concern that the work has not been peer reviewed, the findings from this study have been peer reviewed. One manuscript dealing with the microbial characterization of the CAWS has been published in *Water Science and Technology.*[5] Another manuscript dealing with the microbial risk assessment estimates has been accepted for publication in the *Journal of Water and Health.*[6] In addition, the study received recognition as a scholarly research work and has won the American Academy of Environmental Engineers Excellence in Environmental Engineering Research Honor Award (http://www.aaee.net/Website/E32010Honor Research.htm).

Statement: The risks presented are based on deficient sampling, inappropriate merging of wet and dry datasets and poor interpretation of a limited number of data points and types of gastrointestinal pathogens, resulting in risk estimates that are biased low. For example, a detailed explanation should be provided for why norovirus (believed to be a major cause of gastrointestinal illness in the United States) was present at such low concentrations in wastewaters.

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Response: **Based on the microbial sampling method presented in this investigation and the consistency of the data for multiple sampling events, sufficient site-specific sampling and pathogen data were collected. All samples were analyzed by reputable subcontract laboratories that applied rigorous quality control and quality assurance measures with the analysis. The analyses of viral pathogens, both norovirus and adenovirus, were conducted in Dr. Charles Gerba's laboratory in the Department of Soil, Water and Environmental Science at the University of Arizona. Dr. Gerba is internationally recognized for his expertise in norovirus. The Geosyntec team, including Dr. Gerba, believes that the norovirus results are representative of the site specific CAWS and effluent samples.**

The microbiological data collection for this study included 125 samples: 75 dry weather and 50 wet weather samples collected at the three major WRPs which discharge secondary treated effluent into the waterway; including upstream, downstream, and final effluent samples. The comprehensive microbiological assessment included quantification of not only classical fecal indicator bacteria such as fecal coliform, *E. coli* and enterococci but also the most common potential waterborne pathogens such as *Salmonella* spp, estimated pathogenic *E. coli*, *Cryptosporidium*, *Giardia*, *Pseudomonas aeruginosa*, enteric virus, adenovirus and norovirus, all of which were included with the study.

In the risk assessment study, norovirus was detected at very low levels in the District's secondary treated effluent, which is not a "raw wastewater." Similar findings have been cited in the literature demonstrating effective removal of noroviruses during secondary wastewater treatment without disinfection, thereby improving the quality of the water being discharged (da Silva et al., 2007)[7]. There is no reason to believe that norovirus levels should be high in the secondary treated effluents leaving the District WRPs.

Statement: No meaningful attempt was made to estimate the possible improvement by disinfecting the wastewater.

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Response: The microbial risk assessment study determined that wet weather is the largest source of microbial loads to the CAWS. Therefore, the final report concluded that during the recreational season, which includes both dry and wet weather, disinfecting the WRP effluents would result in an extremely small reduction in the aggregate microbial health risk to the incidental contact recreating population.

This study represents the best effort the current state of the science can provide on CAWS public health assessment. The references cited in this letter are attached in Table 2.

The District and its contractor, Geosyntec team, wish to thank the USEPA staff for their collective responses on this important study. If there are any questions, please feel free to contact Dr. Catherine O'Connor, Assistant Director of Monitoring and Research, Environmental Monitoring and Research Division, at (708) 588-4059.

Very truly yours,

Louis Kollias

Louis Kollias
Director
Monitoring and Research

LK:GR:ps
Attachments
cc: M. Willhite, IEPA
R. Sulski, IEPA
Lanyon/Hill/Granato

TABLE 1: TIME LINE OF ACTIVITIES AND MILESTONES
IN THE CAWS MICROBIAL RISK ASSESSMENT

Time period	Research Task and Activity
September 2002	CAWS UAA Study Initiated by IEPA.
March 2004	UAA Study Stakeholder Advisory Committee (SAC) on Evaluation of Management for the CAWS.
October 2004	In response to IEPA letters dated March 12, August 27, 2004, regarding CAWS UAA Study, the District to pursue the assessment of risks to human health relative to the designated use (non-contact recreation such as canoeing, fishing, etc.).
January 2005	Date of Request for Proposal Advertisement.
June 2005	Research Project Awarded to Geosyntec Consultants.
October 2005	Completed Dry Weather Sampling.
June 2006	Wet Weather Sampling Initiated.
October 2006	Completed Wet Weather Sampling.
November 2006	Interim Dry Weather Report Sent to USEPA Region 5 and IEPA.
March 2007	Received USEPA Comments on Interim Dry Weather Report.
April 2007	Meeting with USEPA Region 5 staff and Conference Call with USEPA Office of Research Development, & USEPA Office of Science & Technology to discuss the review comments on Interim Dry Weather Draft Report.
May 2007	Meeting Minutes Correspondence to USEPA Region 5.
May 2007	Microbial Risk Assessment Results and Proposed Epidemiology Study discussed with USEPA Office of Water in Washington, DC.
May 2008	Complete Final Report with Geosyntec Itemized Responses to USEPA Comments Sent to USEPA.
July 2008	Received USEPA comments on the Final Report.
March 2009	Submitted Final Geosyntec responses to USEPA's comments on the 2008 Dry and Wet Weather Microbial Risk Assessment Report to USEPA Region 5, USEPA Office of Water and IEPA.
July 2010	Received USEPA's Review of Geosyntec's Response to USEPA comments on the final report and the Phase I Interim Report.
Milestones	
2009, 2010	Peer review and publication of two manuscripts on CAWS microbiology and risk assessment.
2010	American Academy of Environmental Engineers, Excellence in Engineering, Honor Research Award.

TABLE 2: REFERENCES

[1] Haas, C.W., Rose, J.B., Gerba, C.P., 1999. Quantitative Microbial Risk Assessment. New York: John Wiley & Sons, Inc., ISBN: 0-471-18397-0.

[2] ILSI 2000. Revised Framework for Microbial Risk Assessment. International Life Sciences Institute Risk Science Institute workshop report. http://www.ilsi.org/file/mrabook.pdf

[3] ILSI 2001. Principles of Risk Assessment of Food and Drinking Water Related to Human Health. ILSI Europe Concise Monograph Series. http://www.ilsi.org/file/ILSIcmRA.pdf

[4] Parkin, R. T. 2008. Foundations and Frameworks for Human Microbial Risk Assessment. Center for Risk Science and Public Health, School of Public Health and Health Services, The George Washington University, Washington, D.C. Submitted to United States Environmental Protection Agency and available at: http://www.epa.gov/raf/files/epa_mra_fw_comparison_report_0609.pdf

[5] G. Rijal et al. 2009. Dry and Wet Weather Microbial Characterization of the Chicago Area Waterway System. *Water Science & Technology*—WST, Vol. 60 No. 7 p. 1847-1855. ©IWA Publishing 2009 doi:10.2166/wst.2009.598.

[6] G. K. Rijal et al. 2010. Microbial Risk Assessment for Recreational Use of the Chicago Area Waterway System. *Journal of Water and Health* © IWA Publishing 2010 in press.

[7] Allegra Kyria da Silva, Jean-Claude Le Saux, Sylvain Parnaudeau, Monique Pommepuy, Menachem Elimelech, and Françoise S. Le Guyader. 2007. Evaluation of Removal of Noroviruses during Wastewater Treatment, Using Real-Time Reverse Transcription-PCR: Different Behaviors of Genogroups I and II. Appl. Envir. Microbiol., December 15, 2007; 73: 7891 - 7897.

ENCLOSURE 1
USEPA COMMENTS ON GEOSYNTEC'S RESPONSE TO COMMENTS:
DRY AND WET WEATHER RISK ASSESSMENT

Summary of Comments and Responses

Many of the comments offered by the United States Environmental Protection Agency (USEPA) are generic statements without providing supporting data upon which the statement is made in the response. Without proper supporting information, it is difficult to evaluate the merit and validity of comments to Geosyntec's responses. However, the response to each USEPA comment has been provided in Enclosure 1: Dry and Wet Weather Risk Assessment, and Enclosure 2: Phase I Interim Report. These enclosures contain the District and Geosyntec's responses/review of the comments.

The responses to USEPA's comments on Geosyntec's responses are highlighted in bold.

Purpose of Risk Assessment vs. Risk Management (p. 6)

E1.1 Comment on Geosyntec Response -- The comment that this report confuses the purposes of risk assessment with risk management, and policy setting remains unaddressed, as there are numerous examples where risk management and policy implications are improperly brought up. Also, this report should be accessible and understandable to a relatively wide audience. Diagrams of conceptual models, tables of parameter values, etc. would be beneficial to enhance the transparency for all readers.

Response to USEPA comment -- This comment raised the following three issues: 1) there are numerous examples where risk management and policy implications are improperly brought up; 2) this report should be accessible and understandable to a relatively wide audience; 3) diagrams of conceptual models, tables of parameter values, etc. would be beneficial to enhance the transparency for all readers. The following are the responses to these comments:

1) **The clarification of the first issue raised is provided in detail above in the letter to USEPA with a summary background on the project rationale and history of the study. The events leading to the study and the correspondence with USEPA and IEPA are referenced in Table 1. In addition, the responses provided by Geosyntec have addressed the objective(s) and the final conclusion which relates to health risk management and policy implications mentioned in the study. The study represents a very straight forward assessment of risk resulting from secondary contact recreation on the CAWS using methodologies that are state of the art. This risk assessment**

was not an academic exercise but rather was conducted to inform an ongoing Use Attainability Analysis (UAA) study. However, the risk assessment methodology deployed is valid in any context.

2) **The District maintains a web site for the CAWS UAA public health studies. The risk assessment reports are available and can be easily downloaded from the web site (www.mwrd.org). The report has been filed with the IPCB and made available to state (IEPA) and federal (USEPA Region 5, S&T, ORD) regulators, and other organizations such as Sierra Club, Friends of the Chicago River, National Resources Defense Council, Environmental Law & Policy Center, etc. Furthermore, the findings of the study have been published in two peer-reviewed scientific journals, and received the American Academy of Environmental Engineers Excellence in Environmental Engineering Research Honor Award, which demonstrates that the study is accessible and understandable to a wide audience (http://www.aaee.net/Website/E32010Honor Research. htm).**

3) **The Table of Contents is attached (Attachment 1), which confirms that there are 67 Tables and 37 Figures in the final report. All input parameters and variables are listed in the text, tables, and figures, including the input parameter distributions used in the analysis, which enhance the transparency for all readers.**

Cont. (pp. 6-7)

E1.2 Comment on Geosyntec Response -- The response to comment provides a clearer and more objective purpose for the risk assessment. i.e., "...evaluate, estimate and compare recreational health risks in the CAWS with and without effluent disinfection." The authors of the report should be very sensitive to the issue of potential or perceived biases, and clearly a study objective to "...evaluate the human health impact of continuing the current practice of not disinfecting the effluents from the District's wastewater treatment plants..." raises potential concerns with respect to real or perceived bias in ways that the response to comment does not.

Response to USEPA comment -- USEPA acknowledges that Geosyntec's response provides a clearer and more objective purpose of the study. The main purpose of the study was to evaluate the likelihood that primary and secondary gastrointestinal illnesses may result from exposure to pathogens during secondary contact recreation in the CAWS during dry and wet weather conditions. As referenced in Table 1, this study was launched to

assist IEPA's UAA Study on the CAWS. The study was conducted with an assumption that the public health risk from secondary contact recreation activity on the CAWS is unknown and a scientific risk assessment study will determine the public health safety risks. The Geosyntec project team and the District went to great length to ensure that real or perceived bias was kept from influencing the conduct of the risk assessment study. This is corroborated by the acceptance of the study and the assumptions upon which it is based by professional peer reviewers and the editorial boards at the Journal of Water and Health and Water Science and Technology where the study was published.

Problem Formulation (PF) (p. 7)

E1.3 Comment on Geosyntec Response -- This response does not address the comment. Problem formulation (PF) is a comprehensive process that is clearly outlined in the NAS chemical risk assessment and USEPA/ILSI MRA frameworks, and is one that is much more comprehensive than a conceptual model and uncertainty analysis. The risk assessment would have been much improved and much more transparent had a comprehensive problem formulation been conducted and documented. The USEPA/ILSI framework identifies the iterative nature of the PF process as integral to the success of a QMRA.

Response to USEPA comment -- The problem formulation and risk assessment methods to calculate the risk estimation conformed to the protocols developed by the National Research Council (National Academy of Sciences, 1983) and the microbial risk assessment technical literature [See Haas et al., (1999) and the ILSI Risk Science Institute Workshop Report (2000)]. The essential elements of the risk assessment performed per the ILSI framework, which is integral to the QMRA and includes: hazard identification; exposure assessment; dose-response estimates; and risk characterization, is comprehensively described in Chapter 5 with supporting references, tables and figures. A report by Parkin (2008) entitled "Foundations and Frameworks for Human Microbial Risk Assessments" which was submitted to USEPA found that problem formulation was not a common element in microbial risk assessments conducted in the United States or throughout the world. It cites USEPA's own 2003 report "Proceedings of the microbial risk assessment framework: Problem formulation workshop, July 28-29, 2003" which states that problem formulations do not always have the same components and are not conducted in a uniform manner.

PF cont. (p. 7)

E1.4 Comment on Geosyntec Response -- While it is true that it is possible for an expert risk assessor to understand what was done in this assessment, it is very difficult, at best,

for anyone else to understand it. It is incorrect that all parameters chosen for the MRA are summarized in Tables 5-1 through 5-8. For example, exposure duration information is not presented in those tables. It is acknowledged that much of the information is presented in the report; however, the comment remains that it would be helpful to have a single table outlining which parameters were used in the QMRA analyses, and justification for the parameter values (or ranges or distributions) selected for the assessment.

Response to USEPA comment – This comment relates to ease of reading the final report and addressing a lay audience which was not the target audience of the report. A single table outlining the parameters that were used on the study and providing justification for input values would be handy for a lay audience but the fact that this table is not included in the final report does not diminish the quality or correctness of the study results. USEPA acknowledges that much of the information is presented in the report, but now the comment remains that it would be helpful to have a single table outlining which parameters were used in the QMRA analyses, and justification for the values/ranges/distributions selected for the assessment. The information requested by USEPA on exposure durations are in Section 5 Figures (Figures 5-2 to Figure 5-4). The justification for the parameter values are in Section 5 from pages 94 through 133.

PF cont. (pp. 7-8)

E1.5 Comment on Geosyntec Response -- The response helps to clarify the emphasis of CSO impact in the CAWS on specific areas (those where recreational activities take place). However, it does take a very careful read of the report to understand how this information was combined and incorporated into the assessment. As indicated above, it is believed that a thorough PF would have enhanced the clarity and transparency of the risk assessment process. Issues brought up by the response include: 1) Justification for selection of sampling locations based on whether or not recreation takes place should be provided. There are policy implications associated with the decision, and its appropriateness is not necessarily straightforward. 2) There are multiple ways to interpret the results (Section 5.4.6) and only presenting the perspectives provided is problematic. Based on the results provided, it appears that disinfection would be effective during dry weather; furthermore, reduction of wet weather discharges in conjunction with effluent disinfection would commensurately decrease risk during wet weather.

Response to USEPA comment -- USEPA acknowledges that Geosyntec's response helps to clarify the CSO impact in the CAWS. Responses to issues (1) and (2) raised by USEPA are provided below.

1) **The microbial risk assessment was predicated on recreational use surveys that were conducted by the IEPA for their UAA study. Sampling locations were selected to provide as accurate characterization of water quality for dry and wet weather conditions as resources and practical considerations would**

allow. As explained in Geosyntec's responses (see attached March 13, 2009 letter to Mr. Tschampa, which includes Geosyntec's responses to USEPA comments), appropriate assessment of the input parameters and statistical analyses were evaluated to ensure that no health exposure risks were overlooked in the final assessment.

2) **The Geosyntec team has interpreted the result in Section 5.4.6 of the April 2008 Geosyntec Report. The study determined that wet weather is the largest source of microbial loads to the CAWS. Therefore, the final report concluded that during the recreational season, which includes both dry and wet weather, disinfecting the WRP effluents would result in an extremely small reduction in the aggregate microbial health risk of recreational users due to secondary contact recreation. USEPA states that disinfection would be effective during dry weather. The study demonstrates that even if one assumes that effluent disinfection during dry weather would result in a complete reduction in microbe loading to the CAWS, this would translate to a benefit (reduction) of less than one case of illness per thousand recreational events (Table 5-14).**

Need for Peer Review (p. 8)

E1.6 Comment on Geosyntec Response -- The response is overstated and imprecise. Although the study used USEPA approved methods for the water quality evaluation, the QMRA component of the study has numerous shortcomings and should not be considered a "state of the science" analysis. Previous comments acknowledge that experts were employed in the water quality evaluation portion of the study. USEPA remains unconvinced about the scientific defensibility of the QMRA component of this study. Previous comments have not been addressed, and responses to comments above and below supply justification for this perspective.

Response to USEPA Comment -- We disagree that the Geosyntec response is overstated and imprecise. This comment is a generic opinion and does not provide any specific examples to substantiate the claim that the QMRA is not scientifically defensible. The Geosyntec response states that the project had three peer reviewers: Drs. Charles P. Gerba, Cecil Lue-Hing and James W. Patterson, who served in the senior scientific advisor committee for the project and provided direction and peer review on every aspect of the work performed. In addition, a manuscript dealing with the microbial characterization of the CAWS has been published in *Water Science and Technology;* another manuscript dealing with the microbial risk assessment estimates has been accepted for publication in the *Journal of Water and Health.* The study received recognition as a scholarly research work and has won the

American Academy of Environmental Engineers Research Honor Award for Excellence in Environmental Engineering.

Unless USEPA raises specific concerns regarding the QMRA, in the fashion that a peer review panel would, it is not possible to evaluate the validity of their generic statements.

Need for Peer Review cont. (pp. 8-9)

E1.7 Comment on Geosyntec Response -- This clarification of the roles of the various team members is appreciated. Several of the subcontractors are highly respected for conducting work such as their respective components of the work described in this report. However, the approach, details, and interpretation of the actual QMRA component of this investigation is unconvincing. The methodology employed for the risk characterization component of the QMRA is unconventional within the field of QMRA and is not justified. The previous question remains unanswered as to whether those responsible for generating the raw data presented in this report are comfortable with the interpretation of their data.

Response to USEPA comment -- This comment is redundant. Please refer to the responses described in E1.3 and E1.5. We have managed dozens of projects over the span of decades time and have never before seen a concern arise as to whether generators of analytical data were comfortable with the interpretation of their data. Unless the USEPA has some specific concern that they are not expressing we do not have any reason to believe that the expert analysts deployed in this study would have any concerns with the way the data they generated was used or interpreted.

Purpose of Disinfection Chapter (p. 9)

E1.8 Comment on Geosyntec Response -- The response helps to clarify the authors' perspectives. However, numerous points in this chapter are unconnected to this goal. For example, for the purposes described, the discussion (and conclusions) of if/when disinfection is appropriate is not germane; given the types of exposure that are described (limited contact exposure that does not including drinking water) the emphasis on DBPs is not justified and misleading; and the discussion about bacterial regrowth does not substantively address this issue. Furthermore, the discussion does not appear to present a balanced perspective on the potential benefits and drawbacks of disinfection.

Response to USEPA Comment -- As illustrated by Geosyntec's response, the main goal of the CAWS QMRA 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 WRPs, versus initiating disinfection of the effluent at these three WRPs. Therefore, Chapter 4 in the final report provides a detailed discussion on disinfection

technologies, disinfection residuals, and disinfection byproducts. Disinfection effectiveness of chlorination/dechlorination, ultraviolet oxidation and ozonation was summarized, because these are the technologies that have been evaluated by the District 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. The literature review from this chapter was connected to the study goal to estimate annual overall risk of microbial induced illness under the current practice of no disinfection versus the expected number of illnesses with disinfection. Furthermore, the discussion summarizes the ability of disinfectants to provide deactivation of wastewater pathogens and a brief review of the human health risks of residual and disinfection byproducts. The information summarized in the report was to acknowledge the chemical risks of DBPs and also to shed light on variability in the performance and uncertainty in the efficacy of disinfection. The USEPA comment implies that the formation of disinfection by-products and bacteria regrowth should not have been addressed and only the benefits of disinfection should have been taken into account. The purpose of this comment is unclear and confusing in the light of the fact that many USEPA manuals are reference in Section 4 of the April 2008 report regarding toxic disinfection by-products, including:

EPA, 1999, *Alternative Disinfectants and Oxidants Guidance Manual*, EPA 815-R-99-014, April.

EPA, 2002, *The Occurrence of Disinfection By-Products (DBPs) of Heath Concern in Drinking Water: Results of a Nationwide DBP Occurrence Study*, EPA/600/R-02/068, September.

EPA, 2003, *Ultraviolet Disinfection Guidance Manual*, EPA 815-D-03-007, Office of Water, June.

A more formal assessment of economic and environmental impacts of effluent disinfection was conducted for the District in a different study.

Purpose of Disinfection Chapter cont. (pp. 9-10)

E1.9 Comment on Geosyntec Response -- This response is appreciated. However, this perspective is not brought out in the report. The disinfection chapter should put the issue of DBPs into clearer perspective and explain that DBP risk is typically discussed within the context of drinking water and ecologic risk assessment, not incidental human ingestion-type exposures. The emphasis of the potential formation of DBPs is out of place without a commensurate discussion on exposure, i.e., what potential adverse health effects might reasonably be expected through exposure to these waters from occasional incidental contact.

Response to USEPA Comment -- The USEPA comment that DBP perspective is not discussed in the report is incorrect. In Chapter 4, page 91,

last paragraph text on page 91, Paragraph 3 of the report states, "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.

Purpose of Disinfection Chapter cont (p. 10)

E1.10 Comment on Geosyntec Response -- The comment refers to the statement in the report that "risk assessment for exposure to chemical constituents, including DBPs, is far more complex than the MRA." This statement in the report is incorrect and misleading. Furthermore, issue of balancing chemical and microbial risks necessarily must address the issue of exposure, which is lacking in this section of the report.

Response to USEPA comment -- The quantification of chemical risks due to disinfection by-products was outside the scope of work of this study and as such a detailed discussion of the methodologies or limitations to conducting such an assessment were deemed irrelevant. The report clearly identifies the potential for byproducts to be produced by some disinfection methodologies but makes no attempt to assess the risk that these byproducts would pose to secondary contact recreators nor does it attempt to factor the fact that byproducts are produced into the overall evaluation of risk reduction posed by disinfection.

Purpose of Disinfection Chapter cont (pp. 10)

E1.11 Comment on Geosyntec's Response -- The comment is not substantively addressed by the response. The first part of the comment refers to the statement quoted above ("risk assessment for exposure to chemical constituents..."), which is incorrect. The second part of the comment indicates that the document lacks a thorough PF and conceptual model, both of which are true. A conceptual model for the QMRA would be more comprehensive than that presented for exposure in Section 5.2. The scope of the sensitivity analysis and justification for that scope should also be provided in the PF.

Response to USEPA comment -- 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. The clarification response provided by Geosyntec and the response(s) to several USEPA comments on problem formulation and conceptual model has been elucidated clearly in the previous response(s) to USEPA comments (see E1.3, E1.5, E1.7). The information presented in this chapter regarding

disinfection byproducts is not a component of the QMRA, does not have any impact on the QMRA's accuracy or completeness and should not distract or detract from the study's findings.

General Issues in Chapter 5 (p. 10)

E1.12 Comment on Geosyntec's Response --This response is incorrect, inadequate, and confuses several important factors. The USEPA/ILSI document describes a framework, not a model. Dr. Gerba was a member of the committee that helped to develop the framework; however, this report does not follow the recommended framework nor encompass the factors described in that framework. Furthermore: 1) Chapter 5 mentions a disease transmission model which could be a state of the art model, but there is little to no information provided about this model; 2) all of the secondary attack rates used in this report attributed to the WERF 2004 report (which correctly is cited as Soller et al. 2004) were misinterpreted and are incorrect; and, 3) the risk characterization methodology employed is unconventional and with limited precedent in the field of QMRA, and unjustified in the report.

Response to USEPA Comment --The three issues raised above are discussed below:

1) **For this investigation, two routes of disease transmission were considered: primary transmission by recreational contact exposure in CAWS and secondary transmission, which includes person-to-person transmission. The Geosyntec response strongly asserts that the same risk assessment approach as in the reference provided in the USEPA's comment were used in the CAWS risk assessment study. The input to the secondary transmission disease model was derived from Cook County census records regarding the number of people living within one household.**

2) **The reviewer's assertion that the secondary attack rates were misinterpreted and are incorrectly reported is not true and USEPA does not provide any specific evidence to support their statement that all of the secondary attack rates used in the study were misinterpreted and are incorrect. The summary of secondary attack rates used in the study are described in Table 5-6 for each pathogen which reflects the best data available on the secondary spread of gastrointestinal illness.**

3) **The microbial risk assessment approach adapted in the report is based on previous work (Soller et al. 2004), and is consistent with the National Research Council (National Academy of Sciences, 1983) and the microbial risk assessment literature (Haas et al., (1999) and the ILSI Risk Science Institute**

Workshop Report (2000)). The risk assessment methodologies employed in the study are those that are widely utilized in infectious disease risk estimation. The CAWS study provides a defined risk characterization framework that includes actual pathogen enumeration, microbial dose response, site specific exposure data incorporated into the simulation process as full probabilistic distributions which is justified in the report.

General Issues in Chapter 5 cont (pp. 10-11)

E1.13 Comment on Geosyntec Response -- The original comment has not been addressed; that is, there are numerous statements that are not sufficiently justified. Several specific examples follow: 1) use of rotavirus as a surrogate will overestimate risks; this may or may not be true, as noroviruses are a predominant pathogen in undisinfected sewage, are highly infectious, and the most common cause of GI illness among known gastrointestinal pathogens in the US; 2) all of the secondary attack rates used in this report attributed to the WERE 2004 report were misinterpreted and are incorrect, and the secondary attack rates that were used are generally based on personal communication not published data; 3) dose-response for *E. coli* — it is not clear that this approach is in fact conservative (health protective or not); and, 4) viability is accounted for, but recovery efficiency is not and justification for this approach which is covered in previous USEPA MRAs is not provided.

Response to USEPA Comment -- The original comment was discussed during the meeting on April 10, 2007 and also discussed in the final report. The following provides clarification to specific issues raised in this comment.

1) **Section 5.3.1 discusses the rationale for the use of rotavirus data for a norovirus dose-response. No human studies are available to derive a dose-response relationship for norovirus. USEPA has suggested the use of rotavirus as a surrogate for dose-response relationships with other enteric viruses and a similar approach was used by WERF (2004) to assign dose-response parameters. The reviewer does not specify what additional information is required to address the question.**

2) **This comment has been addressed in E1.13.1 above. Additional response is provided in E1. 34.**

3) **Most *E. coli* measured in the waterway are not pathogenic, therefore an assumption was required to account for the fraction of pathogenic *E. coli*. A conservative estimate of 2.7% was selected for the fraction of pathogenic *E. coli* which was based on a study of the Little Calumet River (Peruski, 2005).**

4) **The parameters employed in the risk assessment were those that are widely utilized in risk assessments. The reviewer describes previous USEPA MRAs but does not specify which study.**

General Issues in Chapter 5 cont (p. 11)

E1.14 Comment on Geosyntec Response -- The comment is not substantively addressed. The point was: given 30% of the average annual inputs into the waterways can be from non-POTW sources, more results and discussion is needed on this topic. The authors indicate that the results of the analysis demonstrate that the expected illness rates are well below the 1986 AWQC illness rates for primary contract recreation. This is not a main point, as the level of acceptable public health protection for secondary contact may or may not be the same as that for primary contact recreation. The results do seem to indicate that CSOs and other wet weather inputs do substantially contribute to the risk from recreation in CAWs. More discussion of the results related to this point and inclusion in the PF is needed for proper interpretation of the results.

Response to USEPA comment -- The QMRA study accounted for the effect of wet weather by collecting and analyzing samples from the CAWS during wet weather events. The microbial risk assessment study determined that wet weather is the largest source of microbial loads to the CAWS. The study was not designed to provide insight concerning contribution to risk attributable to various wet weather related sources.

General Issues in Chapter 5 cont (pp. 11-12)

E1.15 Comment on Geosyntec Response -- Tabular and/or graphical summaries of the ingestion distributions would be helpful. While the ingestion rates (Fig 5-2 and Table 5-4) and exposure durations (Fig 5-3) are provided, it is difficult for most readers to conceptualize the expected volumes ingested associated with most activities. A screening level analysis conducted during review of this document indicates that those volumes are not substantially different than the ingestion volumes noted for primary contact recreations (Dufour et al., 2006). This point should be made clearly.

Response to USEPA Comment – The tabular and/or graphical summaries of the ingestion distributions beyond what is provided in the report (Fig. 5-2, Fig. 5-3 and Table 5-4) has been included in a manuscript which has been accepted for publication in the Journal of Water and Health (Rijal et al., 2010). USEPA reviewers conducted a screening level analysis and found that the ingested volumes in the study are within the range for primary contact recreation (Dufour et al., 2006) which is a conservative element of the study.

Stylistic Comments (p. 12)

E1.16 Comment on Geosyntec Response -- Whether or not this report follows a Geosyntec format or not, the fact is the format is inconvenient and makes it difficult to critically evaluate the text, tables, and figures in a report of this magnitude.

Response to USEPA comment -- It should be noted that the same format was used for the Interim Dry Weather Report and the EPA reviewers of that report did not have any concerns about the format. We concur that the study is very complex and voluminous with regard to data, computations and analysis making it challenging to report and review. The quality and correctness of the QMRA however is not dependent on its ultimate presentation.

Technical Comments (p. 12)

E1.17 Comment on Geosyntec Response -- It is not clear why Bootstrapping was selected over fitting of distributions. Given the potential risk implications associated with the upper tails of the true underlying distributions, it is not clear if the Bootstrapping approach results in a conservative or non-conservative approach relative to the true (but unknown) pathogen distributions. Discussion on this point to clarify and justify the approach is needed. It is highly unlikely that the variability in the empirical data captures the true variability, given the low number of samples collected at each location during each season (refer to subsequent comments on this issue).

Response to USEPA comment -- Again there seems to be a misinterpretation of the methodology involved in the risk assessment. A probabilistic approach was selected to evaluate the risk of GI illness for the designated recreational users of the CAWS. Probabilistic risk assessment utilized input distributions, rather than point estimates, to better represent the variability and uncertainty that exist for each input parameter. Thus, instead of using one value for exposure duration, water consumption, or pathogen concentration, a range of possible values (or more correctly, a probability density function) is used. This is a more precise reflection of actual populations and results in a more accurate prediction of potential risk. The probabilistic approach (one-dimensional, based on both variability and uncertainty) selected for this risk impact analysis is Monte Carlo simulation using Crystal Ball® Pro software operating on a personal computer (Jaidi et al. 2009). For each simulation, a hypothetical recreational user (receptor) was created based on underlying exposure distributions and the risks for the activity were computed. The process was repeated one million times (i.e. the probability for a recreator to become ill was examined by simulating one million recreational encounters) and the outcome of the infection was tracked for each simulation. The probability of developing GI illness was computed

by comparing the ingested dose with the potential of each pathogen to produce illness at that dose.

Regarding the pathogen distributions, wet weather samples were collected during a variety of events including worst case events involving pumping of hundreds of millions of gallons of CSOs to the CAWS. Dry weather samples collected immediately downstream of the water reclamation plants also represent the most conservative conditions.

Technical Comments cont (pp. 12-13)

E1.18 Comment on Geosyntec Response -- Previous responses indicate that summary tables (particularly embedded within the text) would facilitate review. Information presented in this way enhances transparency. Moreover, a single table summarizing all parameters employed in the QMRA model was requested and not supplied.

Response to USEPA comment--The parameters employed in the QMRA are described in Section 5 of the report. USEPA has not previously requested a single table as stated in the comment.

Technical Comments cont (p. 13)

E1.19 Comment on Geosyntec Response -- Integrating dry and wet weather results to simulate the climatic conditions expected within a recreational season, based on actual weather and pumping station discharge occurrence data should have the effect of attenuating the predicted values for high risk events. Table 5-8 indicates that 85% of the days in the recreational year are within 72 hours of wet/CSO events (based on data presented in section 5.4.3, after 72 hours concentrations approximate dry weather). Given this information, it is not clear how this approach impacts risks associated with recreation events that occur shortly after rainfall events. Discussion is needed to clarify this point and or justify this approach.

Response to USEPA comment -- The final report presents illness rates for the North Side, Stickney and Calumet Waterway Segments under dry, wet and combined dry and wet weather events (which include the days between dry and wet weather events). Table 5-17 and discussion on pages 130 – 133 provides the clarification on issues raised in this comment.

Technical Comments cont (pp. 13-14)

E1.20 Comment on Geosyntec Response -- It is correct that the durations of the wet weather events are provided in Table 2-3 as footnotes. It is suggested that this is important information and could have been more prominent in the report. Furthermore, it is not clear that the assertion is correct that 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. The data presented indicate that 85% of the days in the recreation season are such that they could be influenced by current or prior wet weather events. Thus, these data in this portion of the QMRA do not necessarily seem intentionally conservative.

Response to USEPA Comment -- This comment is similar to previous USEPA comment (E1.19). Again, there seems to be a misinterpretation of the methodology involved in the risk assessment. The inputs used in the simulations were based on the data collected from the waterway. The CAWS recreational use was assumed to occur randomly over the course of the recreational season which includes both dry and wet weather conditions. People may be exposed to the waterway on rainy days or in the days immediately after a rain event. In fact, the risk assessment is conservative and likely overestimates the risk because it does not take into account the decrease in recreational use of the CAWS during rain events.

Technical Comments cont (p. 14)

E1.21 Comment on Geosyntec Response -- The pathogen concentrations reported in this study are typically at the lower end of those reported in the literature for secondary effluent (perhaps because of poor recoveries and/or sample representativeness). Clearly this is an important issue and the disparity should be discussed and explained in the report and contrasted to the peer reviewed data that are available.

Response to USEPA comment -- The pathogen concentrations in the CAWS were determined by EPA-approved microbial sampling methods presented in the report. The relatively low pathogen concentrations were consistent for multiple sampling events and at multiple sampling locations. All samples were analyzed by reputable subcontract laboratories that applied rigorous quality control, quality assurance measures with the analysis. The analyses of viral pathogens, both norovirus and adenovirus, were conducted in Dr. Charles Gerba's laboratory in the Department of Soil, Water and Environmental Science at the University of Arizona. Dr. Gerba is internationally recognized for his expertise in norovirus. The Geosyntec team, including Dr. Gerba, believes that the norovirus results are representative of the site specific CAWS and effluent samples.

A more likely explanation for the pathogens being detected at the low end of the reported range for secondary treated effluent is the fact that the effluents generated by the District's North Side, Stickney, and Calumet WRPs are or exceptional quality relative to typical secondary effluents. This is routinely documented in the Discharge Monitoring Reports submitted to IEPA under the District's NPDES permits. There is no reason to believe that pathogen levels should be high in the secondary treated effluents leaving the District's WRPs.

Technical Comments cont (p. 14)

E1.22 Comment on Geosyntec Response -- This response does not address the comment. The comment is that the Appendices (note A through D) are referred to in the report but are not included with the report nor are they available on the website where the report is available. Requesting raw data is not the same as Appendices to a report. If Appendices are referred to in the report and are integral to its understanding, then they should be available as a separate file in the same repository as the report.

Response to USEPA Comment – Due to the large volume of datasheets, Appendices were not scanned to be posted on the website. However, the District will create a PDF copy of appendices to be made available to USEPA upon request.

General Comments (pp. 14-15)

E1.23 Comment on Geosyntec Response -- As indicated previously, all comparisons to swimming associated risk benchmarks are not germane, as the acceptable level of risk for secondary contact may or may not be the same as those for primary contact recreation. On the second point, the comment still holds, statistically derived confidence intervals for the reported risks are not provided. Sensitivity analysis is not a substitute for reporting confidence intervals and/or distributional estimates for risk results. Based on our understanding of the approach, it is possible that this "micro-simulation" (a term used in the scientific literature for this type of approach, but typically not used in QMRA) does not lend itself to confidence interval development; but if that is the case, this limitation should have been explained in the PF along with a justification for selection of the approach over a more conventional approach.

Response to USEPA Comment -- All comparisons to swimming associated risk benchmarks were made in the QMRA study as a result of Geosyntec considering all available data and information on the topic. The footnotes to Table 5-10 provide clarifications and citations of the sources of the information presented. The use of the swimming associated risk benchmark does not constitute an endorsement or recommendation of its application to secondary contact cases but rather is provided as a general context for the results of the study. This comparison is consistent with the work published by Soller et al., 2003 and 2006. In these published articles the simulated risk assessment estimates were compared with USEPA's swimming related risk benchmark. The reporting format in these studies is similar to the CAWS QMRA study.

Like the Soller et al., 2006 study, the sensitivity analyses were reported on the CAWS risk results to determine which of the input parameters presented in Table 5-17 the model is most responsive to. Section 5.4.7, pages 130 to 133 include 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.

General Comments cont (p. 15)

E1.24 Comment on Geosyntec Response -- As noted above, it is correct that the duration of the CSOs is found in the footnotes to Table 2-3. However, the essence of the comment that focus should have been given to the performance of these wastewater facilities with respect to frequency and duration of unacceptably high pathogen loads has not been addressed. The report indicates that "wet weather concentrations are significantly greater than the dry weather concentration at each WRP waterway." However, a clear comparison of wet versus dry weather results for the WRPs could add clarity. An interesting analysis would have been to evaluate the potential water quality benefits of reducing CSO inputs during wet weather events.

Response to USEPA comment -- The performance of the wastewater treatment facilities with respect to microbial load assessment in dry and wet weather has been addressed (District, 2007; Geosyntec, 2008; Rijal et al., 2009, Rijal et al., 2010). In the CAWS QMRA study, risks were estimated for recreational users participating in activities involving different levels of exposure under dry, wet or a combination of weather events over the course of a recreational year. Wet weather and dry weather simulations provided a range of risks. Overall risks developed for the combined dry and wet weather dataset for the waterway segments are provided in the report and the published articles (Geosyntec, 2008; Rijal et al., 2009; Rijal et al., 2010). The USEPA suggestion to evaluate the potential water quality benefits of reducing CSO during wet weather events was beyond the scope of the study.

General Comments cont (pp. 15-16)

E1.25 Comment on Geosyntec Response -- This comment and the response bring up a number of important points: 1) Fundamental to the QMRA analysis is the use of the water quality (pathogen) data in the QMRA portion of the report. Given the low number of observations at each location studied in general, and detected observations in particular for some locations (example: dry weather calicivirus results for Calumet outfall =5 samples/i positive; wet weather calicivirus results for Calumet outfall =3 samples/2 positive) one important question is how well the bootstrapping approach replicates the true (but unknown) concentration of the various pathogens in the waters of interest. This issue is not discussed in the report and has not been responded to. It is suspected that the true variability in pathogen concentrations are not captured by the low numbers of samples, which raises the question of whether the true variability is encapsulated in the QMRA calculations. 2) While it is correct that 125 samples were taken total, when those are divided into numerous locations and 2 seasons, the number of data points available to characterize each location by season is quite small (see example above). Justification

that such a number of samples can reasonably be used to robustly characterize pathogen concentrations should be provided. 3) Calicivirus was reported in one outfall sample at a relative high concentration and was discarded from the analysis as an outlier. Given the relatively low number of available samples at this location for this season (5 total), the implications should be discussed, but preferably left in as part of the description of variability. 4) A description of how the bootstrapping approach handled data that were below detectable limits is not provided. Elaboration on this point and the implications to the QMRA are needed.

Response to USEPA Comment -- Responses to the four issues raised in this comment are provided below:

1) **The assertion that low numbers of samples collected in this study is not true. During each dry weather 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 comprehensive microbiological assessment included quantification of not only classical fecal indicator bacteria such as fecal coliform, *E. coli* and enterococci but also the most common potential waterborne pathogens such as *Salmonella* spp, pathogenic *E. coli*, *Cryptosporidium*, *Giardia, Pseudomonas aeruginosa*, enteric virus, adenovirus and norovirus. The viral pathogen (Calicivirus [norovirus] and adenovirus) results referenced above, were conducted in Dr. Charles Gerba's laboratory in the Department of Soil, Water and Environmental Science at the University of Arizona. Dr. Gerba is internationally recognized for his expertise in adenovirus and norovirus. The Geosyntec team, including Dr. Gerba, believes that the pathogen results are representative of the site specific CAWS and effluent samples. Moreover, we are not aware of any other microbial risk assessment study that has collected more microbial samples than this study.**

2) **The analysis of 125 samples (75 dry weather and 50 wet weather samples) provides a very robust database of microbial pathogens and indicators in the CAWS. The published studies, such as Soller et al., 2003 and 2004, were based on indicator bacteria monitoring with no actual pathogen data and were based on small sample size. Also, the USEPA does not have guidelines on valid sample size required for a QMRA.**

3) **It is true that the calicivirus (norovirus) concentration at one outfall sample was estimated to be at a relative high concentration. The University of Arizona analyst reviewed the PCR MPN assay and qualified the result as an outlier. There were 6 samples collected and not 5 as stated in the comment. It**

is clearly described in the report by Geosyntec experts that of the samples collected at one outfall with MPN assays, the high estimated values were due to a positive result in the highest MPN method dilution. An artifact of MPN PCR method is very common and is caused by laboratory error or contamination of the sample.

4) **This comment was addressed in E1.17.**

Statistical Analyses Comments (p. 17)

E1.26 Comment on Geosyntec Response -- USEPA understands the approach taken to integrate exposure over the season. The issue is whether or not this approach is appropriate and whether the approach results in risk values that do not accurately characterize high risk conditions. The data presented clearly indicate that 85% of days during the recreation season are influenced by wet weather events. The comment raises this issue and highlights that discussion and clarification in the report on this point is lacking.

Response to USEPA comment -- This comment clearly indicates that USEPA reviewers understand the approach taken to integrate exposure over the recreational season. This comment has been addressed by the Geosyntec responses. The remaining comment regards suggestions that could have been helpful in writing the report and does not reflect deficiencies in the study.

Statistical Analyses Comments cont (p. 17)

E1.27 Comment on Geosyntec Response -- This response does help to clarify the comment. Based the data and response, USEPA understands that the waterway is impacted by wet weather for approximately 72 hours.

Response to USEPA comment -- This comment does specify that USEPA understands that the waterway is impacted by wet weather.

Statistical Analyses Comments cont (pp. 17-18)

E1.28 Comment on Geosyntec Response -- USEPA reviewers understand the approach that was taken, but as indicated above are concerned that the number of samples available for each location condition evaluated is not sufficient to capture the true variability of the pathogen concentrations in the waters of interest. No justification is given to support the use of 5 (or less in many cases) observations in the bootstrapping procedure. Moreover, the report appears to be silent on how observations reported below detectable limits were handled by the bootstrapping procedure; and how that approach impacts the reported QMRA results.

Response to USEPA Comments -- Surrogate values of 1/2 the detection limit were used for microbial values that were below the detection limit in the statistical presentation of the data and in the bootstrap simulations.

Parasitic Protozoa Comments (p. 18)

E1.29 Comment on Geosyntec Response -- The misunderstanding occurred because unlike the main body of the report, the executive summary does not indicate that the surface and one meter depth samples were combined.

Response to USEPA comment -- This is an editorial comment regarding the final report and is not addressing the quality of the study.

Parasitic Protozoa Comments cont (pp. 18-19)

E1.30 Comment on Geosyntec Response -- The response correctly indicates that recovery rates are reported in Section 2.4.3. However, several salient issues emerge from the response. First, the reported concentrations of *Giardia* and *Cryptosporidium* locusts in secondary effluent and in CSO water (as represented by the pumping station data) are at the low end of these types of matrices. Discussion should be provided in the report indicating why this is the case. Second, in terms of the QMRA analyses, the concentrations should be adjusted to account for the recovery rates, particularly in light of the fact that the observed results are adjusted for *Giardia* viability based on DAPI results and *Cryptosporidium* infectivity. The authors can refer to previous QMRA conducted by USEPA for drinking water as reference.

Response to USEPA comment -- This comment raises two issues which are discussed below:

1) **This comment was addressed in E1.21. It is beyond the scope of the study to determine why the pathogen concentration in Chicago WRPs and CSOs are so low.**

2) **According to Clancy Environmental Consultants, Inc., the laboratory that performed analyses for the study, it is neither the intent of the method nor it is appropriate to adjust the results for recoveries. USEPA has confirmed this statement, based on email response from Ms. Carrie Miller, Cryptosporidium Laboratory Approval Manager USEPA (Attachment 2). Ms. Miller acknowledged that matrix spike/viability recoveries will not be used to adjust sample results for Long Term 2 Enhanced Surface Water Treatment Rule (LT2).The LT2 rule requires that public water systems (PWSs) be classified in treatment bins using the total number of protozoa counted without further adjustment (FR January 5, 2006, LT2 Rule Supplementary Information, IV. B. 2). The treatment bins are constructed to reflect**

this approach. USEPA expected that PWSs would achieve comparable performance using Method 1623 to the results reported during the Information Collection Rule Supplemental Surveys (ICRSS).

There is no USEPA guidance on an appropriate methodology and/or statistical tool(s) that incorporate data adjustment information about viability and infectivity into the QMRA model for surface water risk assessment. The QMRA does not adjust for recovery and viability which may underestimate the concentration of organisms in some samples. The USEPA comment is in reference to drinking water QMRA studies, however, it should be noted that the concentrations used in developing the dose-response studies are not all adjusted for recovery rates. Adjusting in this study and using a non-adjusted dose-response study would lead to a bias in the results.

Quantification of the infectivity and viability of observed microorganisms has not yet been fully addressed by modelers and regulators (Schmidt and Emelko, 2010). Methods to evaluate the infectivity and viability have been proposed, but are not in wide-spread use in recreational water related QMRA studies.

Schmidt, P.J., Emelko, M.B., 2010. QMRA and decision-making: Are we handling measurement errors associated with pathogen concentration data correctly? Water Research. doi: 10.1016/j.watres.2010.08.042.

Parasitic Protozoa Comments cont (p. 19)

E1.31 Comment on Geosyntec Response -- The main thrust of this comment has not been addressed. The report correctly indicates that the method for determination of *Giardia* viability has not been validated. Yet the data are presented and subsequently used in a manner as if the results are exact. The comment raises the issue of the precision and robustness of the reported values ("viability = 26%"). Since these data are used in the QMRA analyses to reduce the observed *Giardia* concentrations, the relative level of precision and confidence in these data should be discussed.

Response to USEPA comment -- This comment was addressed in E1.30. Also, the test for *Giardia* viability is the only one currently available. The report is transparent and clearly presents the limitation of the *Giardia* viability data.

Parasitic Protozoa Comments cont (p. 19)

E1.32 Comment on Geosyntec Response -- The salient aspect of this comment has not been addressed. Specifically, there is considerable uncertainty introduced into the used datasets which has not been expressed when using and reporting risks from these data. As indicated

above, if the QMRA is going to modify the results based on viability (or infectivity), then it should also account for recovery.

Response to USEPA comment – The recovery of Matrix Spike and Matrix Spike Duplicate Samples (MS/Meds) and ongoing precision and recovery (OPR) was determined by the analytical laboratories and the results are reported in Section 2.4.3 of the report. Overall, all recoveries of MS/Meds and OPR were well within the acceptance criteria specified for OPR samples in EPA Method 1623. Matrix spike recoveries are quality control methods and are not optimized to approximate actual recoveries. There is no standard of correctness obligating correction for recovery inefficiency when viability is corrected. Therefore, the recovery was considered only in evaluation of the performance of the methods.

This comment was also addressed in E1. 30.

Enteric Viruses Comments (pp. 19-20)

E1.33 Comment on Geosyntec Response -- The response to this comment is inadequate. Regarding the Appendices, refer to our previous response. The second paragraph of the response ("in addition...") is illogical. The volume ingested by a swimmer has no bearing on the appropriate volume to be analyzed by a microbiological method. The issue of inappropriate number of significant digits for the MPN assay has not been addressed.

Response to USEPA comment -- The issue of MPN assay for viruses was addressed by Dr. Gerba during a face to face meeting with USEPA Region 5 on April 10, 2007. In addition more detailed discussion about the MPN method was provided to IPCB during Dr. Gerba's hearing on September 9-10, 2008. Dr. Gerba believes that the MPN results are representative of the site specific CAWS and effluent samples.

Enteric Viruses Comments cont (p. 20)

E1.34 Comment on Geosyntec Response -- The response is partially correct that the approach employed results in a conservative estimate of adenovirus concentration for the risk assessment based on the available data. However, the report utilizes the less conservative dose-response for echovirus 12 rather than one specifically for adenovirus. In this regard, the report correctly indicates that the only adenovirus dose-response is for respiratory subtype, however the technical justification for the dose-response function that was selected is insufficient and the impact on the QMRA results are unknown. Further, respiratory infection may well be more relevant for secondary exposures anyway — again part of the PF.

Response to USEPA comment -- 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 the total concentration of cultural PCL/PRF/5 cell line viruses with PCR confirmation was assumed to be adenovirus contributing to gastrointestinal illness. Also, Section 5.3.3 of the report states the following-- "Several dose-response relationships are reported for adenovirus but none of these are specifically for Ad40 or Ad41, subtypes primarily associated with gastrointestinal illness. For example, an exponential model has been proposed for the respiratory subtype Ad4 with a k value of 2.397 (Haas et al., 1999). This would suggest a highly infectious pathogen and could be used as a surrogate for the risk assessment. However, only a portion of the measured adenovirus corresponds to subtypes responsible for gastroenteritis. This will lead to an overestimate of the true risks for gastrointestinal illness. Therefore, the dose-response for echovirus 12 (k = 78.3) was selected as a surrogate for total enteric viruses with an infectivity in the middle of this range."

Studies have estimated the secondary attack rate for adenovirus in adults at 19% and in children at 67% (Fox et al., 1977). A prospective study of children enrolled in day-care centers in Texas generated data elucidating the role of enteric adenoviruses in group settings (Van et al., 1992). Children six to 24 months-old were monitored over five years. Ten outbreaks affecting 249 children were associated with enteric adenoviruses. The infection rate during the 10 outbreaks ranged from 20 to 60 percent (mean 38 percent), and 46 percent of the infected children remained asymptomatic. Based on these studies a composite secondary attack rate for both adult and children of 38% was used in the present analysis.

Enteric Viruses Comments cont (p. 21)

E1.35 Comment on Geosyntec Response -- The issue of significant figures for virus results was not addressed. It is agreed that the pathogen concentrations reported in the secondary effluent are on the low side of those reported in the technical literature. Some discussion is warranted explaining why this is the case for this particular set of treatment plants. This is particularly true in light of the bacterial indicator data results as described in the comment.

Response to USEPA comment -- This comment was addressed in E1.25 and E1.30.

Disinfection Comments (p. 22)

E1.36 Comment on Geosyntec Response -- The efficacy of disinfection is known to vary, and ranges of efficacy should be more prominent in this report. Section 4 does contain a substantial amount of valuable information. However, it also contains information that is tangential to this report and in places gives the impression that the authors wanted to emphasize a

perspective that disinfection may not be appropriate in this case. For example, Section 4.4 goes into great detail about DBPs, yet exposure via limited contact recreation is not incorporated into that discussion. Clearly, relative levels of exposure are critical for an even discussion on this topic. Further, the chapter begins and concludes with questions as to if/when disinfection is needed. This chapter should simply present the available technical data about disinfection alternatives and their relative efficacy.

Response to USEPA comment -- This comment was addressed in detail in E1.8, E1.9, E1.10 and E1.11.

Microbial Risk Comments (p. 22)

E1.37 Comment on Geosyntec Response -- The response to this comment does not address the comment in any substantive manner. The QMRA component of this investigation was lacking in several critical ways and is not based upon "state-of-the-science" methodologies: 1) some of the dose-response relationships that were used were inappropriate in that they were out of date (*Cryptosporidium*, Norovirus), not appropriate (adenovirus, *E. coli*), or did not account for strain variability (*Salmonella enterica*); 2) the secondary attack rates were misinterpreted from the literature, and the secondary attack rates that were used were based principally on personal communications; 3) the documentation provided no information about the disease transmission model; 4) the exposure assessment and implementation via bootstrap techniques likely did not account for the true variability of pathogen concentrations in the waters of interest; and, 5) the QMRA used an unconventional risk characterization approach for characterizing risk ("micro-simulation approach" Section 5.4.5) rather than a more widely accepted approach that has been described in numerous peer reviewed publications in the QMRA literature. Furthermore, the approach given did not allow for confidence intervals to be reported. Based on these limitations, it is the opinion of the expert USEPA reviewers that the QMRA component of this study is simply not credible.

Response to USEPA comments -- This comment was addressed in detail in E1.11, E1.12, E1.13, E1.14, E1.15, and E1.16. Outbreak and human feeding studies suggest a dose-response parameter (*k*) of 238 for *Cryptosporidium* (Haas et al., 1999). The USEPA reviewers, who are referenced but not identified above, have an opinion that is at odds with the expert advisory team that Geosyntec established for this project including Dr. Charles Gerba. Further, the QMRA has been published in the peer reviewed literature, this would not be possible if it was "not credible". Finally, the study received a meritorious award from the American Academy of Environmental Engineers.

Microbial Risk Comments cont (p. 22)

E1.38 Comment on Geosyntec Response -- Detailed review of Section 5.2.2 indicates that the response is inaccurate and incomplete. A fair representation of the water ingestion rates

would be that they are based on professional judgment tangentially informed by literature values for full body contact activities. The number of significant digits presented in Table 5.3 is highly dubious (median of 7.52 mL/hr for example). Although the reported ingestion rates and distributions seem reasonable, the authors should acknowledge that they really are little more than a somewhat informed guess.

Response to USEPA comment -- USEPA's comment is an unclear statement that inaccurately portrays the nature and methodology used in the risk assessment. Section 5.2.2. presents information on the exposure input parameters and provides references from peer review literature and EPA publications.

Microbial Risk Comments cont (pp. 22-23)

E1.39 Comment on Geosyntec Response -- This comment and response highlight the importance of conceptual models and transparency. Several limitations of the QMRA component of this report have been identified above. In addition, the lack of clarity in the documentation is an essential issue with this report.

Response to USEPA comment -- This comment has been addressed in detail in E1.25, E1.26, E1.27 and E1.30.

Other Comments (p. 23)

E1.40 Comment on Geosyntec Response -- Indeed Table 5-9 does present wet weather results. It is not clear however, exactly what time period those results represent.

Response to USEPA comment -- Table 5-9 clearly presents the dry and wet weather risks. The study time period is described in the final report (see Table 2-3).

Other Comments cont (ps. 23)

E1.41 Comment on Geosyntec Response -- The response provided is out of context and does not answer the question posed. The USEPA-methods are for the analytical methods, the question refers to the QMRA component. Previous USEPA microbial risk assessments for drinking water have addressed the issue of method recovery. Moreover, the report clearly indicates that "the method for determination of viability of *Giardia* cysts has not been validated." Therefore, with the logic the response provided, accounting for viability would not be scientifically defensible.

Response to USEPA comment -- This comment was addressed in E1.25, E1.26, E1.27 and E1.30.

Other Comments cont (p. 23)

E1.42 Comment on Geosyntec Response -- Thank you for the assessment. However, this report does at a minimum suggest that the results of this study should be compared to levels of health protection provided by the 1986 AWQC for recreational waters (that is, primary contact recreation). This suggestion and comparison is made in numerous places in the report. Such a comparison is out of context and inappropriate. USEPA has not established the level of public health protection which secondary contact waters provide. The levels of public health protection provided by AWQC for primary contact waters may or may not be the same for secondary contact waters.

Response to USEPA comment -- Geosyntec has addressed this comment in E1.23 and elsewhere. We concur that there is no USEPA established level of protection for secondary contact waters. The primary contact benchmark was used in this report to provide a frame of reference or context and is the only clear point of reference that currently exists on risk benchmarks.

ENCLOSURE 2
RESPONSE TO USEPA COMMENTS ON GEOSYNTEC'S RESPONSE TO COMMENTS ON THE PHASE I INTERIM REPORT: DRY WEATHER RISK ASSESSMENT

Bias in Risk Assessment (pp. 30-31)

E2.1 Comment on Geosyntec's Response -- Refer to comments on Section 4 (Enclosure 1) in the final wet and dry season report.

Response to USEPA comment -- Refer to District responses on the Purpose of Disinfection Chapter (E1.8 through E1.11).

Risk Assessment Lacks Components (pp. 30-31)

E2.2 Comment on Geosyntec's Response -- This comment was not sufficiently addressed in the final report.

Response to USEPA comment – The USEPA comment is vague and does not provide specifics on what has not been sufficiently addressed. USEPA agrees that the report contains a fair amount of upfront material but asserts that the Risk Assessment lacks necessary components, including a coherent problem formulation, listing of parameters evaluated in the assessment and why each parameter was chosen, and feels that a range of estimates with the rationale for picking one deterministic point over another would be helpful. 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. 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 incidental water ingestion rates and exposure duration. In addition, Section 5.3 of the final report provides the basis and rational for the selection of dose response parameters used in the microbial risk assessment analysis for each of the pathogens of concern. See additional comments in District response E1.3 and E1.4.

Sensitivity Analysis (p. 31)

E2.3 Comment on Geosyntec's Response -- This comment was not sufficiently addressed in the final report.

Response to USEPA comment -- The reviewer's assertion that the report lacks a sensitivity analysis is incorrect. The reviewer's inference that there is a "propensity for choosing assumptions that minimize risk at each step of the risk assessment" is also incorrect. 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. The report clearly states that in general, the exposure parameters were selected to provide a central tendency or "best approximation" estimate. Since the endpoint of this evaluation is gastrointestinal illness, exposure pathways that contribute to this effect were investigated. Inhalation exposure to spray of droplets containing pathogens which are subsequently swallowed may contribute to the total dose. The total ingestion dose was adjusted to account for this pathway. However, it is unlikely that users engaged in non-immersion activities would be subject to levels of inhaled mists or sprays that would lead to a substantially increased ingested dose. The results of the epidemiological Chicago Health, Environmental Exposure and Recreation Study (CHEERS) did not find increased risks due to activities that may be exposed to water sprays or mists. Secondary transmission rates were generally at the high end of those reported in the technical literature; therefore, the assumptions on secondary transmission are conservative and the resulting illness rates may be biased high. Also, the measured pathogen concentrations under dry weather conditions were limited to sampling locations near the WRPs and were used to represent 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. See additional comments in District responses E1.5 and E1.12 through E1.14. Again, the USEPA comment is vague and does not provide specifics on what has not been sufficiently addressed.

Pathogen Clarification (p. 31)

E2.4 Comment on Geosyntec's Response -- No additional response related to this specific question is needed at this time. However, on a related note, the bacterial indicator data presented in the final report are along the lines that would be expected for secondary effluent, whereas pathogen levels are at the low end of what would be expected. Explanation for these findings were requested, but not provided in the final report.

Response to USEPA comment -- Activated sludge and secondary treatment systems are effective in reducing 90-99% of pathogens. The analytical tests for pathogens were performed at certified laboratories using approved test methods and QA/QC procedures. The results are comparable with the pathogen levels detected during the CHEERS Study. USEPA

acknowledges that the pathogen levels are within the range that is expected but at the low end. We did not study this issue. It should be noted that the secondary treatment effluents at these plants have conventional parameter concentrations that are far below their NPDES quality limitations.

Transparency Needed for Exposure Risk (p. 33)

E2.5 Comment on Geosyntec's Response -- This comment was not sufficiently addressed in the final report.

Response to USEPA comment – The USEPA comment is a general statement that does not give specifics as to what has not been sufficiently addressed. 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. See additional comments in District response E1.12 through E1.14.

QMRA Procedure (pp. 34-35)

E2.6 Comment on Geosyntec's Response -- The rationale for the representative pathogens considered was not adequately addressed in the final report. The poor estimate of pathogen distributions (due to too few data points and poor sensitivity, noting the misleading reporting of pathogens per volume [e.g. noroviruses per 100-L, when in fact only 0.2 L were assayed]) and trying to estimate absolute risks, it is hard to justify that the reported results are scientifically credible.

Response to USEPA comment -- Table 2-1 in Section 2-1 of the Final Report presents a summary of the microorganisms selected for the microbial risk assessment study and the rationale for their selection. See additional comments in District response E1.12 through E1.14, E1.23, E1.25 and E1.33. The USEPA comment is a general statement that does not specify what additional information would be considered adequate.

Conservative Assumptions (pp. 36-37)

E2.7 Comment on Geosyntec's Response -- This is a fundamental issue with the QMRA that was not adequately addressed in the final report.

Response to USEPA comment -- Geosyntec believes that conservative assumptions were made in estimating the microbial risks in the CAWS. For example, secondary transmission rates used were generally at the high end of

those reported in the technical literature. Pathogens measured under dry weather conditions collected near the WRPs were used to represent the concentration of the entire waterway. Pathogenic *E. coli* was conservatively assumed to represent 2.7% of the total measured concentrations. See additional comments in District response E1.12 through E1.14. Again, the USEPA comment is vague and does not specify exactly what has not been adequately addressed.

Calicivirus (p. 37)

E2.8 Comment on Geosyntec's Response -- Norovirus is believed to be a major cause of GI illness in the United States, shed in extremely high concentrations in infected individuals, and resistant to treatment. Concentrations reported in this study and frequencies of detection were surprisingly low for CSO waters and secondary effluent. A detailed explanation for these findings should be provided.

Response to USEPA comment -- Activated sludge and secondary treatment systems are effective in reducing 90-99% of pathogens. The analytical tests for pathogens were performed at certified laboratories using approved test methods and QA\QC procedures. The results are comparable with the pathogen levels detected during the CHEERS Study. See additional comments in District response E2.4.

Adenovirus (p. 37)

E2.9 Comment on Geosyntec's Response -- The fact that a less conservative dose-response relationship for adenovirus was used was not addressed in the final report. Sufficient justification was not provided for selection of conservative or non-conservative choices throughout the document.

Response to USEPA comment -- 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, the total concentration of culturable viruses using the PLC/PRF5 cell line with positive PCR adenovirus confirmation was assumed to be adenovirus and contribute to gastrointestinal illness. The USEPA comment does not specify what additional justification they are looking for.

Echovirus vs. Rotavirus (pp. 37-38)

E2.10 Comment on Geosyntec Response -- In this case, the comment refers to enteric viruses and not specifically adenoviruses. This comment is correct and was not addressed in the final report.

> **Response to USEPA comment -- Section 5.3.3 discusses the rationale for the use of rotavirus data for a norovirus dose-response. No human studies are available to derive a dose-response relationship for norovirus. USEPA has suggested the use of rotavirus as a surrogate for dose-response relationships with other enteric viruses and a similar approach was used by WERF (2004) to assign dose-response parameters. The reviewer does not specify what additional information is required to address the question.**

Secondary Transmission (p. 38)

E2.11 Comment on Geosyntec Response -- The response to comment is inaccurate. Section 5.2.4 presents no information about a disease transmission model; one is mentioned but no details are given. Secondary transmission rates were misinterpreted from the scientific literature (Soller et al., 2004) and the rates that were used were based largely on personal communications.

> **Response to USEPA comment -- Section 5.4.2 explains that to account for secondary transmission, a dynamic risk model was developed that considers secondary exposure through contact with CAWS 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. The reviewer's assertion that the secondary transmission rates were misinterpreted is not true.**
>
> **The 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 CAWS exposure in the population most at risk. See additional comments in District response E1.12 through E1.14. The USEPA comment is vague and does not provide specifics on how the information was misinterpreted.**

Inadequate Reporting of Risk Assessment Results and Methods (pp. 38-39)

E2.12 Comment on Geosyntec Response -- This comment was not adequately addressed in the final report. A much clearer presentation with conceptual models and tables of

parameter and parameter values (or ranges or distributions) would have eased review of this document, which was very difficult to understand.

Response to USEPA comment -- Section 5.0 (pages 94-140) discusses the data used, assumptions made and detailed procedures involved in the risk assessment calculations. Section 5 includes 17 tables, 4 graphs and a map. See additional comments in District response E1.1. The USEPA comment does not provide specifics on what additional information would ease the review of this document.

Interval estimates and sensitivity analysis (p. 39)

E2.13 Comment on Geosyntec Response -- The essence of this comment was not addressed in the final report. Part of the issue is that the risk characterization method employed does not appear to allow for development of confidence intervals or cumulative distribution curves. The results of each of the 1,000,000 simulations result in an outcome that is illness or no-illness; and those results are summed and scaled (to a metric of per 1000 individuals exposed). This is an unconventional approach that has little (if any) peer-reviewed precedent in the field of QMRA. No justification is provided for use of this method over other more common approaches.

Response to USEPA comment -- The findings of this study have, in fact, been peer reviewed. A manuscript dealing with the microbial characterization of the CAWS has been published in *Water Science and Technology;* another manuscript dealing with the microbial risk assessment estimates has been accepted for publication in the *Journal of Water and Health.* In addition, the study received recognition as a scholarly research work and has won the American Academy of Environmental Engineers Research Honor Award for Excellence in Environmental Engineering. Detailed references to these publications are provided in the letter to USEPA Region 5.

Variability and uncertainty (p. 39)

E2.14 Comment on Geosyntec Response -- The sensitivity analysis that is provided in Section 5.4.7 of the report does not address this comment (see also comment above). The risk characterization method seems to have severely limited this QMRA effort.

Response to USEPA comment -- 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. Uncertainties associated with the risk estimates and limitations are also discussed. See additional comments in District response E1.12 through E1.14. The reviewer comment does not provide specifics on how the QMRA effort seems to be limited by this method.

Limitations were not discussed (pp. 39-40)

E2.15 Comment on Geosyntec Response -- This comment was not substantively addressed in the final report. It is not sufficient to discuss sensitivity and uncertainty analysis (Section 5.4.7). Rather, an important component of a good risk assessment is an honest and open acknowledgement and discussion of limitations and how those limitations can impact the interpretation of the risk assessment. A discussion of this sort is not provided in this report.

> **Response to USEPA comment -- 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. Uncertainties associated with the risk estimates and limitations are also discussed. Please refer to responses described in E2.3 and E1.12 through E1.14.**

Questionable Assumptions (p. 40)

E2.16 Comment on Geosyntec Response -- This comment was not substantively addressed in the final report.

> **Response to USEPA comment -- The reviewer's comment does not provide any specifics. Section 5.4.7 of the Final Report presents a sensitivity analysis and discusses uncertainties associated with the risk estimates. Please refer to responses described in E2.3 and E1.12 through E1.14.**

Specific Comments (p. 41)

E2.17 Comment on Geosyntec Response -- This comment was not substantively addressed in the final report. There still is not a good explanation of why these datasets were considered statistically insignificant. What statistical test was used to make this determination?

> **Response to USEPA comment -- As explained, 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.**

Specific comments (p. 42)

E2.18 Comment on Geosyntec Response -- This comment was not substantively addressed in the final report. The response does not seem to be reflected in the report, and the response is the first mention of a larger database. It is not clear if or how this larger database was used in this report.

Response to USEPA comment -- This comment is based on the Dry Weather Interim Report. EC/FC ratios were discussed during a face-to-face meeting with USEPA in April 2007 and these ratios were not considered in the final risk assessment.

Specific comments (p. 43)

E2.19 Comment on Geosyntec Response -- This comment was not substantively addressed in the final report.

Response to USEPA comment -- USEPA initially commented that "citations need to be provided for statements to the effect of because the RT PCR does not provide infectivity information; it impedes meaningful health risk evaluation."

The report does not make this statement or claim. Section 3.3 of the Final Report simply states, "Norovirus detection was done by RT-PCR since it is a RNA virus. While PCR cannot be used to determine the infectivity of the virus, the number of genomes in a volume of water can be estimated by using the most probable number method." The report does not assert that this fact impedes meaningful health risk evaluation.

The reviewer also comments "Inhalation not considered important - need citations to support this anti-conservative simplification and assumption." The Final Report 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 reviewer's comments are incorrect.

Echovirus vs. Rotavirus (pp. 43-44)

E2.20 Comment on Geosyntec Response -- In this case, the comment refers to enteric viruses and not adenoviruses. This comment is correct and was not addressed in the final report. As indicated above, this is one of the problems with the QMRA.

Response to USEPA comment -- Response to USEPA comment -- Section 5.3.3 discusses the rationale for the use of rotavirus data for a norovirus dose-response. No human studies are available to derive a dose-response relationship for norovirus. USEPA has suggested the use of rotavirus as a surrogate for dose-response relationships with other enteric viruses and a similar approach was used by WERF (2004) to assign dose-response parameters. The reviewer does not specify what additional information is required to address the question.

Specific comments (p. 44)

E2.21 Comment on Geosyntec Response -- This comment was not substantively addressed in the final report.

> **Response to USEPA comment -- Section 5.3.3 of the Final Report discusses the dose response assessment of adenovirus. Several dose-response relationships are reported for adenovirus but none of these are specifically for Ad40 or Ad41, subtypes primarily associated with GI illness. This will lead to an overestimate of the true risks for GI 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 reviewer does not specify what additional information is required to substantively address the comment.**

Specific comments (p. 44)

E2.22 Comment on Geosyntec Response -- This comment was not substantively addressed in the final report.

> **Response to USEPA comment -- As stated in Section 5.1 of the Final Report, 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. The reviewer's comment does not specify what additional information is required to substantively address the comment.**

Specific comments (p. 45)

E2.23 Comment on Geosyntec Response -- As stated in previous comments, this investigation uses an unconventional approach for QMRA risk characterization; and one with limited (if any) peer reviewed precedent. This approach, while having multiple drawbacks, seems to have little benefit compared to more traditional techniques. No justification is provided for the selection of this approach.

> **Response to USEPA comment -- The USEPA comment asserts that there are multiple "drawbacks" to the approach for risk characterization but does not enumerate them. The USEPA also provides no justification for their statement that the approach "seems" to have little benefit compared to more traditional techniques. The QMRA approach was based on previous work (Soller et al., 2004), and is consistent with the recommendations of the**

National Research Council (National Academy of Sciences, 1983) and the microbial risk assessment literature [Hass et al., (1999) and the ILSI Risk Science Institute Workshop Report (2000)]. The approach has been peer reviewed and recognized as a scholarly work (See District comment E2.13).

Specific comments (p. 45)

E2.24 Comment on Geosyntec Response -- No detail is provided for the disease transmission model in section 5.4.2. The secondary infection rates were misunderstood from the literature, and the rates that were used seemed based on personal communications. This comment was not addressed in the final report.

Response to USEPA comment -- The assertion that secondary infection rates from the literature were misunderstood is unsubstantiated and as such it is not possible to rebut the assertion. Please refer to response described in E.34. As indicated in this response, secondary attack rates were developed from literature derived sources where available. However, several pathogens have multiple literature reported secondary attack rates. Some pathogen secondary attack rates were strain or receptor/exposure specific. Other pathogens had no authoritative secondary attack rate at all. To ensure the secondary attack rates used in the analysis were appropriate, professional judgment was applied when reviewing the studies to derive a final secondary attack rate for use in the analysis. The literature values are discussed in the text and listed as footnotes to Table 5-6 of the report. The final selected secondary attack rates were developed through discussions between Dr. Charles Gerba and Dr. Keith Tolson. These values are likely biased high (i.e., show a higher rate of secondary attack than what would be expected to occur).

Specific comments (p. 46)

E2.25 Comment on Geosyntec Response -- It is not clear that this assessment comprehensively addresses the pathogens of primary public health concern in a robust and health protective manner. This comment was not addressed in the final report.

Response to USEPA comment -- The pathogens selected for inclusion were those that could be measured by USEPA-approved methods and validated University of Arizona laboratory SOPs. Also, the selected pathogens are associated with documented outbreaks of waterborne disease. It is not clear what the reviewer considers a comprehensive assessment of primary public health concerns in a "robust and health protective manner."

Specific comments (p. 46)

E2.26 Comment on Geosyntec Response -- The response does not address the question, and the comment was not addressed in the final report.

Response to USEPA comment -- Section 5.3.3 discusses the rationale for the use of rotavirus data for a norovirus dose-response. No human studies are available to derive a dose-response relationship for norovirus. USEPA has suggested the use of rotavirus as a surrogate for dose-response relationships with other enteric viruses and a similar approach was used by WERF (2004) to assign dose-response parameters. The reviewer does not specify what additional information is required to address the question.

Specific comments (pp. 46-47)

E2.27 Comment on Geosyntec Response -- The secondary infection rates were misinterpreted from the literature, and the rates used were based on personal communication. This comment was not addressed in the final report.

Response to USEPA comment – As stated in the Geosyntec response, the transmission rates used were generally at the high end of those reported in technical literature, resulting in secondary illness rates that may be biased high. The reviewer's response does not specify how infection rates were misinterpreted from the literature or explain what additional investigation is required. See additional comments in District response E2.24.

Specific comments (p. 47)

E2.28 Comment on Geosyntec Response -- Section 5.4.2 is woefully inadequate to describe a disease transmission model. It is impossible to review the appropriateness of that model or the parameter values used because no details are provided in this section or anywhere else in the report.

Response to USEPA comment -- Section 5.4.2 explains that to account for secondary transmission, a dynamic risk model was developed that considers secondary exposure through contact with CAWS 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. 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 CAWS exposure in the population most at risk. Table 5-6 of the report presents a summary of secondary attack rates used in this analysis.

Risk Assessment (p. 48)

E2.29 Comment on Geosyntec's Response -- The response to this comment is severely overstated. The data that were collected that were collected for this investigation were good. However, the number of data points for use in the QRMA was extremely limited because multiple sites and conditions (wet/dry) were evaluated. In many cases, five or fewer data points were used to characterize the pathogen concentrations in the water. The QMRA portion of this investigation has serious issues as indicated above. Based on the consensus of the USEPA reviewers, the results of the QMRA analysis are not credible.

> **Response to USEPA comment – It appears that the reviewer confuses the number of pathogen and indicator samples with the number of sampling locations. Overall, 125 samples (75 dry weather and 50 wet weather samples) (not five samples) were analyzed for each pathogen and indicator microorganism. Geosyntec has addressed this comment and strongly disagrees with the statement that the results of the QMRA analysis are not credible. The inputs for this study are among the best recreational use microbial risk databases ever assembled.**

ENCLOSURE 3

Protecting Our Water Environment

Metropolitan Water Reclamation District of Greater Chicago

100 EAST ERIE STREET CHICAGO, ILLINOIS 60611-3154 312-751-5600

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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
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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, 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.

<u>Health and Ecological Criteria Division</u>

- 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."

K

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:

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- 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, Campylobacter, 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 these 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.

Additional specific comments:

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: ***This 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 naive 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.