Memorandum

To: Stormwater Quality Standards Study Task Force

From: CDM

Date: April 10, 2006

Subject: Scientific Basis for EPA Recommended Water Quality Objectives for Bacteria

Introduction
At the direction of the Stormwater Quality Standards Study Task Force, CDM researched the technical or scientific basis used to establish the recommended bacteria water quality objectives contained in the draft Environmental Protection Agency (EPA) guidance document, Implementation Guidance for Ambient Water Quality Criteria for Bacteria, (November 2003), including any assumptions, “safety factors” and other information relative to “acceptable” vs. “unacceptable” risks used in determining recommendations. This information was to be gathered to provide an assessment of the applicability of the assumptions, conditions and safety factors in EPA guidance relative to conditions within the Santa Ana River watershed.

Methodology
The requested research was conducted by following three general steps:

- CDM reviewed the history of EPA recommendations for the establishment of bacteria water quality objectives to protect recreational uses published in guidance documents dating back to 1968.

- Key documents cited in the EPA guidance documents were obtained (if available) and subsequently reviewed to gather additional information that provided a more complete understanding of the information contained in the EPA documents.

- Related documents that addressed the subject of the establishment of appropriate objectives for the protection of recreational uses were reviewed. This source list was initially generated by reviewing the citations in the recent National Academy of Sciences report, Indicators for Waterborne Pathogens, (National Research Council 2004).

While information was gathered on both freshwater and marine studies, the majority of the information presented in this technical memorandum focuses on the freshwater studies.
However, where potentially relevant, information from marine studies also has been included.

**Summary of Findings**

The federally recommended bacteria objectives are, to a degree, somewhat subjective; however, this does not discount or minimize the fact that increased pathogens have been shown to be related to increased illness. This has been demonstrated in numerous studies conducted around the world, especially in marine waters. However, while there should be no disagreement that this relationship exists, what can be debated and considered is how the federal recommended objectives be applied to different types of waters.

Following is a summary of findings that provides some understanding regarding how the federal objectives were derived. With this understanding in mind, the applicability of the federally recommended bacteria objectives to waterbodies with varying qualities may be considered. More detailed information follows this section.

- The bacteria objectives recommended by EPA are based on two epidemiological studies conducted during summer months generally from 1979 to 1982 at Keystone Reservoir in Oklahoma and Lake Erie in Pennsylvania.

- Bacteria objectives are intended to protect swimmers or primary contact activity where there is a high risk of ingestion of water. McKee (1980), which provides part of the basis for EPA’s recommended freshwater primary contact objectives (i.e., the studies involving Keystone Reservoir), provides a clear distinction between swimmers and non-swimmers:
  - Non-swimmers were those who either did not go in the water (non-bathers) or went in the water but did not get their head or face wet (waders). *Persons who reported that they were in the water for less than ten minutes were classified as non-swimmers regardless of whether they got their head or face wet, in view of their short water exposure time.* No explanation was offered for why ten minutes was selected as this threshold.
  - Swimmers were those who did swim or otherwise get their head or face wet.

Although the specifics of the Lake Erie study were not available (as they were for Keystone Reservoir), Dufour (1984) states that “swimming activity was rigidly defined” in the context of studies at both locations; thus, we have no reason to believe that the swimmer definition provided by McKee (1980) was any different than that which was used at Lake Erie.

With the exception of a few waters in the Santa Ana River basin, e.g., portions of the mainstem Santa Ana River and Big Bear Lake, “swimming” as defined above is not likely to occur – especially given that the study classified short exposure swimming (less than 10 minutes) as non-swimming.
Although there is a pattern of higher illness rates in swimmers, the rates for swimmers and non-swimmers were often not significantly different. In fact, for the symptom category “Highly credible gastrointestinal symptoms” only 2 of the 9 comparisons found a significantly higher illness rate for swimmers (see Tables 2 and 3).

Children are noted as potentially being more susceptible to illness than adults (e.g., see Federal Water Pollution Control Administration 1968; EPA 2003). However, children were included in the freshwater and marine epidemiological studies, and thus the recommended objectives already consider any potential for increased illness rates in children.

Fleisher et al. (1993) discusses how easily risk may have been over or underestimated in the epidemiological studies conducted by EPA; in addition, Fleisher (1991) demonstrates how easy data may be manipulated to achieve different interpretations. Ultimately, Fleisher et al. (1993) argues that the problem is best dealt with thorough risk management decisions.

The acceptable risk used to establish recommended bacteria objectives is arbitrary. From the EPA Gold Book (EPA 1986):

“The levels displayed in Table 1 [Gold Book, 1986] depend not only on the assumed standard deviation of log densities, but also on the chosen level of acceptable risk. While this level was based on the historically accepted risk, it is still arbitrary insofar as the historical risk was itself arbitrary” (the basis for the historical risk is described in Federal Water Pollution Control Administration 1968).

The single sample maximum values published in EPA (1986) for beaches ranging from “designated beach area” to “infrequently used” were intended to apply to swimmable areas or areas where primary contact recreation is possible.

Cabelli’s (1983) comments on the recommended bacteria objectives for marine waters included recommendations on how these objectives can best be used:

- The recommended objective provides a relatively reliable generalization which is amenable to risk analysis, allows a wider choice of options at both the federal and local levels, and can be defended on the basis of epidemiological data.
- A cost-benefit or cost-effectiveness type model should be developed for determining the acceptable risk or incidence of illness in the context of general and local factors.
- The “most resource responsible use” of the proposed objectives is for translation into effluent guidelines governing the design of sewage treatment facilities, the location of their outfalls and the decisions to be made relative to the degree of treatment and disinfection required.

EPA (2003) recognizes the need for a risk-based approach. This recognition makes sense given the basis for the objectives, the potential bias in the approach, the wide range of waterbody types to which these objectives could be applicable to, and the range of
recreational activities that may occur in these waters. Recently, the EPA illustrated how it accepts states using a risk-based thought process in establishing bacteria objectives to protect different levels of recreational activity (see EPA Kansas approval letter in Appendix B of “Review of State Recreational Uses and Bacteria Objectives” in CDM Stormwater Quality Standards Study Task Force Technical Memorandum, December 12, 2005).

Supporting Documentation
The following sections provide a summary of the findings from documents reviewed to date. Complete references are provided at the end of this document.

History of EPA Recommended Bacteria Water Quality Objectives for the Protection of Recreational Uses
Between 1968 and 1986, the EPA published five guidance documents addressing the establishment of bacteria water quality objectives:

- Report of the National Technical Advisory Committee (“Green Book”), Federal Water Pollution Control Administration (1968)

A sixth document, Implementation Guidance for Ambient Water Quality Criteria for Bacteria (November 2003 Draft), provides additional guidance with regards to how EPA recommends the 1986 criteria be implemented.

Overview
In general, the typically accepted primary contact fecal coliform objectives in use by states today date back to the 1968 Green Book recommendations. These recommendations were based on limited epidemiological data from three studies conducted by the United States Public Health Service (USPHS) on Midwestern waters (Great Lakes in Michigan, Inland River and Ohio River [Ohio]) from 1948-1950. In addition, the concept of a secondary contact use having objectives that are 10 times the primary contact objectives also has its root in the 1968 recommendations.

The only significant change from the 1968 recommended bacteria objectives occurred with the publication Ambient Water Quality Criteria for Bacteria (EPA 1986). This publication based on studies conducted on freshwater beaches in Oklahoma and Pennsylvania and marine beaches in New York, Massachusetts and Louisiana resulted in EPA recommending that states adopt
E. coli and enterococci as the recommended pathogen indicators for the protection of recreational uses in freshwater and marine waters, respectively.

The 1986 recommendations provided a risk-based approach for establishing criteria with a geometric mean based on an acceptable risk level and single sample criteria based on consideration of the frequency of use of the beach. The 2003 draft guidance did not change the 1986 recommended objectives, but instead provided guidelines on how bacteria objectives may be implemented. The following sections provide a brief summary of the recommendations contained within each document referenced above and the basis for those recommendations.

**Green Book**

The Green Book recommended bacteria water quality objectives for three types of recreational uses. These uses, their definitions and associated criteria are as follows:

- **Criteria for Primary Contact Recreation** - The Green Book recommended that primary contact recreation be applied to

  “… activities in which there is prolonged intimate contact with the water involving considerable risk of ingesting water in quantities sufficient to pose a significant health hazard. Examples are wading and dabbling by children, swimming, water skiing and surfing.”

  The recommended fecal coliform objectives were as follows:

  “… based on a minimum of not less than five samples taken over not more than a 30-day period, the fecal coliform content of primary contact recreation waters shall not exceed a log mean of 200/100 ml, nor shall more than 10 percent of total samples during any 30-day period exceed 400/100 ml.”

  The basis for the recommended objectives was USPHS epidemiological studies that showed an epidemiologically detectable health effect at levels of 2,300 – 2,400 total coliforms per 100 ml. Subsequent work indicated that fecal coliforms represented 18% of the total coliforms. This relationship suggested that detectable health effects may occur at a fecal coliform level of about 400 per 100 ml. The addition of a 2X safety factor resulted in the recommendation of 200 per 100 ml.

- **Criteria for General Recreational Use of Surface Waters** - General recreational use is discussed in the context of a “secondary contact” type of use, where there is no significant risk of ingestion. Applicable criteria for this use was recommended as follows:

  “In the absence of local epidemiological experience, the Subcommittee recommends an average not exceeding 2,000 fecal coliform per 100 ml and a maximum of 4,000 per 100 ml except in specified mixing zones adjacent to outfalls.”
The basis for this recommendation was as follows:

“risk [is] considered to be one-tenth that for primary contact recreation…Further research will be necessary to arrive at precise criteria for secondary contact recreation activities.”

Criteria for the Enhancement of Recreation Value of Waters Designated for Recreation Uses Other Than Primary Contact Recreation - The Green Book states that the recommendations for this category:

“are intended to apply where recreation is a designated use for water quality management purposes (but not in cases where primary contact recreation is involved).”

The recommended criteria are as follows:

“In waters designated for recreation uses other than primary contact recreation, the Subcommittee recommends that the fecal coliform content…should not exceed a log mean of 1,000/100 ml, nor equal or exceed 2,000/100 ml in more than 10 percent of the samples.”

Blue Book

The Blue Book, published in 1972, did not support the 1968 recommendations stating that “current epidemiological data are not materially more refined or definitive than those that were available in 1935.” The authors noted:

“When used to supplement other evaluative measurements, the fecal coliform index [criteria recommended in the Green Book] may be of value in determining the sanitary quality of recreational water intended for bathing and swimming. The index is a measure of the “sanitary cleanliness” of the water and may denote the possible presence of untreated or inadequately treated human wastes. But it is an index that should be used only in conjunction with other evaluative parameters of water quality such as sanitary surveys, other biological indices of pollution, and chemical analyses of water. To use the fecal coliform index as the sole measure of “sanitary cleanliness,” it would be necessary to know the maximum “acceptable” concentration of organism; but there is no agreed-upon value that divides “acceptability” from “unacceptability.” Thus, as a measure of “sanitary cleanliness,” an increasing value in the fecal coliform index denotes simply a decrease in the level of cleanliness of the water.”

The Committee that authored the Blue Book ultimately concluded that no recommendations should be made concerning bacteria concentrations in “bathing water” “because of the paucity of valid epidemiological data.” However, the Committee footnoted its findings stating that:
“if an arbitrary value for the fecal coliform index is desired, consideration may be
given to a density value expressed as a geometric mean of a series of samples
collected during periods of normal seasonal flow. A maximum value of 1000 fecal
coliform per 100 ml could be considered.”

Red Book
The Red Book, published in 1976, reversed the 1972 position and reinstated the Green Book
recommendations for primary contact or “bathing waters”:

“Based on a minimum of not less than five samples taken over a 30-day period, the
fecal coliform bacterial level should not exceed a log mean of 200 per 100 ml, nor
should more than 10 percent of the total samples during any 30-day period exceed
400 per 100 ml.”

No definition is provided for “bathing waters,” and there is no discussion of bacteria
objectives for recreational uses other than primary contact.

Gold Book and Ambient Water Quality Criteria for Bacteria
The Gold Book, published in May 1986, includes the bacteria objective recommendations
published in Ambient Water Quality Criteria for Bacteria (EPA 1986) (“bacteria guidance”) - the
document that changed the recommended bacteria objectives for freshwater from fecal
coliform to E. coli. The Gold Book summarizes the findings of several documents that were
used to generate the bacteria guidance document. These key documents: Cabelli (1983),
Dufour (1984), and McKee (1980) provide more detailed information and are discussed below.
However, some of the key points are summarized here:

- The 1986 guidelines established the risk-based approach that considers an acceptable
  number of illnesses. For the 1986 document, the acceptable illness rate for freshwater was 8
  illnesses/1000.
- No studies were done to determine what is an “acceptable illness rate.” Instead, the
  “acceptable illness rate” was established by back-calculating the risk associated with the
  200 fecal coliforms/100 ml objective already in use (see above for basis of the fecal coliform
  objectives).
- The Gold Book states that the recommended objectives depend on the chosen level of
  acceptable risk and admits, that “while this level was based on the historically accepted
  risk, it is still arbitrary insofar as the historical risk was itself arbitrary.”
- The 1986 bacteria guidance was focused on designated beaches: The situation needing the
  most rigorous monitoring is the designated swimming beach. Such areas are frequently
  lifeguard protected, provide parking and other public access and are heavily used by the
public. *Public beaches of this type were used by EPA in developing the relationship described in this document*” (emphasis added).

- The EPA document notes that the equations used to calculate geometric mean indicator densities for *E. coli* and enterococci corresponding to the accepted gastrointestinal illness rates are for “steady state dry weather conditions.”

- The basis and purpose for the single sample maximum values is as follows:

  “To set the single sample maximum, it is necessary to specify the desired chance that the beach will be left open when the protection is adequate. This chance, or confidence level, was based on Agency judgment. For the simple decision rule considered here, a smaller confidence level corresponds to a more stringent (i.e. lower) single sample maximum. Conversely, a greater confidence level corresponds to less stringent (i.e., higher) maximum values. This technique reduces the chances of single samples inappropriately indicating violations of the recommended criteria. By using a control chart analogy and the actual log standard deviations from the EPA studies, single sample maximum densities for various confidence levels were calculated. EPA then assigned qualitative use intensities to those confidence levels. A low confidence level (75%) was assigned to designated beach areas because a high degree of caution should be used to evaluate water quality for heavily used areas. Less intensively used areas would allow less restrictive single sample limits. Thus, 95% confidence might be appropriate for swimmable water in remote areas."

*Note:* Table 4 in the in EPA (1986) bacteria guidance clearly states that the single sample maximums based on confidence levels are applicable to waters for *full body contact recreation*. However, while the text of EPA 2003 clearly states that different objectives may apply to waters that are not designated primary contact recreations, Table 1-1 in EPA (2003), which summarizes the Table 4 objectives from EPA (1986), does not explicitly state that the single sample maximums are for full body contact recreation. Unless the full text is read, the intended applicability of Table 1-1 may be misunderstood.

**2003 Draft Implementation Guidance**

The 2003 draft guidance does not change the 1986 objective recommendations, but instead provides guidance on how these objectives may be implemented and provides alternatives to directly establishing the 1986 recommendations, especially where primary contact recreation is not an existing use or primary contact use is not attainable because of high flows, temperature or non-human sources of bacteria.

**Recreational Categories**

With regards to primary and secondary contact, this document provides additional guidance regarding where these uses may apply:
“States… should assure that primary contact recreation uses are designated for waterbodies where people engage, or are likely to engage, in activities that could result in ingestion of water or immersion. These activities include swimming, water skiing, kayaking, and any other activity where contact and immersion in the water are likely. Certain conditions, such as the location of a waterbody, high or low flows, safety concerns, or other physical conditions of the waterbody may make it unlikely that these activities would occur. However, states… should take into consideration that there will be individuals, particularly children, who may be more likely to swim or make other use of the waterbody such that ingestion may occur. States… should take those populations into account when making designated use determinations.”

“For waterbodies where a state… demonstrates through a use attainability analysis that “swimmable” standards are not attainable, adoption of secondary contact uses and the associated water quality criteria may be appropriate. EPA defines secondary contact uses as including activities where most participants would have very little direct contact with the water and where ingestion of water is unlikely. Secondary contact activities may include wading, canoeing, motor boating, fishing, etc.”

For waters designated with a secondary contact use, the EPA notes and recommends the following with regards to the establishment of water quality objectives:

“EPA is unable to derive a national criterion for secondary contact recreation based upon existing data, because secondary contact activities involve far less contact with water than primary contact activities. During the development of this guidance document, EPA explored the feasibility of deriving criteria for secondary contact waters and found it infeasible for several reasons. In reviewing the data generated in the epidemiological studies conducted by EPA that formed the basis for its 1986 criteria recommendations, EPA found that the data would be unsuitable for the development of a secondary contact criterion. The data collected were associated with swimming related activities involving immersion. Secondary contact recreation activities generally do not involve immersion in the water, unless it is incidental.”

“Despite the lack of epidemiological studies/data necessary to develop a risk-based secondary contact recreation criterion, EPA believes that waters designated for secondary contact recreation should have an accompanying numeric criterion… Accordingly, states… may wish to adopt a secondary contact criterion which is five times their primary contact criterion. EPA recommends that secondary contact criteria be geometric mean values using a 30 day, seasonal, or annual averaging period. Clearly identifying the averaging period is very important to support attainment and permitting decisions. Another approach would be the adoption of a secondary contact criterion as a maximum, not to be exceeded value. EPA feels that this would also be an appropriate approach, particularly for states… that are unable to collect sufficient monitoring data to calculate a geometric mean value. States… may also pursue other approaches for secondary contact
waters, and EPA will work with the state...to ensure the approach is protective of the designated use and meets the above objectives.”

**Single Sample Maximum Versus Geometric Mean for Measuring Compliance**

With regards to the use of a single sample maximum in addition to a geometric mean for measuring compliance, this document provides additional guidance. EPA recommends adopting both a geometric mean and an “upper percentile value”. The term “upper percentile value” is used in place of “single sample maximum” to more accurately reflect their derivation and more adequately reflect the range of recommended usage of this aspect of EPA’s criteria. Although the upper percentile value is intended primarily for beach monitoring and notification programs, including it in water quality standards provides the flexibility to determine the circumstances in which either the geometric mean or the upper percentile value (or both) would be most appropriate when determining attainment. Per the 2003 Draft Implementation Guidance, the “single sample maximum” was never intended to be a value not to be exceeded when referring to attainment decisions and National Pollutant Discharge Elimination System (NPDES) permitting under the Clean Water Act. Therefore, EPA proposed dropping the use of the term in favor of the more statistically correct term “upper percentile value.”

EPA encourages using only one bacteria indicator. Once a state adopts *E. coli* and/or enterococci as indicators to replace fecal coliform, the EPA recommends removing fecal coliform criteria from recreational waters, as retaining it may result in unnecessary additional permitting and monitoring requirements. To facilitate a period of transition, EPA states that both fecal coliform and *E. coli* / enterococci may be included in water quality standards for a limited period of time, generally one triennial review cycle. Temporarily using both *E. coli* / enterococci and fecal coliform criteria could prove useful for enabling regulatory decisions and actions to continue while collecting data for newly adopted *E. coli* / enterococci criteria.

EPA stresses that with this option available, lack of data should not delay adoption of *E. coli* and/or enterococci criteria.

**Non-Human Sources of Bacteria**

According to the guidance, in many circumstances waterbodies are impacted by not only human sources of fecal contamination, but also domesticated animals and wildlife. Available data suggest there is some risk posed to humans as a result of exposure to microorganisms resulting from non-human fecal contamination, particularly those animal sources with which humans regularly come into contact, i.e., livestock and other domestic animals. Accordingly, EPA believes it is inappropriate to conclude that these sources present no risk to human health from waterborne pathogens. Accordingly, states should account for bacteria from all non-wildlife sources in water quality standards.

EPA guidance states that broad exemptions from bacteriological criteria should not be used based on the presumption that high levels of bacteria originating from non-human fecal
contamination present no risk to human health. Rather, limited exemptions should be used only when high levels of bacteria are shown to be from wildlife sources. This revises EPA’s previous policy as stated in its 1994 Water Quality Standards Handbook, which allowed states and authorized tribes to justify a decision not to apply the bacteriological criteria to particular recreational waters when high concentrations of bacteria were found to be of animal origin.

A recent study performed in Mission Bay in San Diego, California may be an example of a study than could be used as support for a “limited exemption” as described by EPA. The study included an investigation of potential human sources of indicator bacteria into Mission Bay, and an investigation into non-human sources using emerging molecular source tracking techniques. Bacteria transport and sediment source evaluations were also a part of the study.

The Mission Bay study concluded that the large majority of enteric bacteria in Mission Bay originates from birds, and contributions from human sources are insignificant. Avian sources amounted to 67% of the bacteria contained within study samples; human sources amounted to 5%. The report states that because little can be done about the number of birds in Mission Bay, management solutions should focus on areas that contribute to the initial bacteria load from birds (San Diego, Mission Bay Clean Beaches Initiative Final Report, 2004).

**Methods and Basis for Establishment of EPA Recommended Bacteria Objectives**

The review of the scientific basis used by the EPA to establish water quality objectives to protect recreational uses is found in three key documents:

- **Cabelli, V.J. 1983. Health Effects Criteria for Marine Recreational Waters** – Although the emphasis is on the establishment of bacteria objectives for marine waters, some interesting recommendations are contained in this document.

- **Dufour, A.P. 1984. Health Effects Criteria for Fresh Recreational Waters** – This EPA document provides the basis for the *E. coli* criteria for freshwaters. The document’s content is based in part on the research conducted by McKee (1980).

- **McKee, G.L. 1980. Development of Health Effects Criteria for Fresh Water Bathing Beaches by Use of Microbial Indicators** – One of the study sites used to develop the *E. coli* freshwater objectives was in Oklahoma and the studies conducted at this site were done as part of a Ph.D. dissertation at the University of Oklahoma.

Following is a summary of the key findings from each of the above documents.

**Health Effects Criteria for Marine Recreational Waters (Cabelli 1983)**

Per this document, the objective of the program was to produce criteria defined as:
“a mathematical relationship of some untoward effect from swimming in sewage polluted water to the quality of that water as measured by any of a number of potential microbial or chemical indicators; thus, they were to be amenable to risk analysis.”

In Cabelli’s summary of why these studies were needed, the author notes:

- Without exception, existing guidelines suffer from two major deficiencies: (1) paucity or lack of epidemiological data to support guidelines; and (2) a consequence of the first deficiency, officials responsible for making decisions are given a “number,” and this inherently limits the options available in decision-making for compliance or noncompliance.

- To resolve the deficiencies, an alternative approach is needed that takes into account risk:

  “This approach then permits a decision as to ‘acceptable risk’ based upon social, economic, medical, public health, and even political considerations (some form of cost-benefit or cost-effectiveness analysis). The acceptable risk of illness or its incidence can then be extrapolated from the criterion to yield a water quality limit (guideline), and the guideline can then be fixed in law to provide a standard.”

The result of this study was a recommendation to replace fecal coliform objectives with enterococci objectives in marine waters. Since the focus of this document is on freshwaters, the specifics of these recommendations will not be discussed further in this document. However, in preparing the recommendations, the author also noted the following regarding the implementation of the proposed objectives:

- The recommended objective provides a relatively reliable generalization which is amenable to risk analysis, allows a wider choice of options at both the federal and local levels, and can be defended on the basis of epidemiological data.

- A cost-benefit or cost-effectiveness type model should be developed for determining the acceptable risk or incidence of illness in the context of general and local factors.

- The “most resource responsible use” of the proposed objectives is for translation into effluent guidelines governing the design of sewage treatment facilities, the location of their outfalls and the decisions to be made relative to the degree of treatment and disinfection required.

**Health Effects Criteria for Fresh Recreational Waters (Dufour 1984)**

Dufour (1984) used the findings from epidemiological studies at two fresh waterbodies to develop the current *E. coli* objectives recommended by EPA for the protection of primary contact recreation. These two locations are Keystone Reservoir on the Arkansas River near Tulsa, Oklahoma and Lake Erie in Pennsylvania. Dufour summarizes the study sites, methodology used and findings, but cites McKee (1980) for a more detailed presentation of the methodology (see below).
Study Sites

Keystone Reservoir

- Beach Sites - (1) first beach set was less than three miles from the point of discharge of a wastewater treatment facility (Beach W) (Note: McKee (1980) explains that Beach W actually consists of two separate beaches, one less than a mile, and the other almost three miles from the point of discharge. Dufour (1984) combines the data from these beaches), and (2) the second beach site was located about five miles from the treatment outfall (Beach E).

- Wastewater Facility - In 1979 the sewage treatment system was two “full retention” lagoons, which discharged an average of 120,000 gallons per day of unchlorinated sewage. The following year the practice of releasing non-disinfected sewage into the lake was discontinued. After April of 1980, approximately 60,000 gallons per day of sewage was passed through one of the lagoons, then through an aeration basin after which it was adequately treated with chlorine before being discharged.

Lake Erie

- Beach Sites - Two sites located in a State Park, situated on a peninsula just north of the City of Erie: (1) Beach B is approximately three-quarters of a mile northwest of a wastewater treatment facility outfall which discharges the treated sewage of a large urban population. (2) Beach A, which is located on the opposite side of the peninsula from the wastewater effluent outfall, does not receive pollutants from a point source and the quality of the water is “usually good.”

- Wastewater Facility - An activated sludge process is used to treat an average of 45 million gallons per day of sewage. The secondary treatment effluent was chlorinated before being discharged into the lake.

It should be noted that the Lake Erie and Lake Keystone studies were performed during non-stormwater conditions. What may be attainable based on these studies versus what may be attainable under a stormwater scenario has not been studied.

Methodology

- The beach surveys or trials were conducted only on weekends to take advantage of the large populations using the bathing beaches and to permit more intensive monitoring of water quality during the time of swimming activity.

- Swimming activity was rigidly defined as having all upper body orifices exposed to the water. Interviewers were instructed to observe the individuals they were interviewing for signs of complete body immersion, such as wet hair. This was not always possible and reliance was then placed in the responses to questions about swimming activity.

- The nonswimming control group was selected from beachgoers who did not meet the definition of a swimmer.
The beach interviews were conducted in two phases:

− In the first phase, trained interviewers approached beachgoers who were about to leave the beach area and solicited their cooperation in the study. The following procedure was followed:
  • Whenever possible, family units were sought because information on multiple individuals could be obtained from one person, usually an adult member of a family.
  • During this initial contact, the following information was obtained on each participant: sex, age, race and ethnicity, if the person swam and got their head and face wet, length of time and time of day in the water, the illness symptoms they may have had in the previous week, and for those who did not swim, the reason for not going into the water.
  • An address and telephone number were requested so that follow-up information could be obtained.
  • If an individual had gone swimming in the previous five days, they were not asked to participate in the study.

− In the second phase, telephone interviews were conducted 8 to 10 days after the swimming experience. The eligibility of each participant was confirmed, i.e., they had not swam in the week following the initial contact, before they were queried about the onset of any symptoms of illness that might have occurred during the time interval between the swimming experience and the follow-up telephone call.

Analysis of Results & Findings

Unlike marine beaches, where wading and sunning are more popular than swimming, the beachgoers at freshwater beaches had a tendency to go into the water for extended periods and to immerse their bodies totally in the water.

Greater water activity results in a much smaller nonswimming population from which a control group can be chosen. To overcome this limitation of the freshwater studies, it was necessary to pool the nonswimming control groups from each beach within a single swimming season to form a single control population.

Pooling of nonswimming control groups for each year increased the probability of detecting a difference in the incidence of illness between swimmers and non-swimmers if it does exist.

The variables used to examine the relationship between swimmers and non-swimmers were (1) the differences in symptomatic illness rates between swimmers and non-swimmers, and (2) the density of bacterial indicators in the water at the time of swimming activity.

Symptoms of interviewees were classified into five categories (Table 1).
Table 1. Definitions of Symptom Categories Used in Beach Studies (Reported in Dufour 1984)

<table>
<thead>
<tr>
<th>Symptom Category</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Gastrointestinal</td>
<td>Positive response for any of the following individual symptoms: vomiting, diarrhea, stomachache, or nausea</td>
</tr>
<tr>
<td>Respiratory</td>
<td>Individual symptoms included sore throat, bad cough, or a chest cold</td>
</tr>
<tr>
<td>Other</td>
<td>Individual symptoms included fever (greater than 100°F), headache for more than three hours, and backache</td>
</tr>
<tr>
<td>Disabling Gastrointestinal Symptoms</td>
<td>Any one gastrointestinal symptom plus any one of the following characteristics: stayed home due to symptoms, stayed in bed due to symptoms or sought medical help due to symptoms.</td>
</tr>
<tr>
<td>Highly Credible Gastrointestinal Symptoms</td>
<td>Combination of unmistakably recognized individual symptoms used to establish the credibility of the gastrointestinal illness; defined as any one of the following: (1) vomiting, (2) diarrhea with a fever or disabling condition (remained home, remained in bed or sought medical advice due to symptoms) and (3) stomachache or nausea accompanied by a fever.</td>
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</tbody>
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In general, the symptom rates for swimmers were higher than those for non-swimmers, in all the categories (see Tables 2 and 3).

Table 2. Symptom Rates (illness incidence rate per 1000) by Category for Swimmers (S) and Non-swimmers (NS) at Keystone Reservoir (Reported in Dufour 1984)

<table>
<thead>
<tr>
<th>Symptom Category (Table 1)</th>
<th>1979</th>
<th>1980</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Beach W¹</td>
<td>Beach E</td>
</tr>
<tr>
<td></td>
<td>S</td>
<td>NS</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>61</td>
<td>52</td>
</tr>
<tr>
<td>Respiratory</td>
<td>94</td>
<td>84</td>
</tr>
<tr>
<td>Other</td>
<td>71*</td>
<td>53</td>
</tr>
<tr>
<td>Disabling Gastrointestinal Symptoms</td>
<td>20.6</td>
<td>17.5</td>
</tr>
<tr>
<td>Highly Credible Gastrointestinal Symptoms</td>
<td>20.6</td>
<td>15.5</td>
</tr>
<tr>
<td>N-Value</td>
<td>3059</td>
<td>970</td>
</tr>
</tbody>
</table>

¹ Beach W comprised of two separate beaches (see McKee 1980)
Most of the symptom rates, especially those unrelated to enteric illness, were not statistically significant (p<0.05). This finding was similar to that observed in the early USPHS studies (4) conducted in the 1950s and in the marine recreational water studies conducted by the USEPA in the 1970s.

Most of the statistically significant differences between swimmer and non-swimmer illness rates, with one exception, occurred in those symptomatic illness categories associated with enteric disease.

The significant swimming related illness rates also had a tendency to occur at the beach with poorer quality water, Beach B (see Table 4 for water quality results).

“These data clearly show that there is a swimming-associated health effect and that the effect appears to be related to the microbiological quality of the bathing water. The illness rates by age showed a pattern similar to that observed in the marine bathing beach studies, wherein the highest rates for gastrointestinal illness occurred in children under 10 years old.”
Table 4. Bacteria densities at Keystone Lake and Lake Erie Bathing Beaches (Reported in Dufour 1984)

<table>
<thead>
<tr>
<th>Year</th>
<th>Beach</th>
<th>E. coli</th>
<th>Fecal Coliform</th>
</tr>
</thead>
<tbody>
<tr>
<td>1979</td>
<td>W¹</td>
<td>138</td>
<td>30-300</td>
</tr>
<tr>
<td></td>
<td>E</td>
<td>19</td>
<td>436</td>
</tr>
<tr>
<td>1980</td>
<td>W¹</td>
<td>52</td>
<td>200 – 920</td>
</tr>
<tr>
<td></td>
<td>E</td>
<td>71</td>
<td>234</td>
</tr>
</tbody>
</table>

¹ Beach W consists of two separate beaches (see McKee 1980)

Development of Health Effects Criteria for Fresh Water Bathing Beaches by Use of Microbial Indicators (McKee 1980)

The freshwater studies conducted at Keystone Reservoir were actually carried by McKee as a Ph.D. dissertation. The summary provided by Dufour (1984) comes directly from this dissertation. McKee offers this statement as his conclusion regarding the study findings:

“When the data from the…beaches was examined, the symptom rates categorized as gastrointestinal, respiratory and “other” were higher among swimmers than non-swimmers. Although the data was not statistically significant, definite trends could be shown in that direction. Good agreement was obtained between geometric means of *Escherichia coli* and *enterococcus* densities and the differential (swimmers minus non-swimmers) rate of gastrointestinal symptoms.”

McKee provides a little more detail regarding the characteristics of the study site and the beaches used for the study:

“The city of Mannford, Oklahoma has a population of approximately 2,300 people. The sewage system for this community was two ‘full retention’ lagoons. These lagoons were located near the Keystone Reservoir in Creek County…The lagoons were within one mile of the Salt Creek North bathing area and within 3 miles of the Keystone Ramp bathing beach area. These two beaches were used as the ‘barely acceptable’ test beaches. The lagoons were too small to retain all of the sewage effluent that the City of Mannford discharged. This sewage effluent was 120,000 gallons per day on the average throughout the summer of 1979…The test beaches had fecal coliform counts that usually exceeded 100 organisms/100 ml of
Pre-test bacterial sampling using *E. coli* and enterococci was done in the summer of 1978 and these organisms were consistently high at the test beaches. A “control” beach on the other side of the reservoir was selected. This beach was Washington Irving South, located on the Arkansas River arm of the Keystone reservoir. The fecal coliform counts were relatively low at this site and pre-testing of *E. coli* and enterococci showed it to be unpolluted.”

McKee provides a detailed summary of the field procedures, particularly how it was decided whether or not to include people in the analysis and, if included, how they were categorized as swimmers or non-swimmers:

- **Selection of interviewees:**
  - Interviews conducted on weekends with family group members
  - Interviewing was planned for every “good” weekend day, i.e., every Saturday and Sunday in June, July and August for which the “probability of fair weather indicated a large number of beach-goers”
  - Interviewers were told to approach as many groups on the beaches as possible and to be attentive to groups who appeared to be near the point of leaving for the day
  - Persons who swam between Monday and Friday of the previous week were not interviewed

- **Follow-up telephone calls:**
  - Follow-up phone calls to obtain information on health status of original interviews were conducted 9 to 11 days after the swimming event - 83% success rate in follow-up interviews
  - Persons who swam between Monday and Friday after the initial beach interview were eliminated to avoid possibility of incubation of symptoms from a weekday swimming experience
  - Persons who swam on the weekend following the initial interview were retained in the study
  - Persons who were encountered on two successive weekends were not interviewed for the second weekend
  - Persons encountered a second time who had a least one intervening weekend but no mid-week swimming were retained for both occasions
  - Person who swam on both Saturday and Sunday of one weekend were included as swimming on the day with the highest microbial count
Link to water quality:
- Microbial counts on the day of swimming were linked to the interview data of each respondent retained in the sample
- Water samples were collected according to the following procedure:
  - Collected periodically during time of maximum swimming activity on each interviewing day
  - Samples collected at approximately 1, 3 and 5 pm
  - Samples taken at chest depth approximately 4 inches below the surface
  - Mannford Sewer Plant also conducted water chemistry testing for a variety of constituents, e.g., BOD, nutrients, TOC, temperature, DO

Classification of swimmers and non-swimmers:
- Respondents were grouped into two categories according to their stated bathing activities:
  - Non-swimmers who either did not go in the water (non-bathers) or went in the water but did not get their head or face wet (waders)
  - Swimmers who did swim or otherwise got their head or face wet
- Persons who reported that they were in the water for less than ten minutes were classified as non-swimmers regardless of whether they got their head or face wet. Any water contact for 10-minutes or less was considered “short water exposure time”.

McKee provides the following summary of findings:

“There were no significant differences between swimmers and non-swimmers using chi-square 2 x 2 tables. However, 12 out of the 18 reported symptom rates showed a greater attack rate among swimmers and non-swimmers. It therefore appears that swimmers are at a greater risk than non-swimmers in general. The relative risk reflects that this trend was also true. The difference between the relative risk at the two beaches show that the barely acceptable beach I & II [combined data from two beaches = Beach W in Dufour (1984)] was higher than the control beach III. Except for the other category, this indicates a trend in favor of swimmers being at a greater relative risk in the categories of gastrointestinal and respiratory symptoms at the polluted beach. Reported symptoms were low in number and therefore this small sample size may not be large enough to detect the small differences between swimmers and non-swimmers or between the barely acceptable and the relatively unpolluted beach symptom rates.”
Other Information Sources

A review of the literature identified numerous other sources of information that are relevant to the scientific basis for bacteria water quality objectives. These studies do not dispute the need for objectives to protect primary contact recreation; in fact, there have been a number of studies to show that there is a relationship between gastrointestinal illness and increased pathogens. However, there are differences of opinion regarding appropriate objectives, the epidemiological methodology, and how objectives should be implemented. The following sections provide a summary of some of these ideas.

Alternatives to EPA Recommendations

- **Ferley et al. (1989)** - This study presents results from an epidemiological study conducted on a freshwater river in France during July and August of 1986. Over 5,700 people were interviewed from eight vacation camps along the river. Results showed that swimmers became ill substantially more often than non-swimmers. Results support use of fecal coliform objectives, but do not well support recommended *E. coli* objectives.

- **Kueh et al. (1995)** - Results from this Hong Kong study show a better correlation between turbidity and swimming associated illness than *E. coli* and such illness. This result could be site-specific, as sewage was a probable cause for the turbidity and a study performed a few years prior indicated a better correlation with *E. coli*. This study recommended a beach water quality objective of 15 NTU turbidity to correspond to 10 cases of gastrointestinal illness symptoms per 1000 swimmers.

- **Seyfried et al. (1985)** - This paper presents the results from an Ontario, Canada study performed to test several different bacterial indicators and their correlation with human illness. Water and sediment sampling was performed. Concentrations of bacteria in sampled beach sediments were significantly higher (10 times higher) than in beach water. Total staphylococci appeared to be a more consistent indicator for predicting total illness rates among swimmers than fecal coliform.

- **Lopez-Pila, J.M., and R. Szewzyk. (2000)** - This study suggests that due to the variability in epidemiological study results among varying regions, microbiological standards should be reexamined from time to time in order to update them with respect to acceptable risk encountered locally. The study offers a more cost effective way to perform epidemiological studies, an alternative way of obtaining health-related standards which are easier to carry out and more affordable than epidemiological studies. The study introduces a model for estimating infectious risk in bathing water from the distribution of fecal indicators, the dose/response relationship of an enteric pathogen and its ratio to fecal indicators.
Critique of EPA Methodology and Implementation Approach

Fleisher in association with various authors have written a number of papers that identify concerns regarding EPA’s epidemiological methodology, e.g., sources of bias, and approach for developing objectives:

\textit{Fleisher et al. (1993) - Setting Recreational Water Quality Criteria}

This paper focuses on the substantial amounts of potential bias present in the methodology used to develop recreational water quality objectives:

“Although there have been four published epidemiological studies reporting mathematical relationships between increasing levels of sewage pollution and increased risk of gastroenteritis among bathers…all have incorporated within them substantial amounts of bias that question the validity of the reported mathematical relationships. These sources of bias are firmly grounded in basic epidemiological theory. Since recreational water quality criteria are frequently based on one or more of the mathematical relationships reported in the literature, the amount of bias present in these epidemiological studies will affect the validity of such criteria. It is the purpose of this paper to discuss several basic epidemiological principles that have been violated in previously published epidemiological studies, and to explore the effect of the resulting bias on the study outcome.”

Although Fleisher et al. (1993) are critical of the epidemiological methodology, they do not argue against the need for objectives, for example:

“Evidence is indeed accumulating that bathers exposed to recreational waters contaminated with domestic sewage are at increased risk of acquiring gastroenteritis…What remains to be established is at what levels of domestic sewage pollution are bathers at increased risk of acquiring gastroenteritis. This issue is critical to establishing recreational water quality criteria.”

Four sources of bias are identified in the epidemiological studies. Considerable detail is provided because the discussion illustrates how the existing data can underestimate or overestimate the true risk:

- Failure to control for the effect of the limited precision inherent in current techniques of indicator density enumeration almost always leads to an underestimation of the true risk. For example, if the Multiple Tube Fermentation Technique yields an estimate of 3,000 indicator organisms/100 mL of sample, the associated 95% confidence interval will range from 990 to 9,080 organisms/100 mL. Similarly, for the Membrane Filtration Technique method, the 95% confidence interval around a point estimate of 3,000 organisms/100 mL is 1,848 to 4,668 organisms/100 mL. Precision may be increased by averaging replicate
determinations made on individual samples. The precision more than doubles by just taking three or four replicate measures regardless of the method used.

- Failure to address the fact that substantial amounts of temporal and spatial variation in indicator pathogens occurs at almost all bathing water locations. Fleisher et al. (1993) noted that this source of bias could be a major reason for the differences in findings among epidemiological studies, both in the terms of the diseases or ailments reported to be associated with swimmers in waters contaminated with domestic sewage, as well as the associated estimates of risk.

The water quality sampling design used in previous epidemiological studies (e.g., McKee 1980) typically consisted of taking 2-4 samples at two or three sites along the length of a study location on each trial day. Studies have shown that pathogen indicator densities at a site can vary widely in just a few hours. With respect to spatial variation, a study demonstrated that even when temporal variation was controlled for in the analysis, pathogen densities changed by more than two orders of magnitude at six sampling locations spaced equidistantly along a 100-meter beach.

A geometric mean is a measure of central tendency, but one should not be interested in using a measure of central tendency to assign exposure since, by definition, this would control or eliminate the effect of the substantial amount of spatial and temporal variation that affect the pathogen densities that swimmers are actually exposed to at most beaches. Instead, one should be more interested in the range of pathogen densities an individual is exposed to. Since the designs of most previous epidemiological studies allowed swimmers to enter the water over the course of an entire trial day, one should be interested in the maximum pathogen density the individual was exposed to, and not the average observed on the day of exposure. Some individuals are exposed to concentrations less than the mean, some are exposed to concentrations above the mean. Yet all individuals are assumed to be exposed to an average. The effect of this bias cannot be estimated but can result in either an under or overestimation of risk.

- Failure to relate pathogen indicator densities directly to the individual bather. To address this source of bias, the study design needs to be modified. Fleisher et al. (1993) discuss an example of how this can be done by more intensive water quality sampling and much closer observation of swimmers so that the water quality results can be tied to individuals. Failure to do so can lead to an under or overestimation of risk.

- Failure to control for non-water related risk factors for the illness under study. The following quotes from Fleisher et al. (1993) illustrate the importance of this issue:

  “Suppose an epidemiological study of bathing-associated illness is being conducted. The exposure of interest is whether an individual has entered the water while the disease outcome of interest is gastroenteritis. Now, further suppose that those who enter the water (the bather group) were more likely to stay at the beach for longer periods of time than
those who chose not to enter the water (the non-bather group). Because the bather group is hypothesized to stay on the beach longer, they also may be more likely to bring along food from home that will remain unrefrigerated or poorly refrigerated until eaten. Now further suppose the results of this...study show a two-fold increase in the risk of acquiring gastroenteritis among the bather group relative to the non-bather group. The question then becomes how much of this two-fold increase in risk can be attributed to exposure to bathing waters...the possibility exists that some of the two-fold increase in the risk of acquiring gastroenteritis we observe among the bathers has nothing to do with exposure to bathing waters, but is instead due to the consumption of poorly refrigerated foods. “

“The importance of identifying and controlling for possible confounding factors cannot be overstressed, especially when studying diseases that have many mechanisms of transmission. Since there are so many non-bathing-water-related risk factors for gastroenteritis (e.g., consumption of poorly refrigerated foods; having an underlying medical condition that predisposes to symptoms of gastroenteritis; side effects of prescription or non-prescription drugs; and consumption of excessive amounts of alcohol)..., it becomes extremely important to rule out possible bias caused by such factors...To date, no previously published epidemiological study that reported association between gastroenteritis and bathing in waters contaminated with sewage had adequately addressed the possible role of the many known non-bathing water related causes of gastroenteritis in the results reported.”

“One could argue that there is no intrinsic reason why the distribution of non-related water risk factors for gastroenteritis should differ between bathers vs. non-bathers. It is, however, quite possible that the underlying reasons that determine whether a person will choose to enter the water could be related to their risk of acquiring gastroenteritis (e.g., non-bathers may be in poorer health than bathers, or conversely, non-bathers might pay more attention to their health and thus be less likely to expose themselves to other risk factors for gastroenteritis such as the consumption of poorly refrigerated foods; the consumption of improperly prepared foods; the consumption of excessive amounts of alcohol, etc.).”

Taking into consideration these sources of bias in existing epidemiological studies, Fleisher et al., (1993) conclude:

“This paper has sought to describe several important sources of bias that are, in all probability, incorporated in the results reported by previous epidemiological studies, and thus in current recreational water quality criteria. All the sources of bias discussed in this paper can be minimized through innovative approaches to the design of future epidemiological studies. Until new epidemiological studies are undertaken which are specifically designed to address the issues raised in this paper, the data base upon which current recreational water quality criteria are based will
remain a composite of previous epidemiological studies that reported diverse estimates of risks and ailments associated with bathing in waters contaminated with sewage. The need for future epidemiological studies is critical if we are to formulate recreational water quality criteria that are based on solid scientific and epidemiological principles. Until this is accomplished, the validity of current recreational water quality criteria should continue to be questioned.”


Fleisher (1991) provides a reanalysis of the EPA data used to generate the marine bacteria water quality objectives (reported by Cabelli 1983). Although this paper emphasized marine criteria rather than freshwater criteria, Fleisher (1991) illustrates how differences in methodology can influence the data interpretation. Specifically, he disagrees with EPA’s data analysis approach and conducts his own reanalysis. He states that even if others disagree with his approach to reanalyze the data, his study illustrates how differences in the analysis methodology will influence the interpretation. He then offers an opinion regarding how this concern should be addressed. Following are a few highlights from the paper:

- **Methodology Concerns**

  Three sites were used for the EPA study: marine water locations in Boston and New York City and a brackish water location in Lake Pontchartrain. Salinity varied from an average of 3 ppt at Lake Pontchartrain to 32 ppt and 30 ppt at Boston and New York City, respectively. Studies have shown indicator organism survival for fecal coliform to be inversely correlated with salinity; other evidence is available that this correlation exists for enterococci as well (citations in Fleisher (1991)). Even with these differences in salinity, results from these three sites were pooled in the final data analysis. This pooling of data has “serious consequences with regard to the validity of the reported findings.”

- **Analysis Concerns**

  - Total gastrointestinal symptoms were more closely related (statistically) to swimming associated illness than “highly credible symptoms.” Yet highly credible symptoms were considered a more reliable measure of swimming-associated illness than total gastrointestinal symptoms (Note; the R² values are not that different: Total gastrointestinal symptoms = 0.67; highly credible symptoms = 0.56).

  - The analysis clustered sample results collected from groups of days rather than using the actual data from each site for each day.

  - Analysis left out three data points – “Two of the three data points that were omitted corresponded to trial clusters that had no reported gastrointestinal symptoms among non-swimmers (The third was omitted due to an unusually low non-swimmer rate).” Fleisher (1991) uses the original data and then conducts his own analysis incorporating
“average GI symptom rates for non-swimmers for the year and location” rather than dropping the datapoints. Using this approach and reanalyzing the regression relationship results in the highly credible symptoms relationship no longer being significant.

- Study Findings

“Although it can be argued that the methods used to derive the analyses [i.e., Fleisher’s approach] are also arbitrary [vs. EPA’s arbitrary approach of just dropping the data points], the striking differences between this analysis and that reported by the EPA study highlight the enormous effect that can be caused by minor manipulation of the data. This phenomena could have considerable relevance to the outcome reported by the EPA study, specifically, the potential effect of clustering sample dates before the analysis.”

“Based on the serious methodological and analytical weaknesses incorporated in the EPA study as shown by this report, it would be premature to conclude that health effects can be quantified sufficiently to support the continued uses of current federal bacteriological criteria governing marine recreational waters. The practical significance of this finding cannot be overstressed. Currently, most local health departments use recreational water quality standards based on the use of the coliform organism. To require a change of indicator organism at this point would be inappropriate. This is especially true in light of the fact that the current “acceptable” level of risk to the swimmer remains the same under previous federal criteria that used fecal coliforms as the indicator organism of choice. Perhaps of more importance is the fact that the reanalysis presented in this report questions the appropriateness of the use of a single maximum allowable mean enterococci density to govern all marine recreational locations in the U.S.”

References


