Office of Water 820-D-11-002

Recreational Water Quality Criteria

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Acronyms

BEACH	Beaches Environmental Assessment and Coastal Health Act of 2000
BMP	best management practices
CCE	calibrator cell equivalent
CDC	U.S. Centers for Disease Control and Prevention
cfu	colony forming units
CWA	Clean Water Act
DNA	deoxyribonucleic acid
E. coli	*Escherichia coli*
EPA	U.S. Environmental Protection Agency
E.U.	European Union
FC	fecal coliforms
FIB	fecal indicator bacteria, which includes total coliforms, fecal coliforms, *E. coli* or *Enterococcus*
FS	fecal streptococci
GI	gastrointestinal
GM	geometric mean
HCGI	highly credible gastrointestinal illness
MF	membrane filtration
mL	milliliters
MPN	most probable number
NEEAR	National Epidemiological and Environmental Assessment of Recreational Water
NGI	NEEAR-GI
NOAEL	no observable adverse effect level
NPS	non-point source pollution
NPDES	National Pollutant Discharge Elimination System
NTAC	National Technical Advisory Committee
PC	prospective cohort
POTW	publicly owned treatment works
QMRA	quantitative microbial risk assessment
qPCR	quantitative polymerase chain reaction
RCT	randomized control trial
RWQC	recreational water quality criteria
SCCWRP	Southern California Coastal Water Research Project
SPC	sample processing control
SSM	single sample maximum
States	states, tribes, and territories
STV	statistical threshold value
TC	total coliform
TMDL	total maximum daily load
TSM	technical support materials
U.K.	United Kingdom
U.S.	United States
USDA	U.S. Department of Agriculture

U.S. EPA	U.S. Environmental Protection Agency
U.S. PHS	U.S. Public Health Service
UV	ultraviolet (light)
WERF	Water Environment Research Foundation
WHO	World Health Organization (United Nations)
WQBEL	water quality-based effluent limits
WQC	water quality criteria
WQS	water quality standard

1.0 Executive Summary

The Clean Water Act (CWA), as amended by the Beaches Environmental Assessment and Coastal Health (BEACH) Act in 2000, requires the U.S. Environmental Protection Agency (EPA) under §104(v) and §304(a)(9) to conduct studies associated with pathogens and human health and to publish new or revised criteria for pathogens and pathogen indicators based on those studies. This document was prepared following an extensive review of the available scientific literature and evaluation of new information developed in response to §104(v). This document provides EPA's recommended CWA §304(a) Recreational Water Quality Criteria (RWQC) for States, lays out the science related to the 2012 RWQC, how these scientific findings were used during the development of the 2012 RWQC, and the water quality methods associated with the 2012 RWQC.

What is new in the 2012 RWQC compared to the 1986 Criteria?

1. EPA has developed and validated a qPCR method as a rapid analytical technique for the detection of enterococci in recreational water. The method can be used to develop site-specific criteria for beach monitoring.

2. EPA is introducing a new term, Statistical Threshold Value (STV), as a clarification and replacement for the term single sample maximum (SSM). In addition there are no longer recommendations for different use intensities.

3. EPA is providing information on tools for assessing and managing recreational waters, such as predictive modeling and sanitary surveys.

4. EPA is providing information on tools for developing alternative RWQC on a site-specific basis. These tools include the continued use of epidemiological studies in both fresh and marine waters and the development of quantitative microbial risk assessment (QMRA).

1.1 Contents of this Document

Section 1 provides an executive summary and introductory information regarding the history of water quality criteria (WQC) and the CWA.

Section 2 provides an overview of the most recent scientific findings used to support the criteria and explains the scope of the 2012 RWQC. The studies and projects EPA conducted as part of the 2012 RWQC development are described in the *Critical Path Science Plan* and other documents (see Appendix B). The projects align into these major categories: epidemiological studies, quantitative microbial risk assessment (QMRA), site characterization studies, indicators/methods development and validation studies, modeling, level of public health protection, and literature reviews. EPA also considered relevant studies conducted by independent researchers.

Section 3 describes the scientific aspects that were considered during the development of the 2012 RWQC. These include indicators of fecal contamination and enumeration methods, linking water quality and health, scope of protected populations, types of waterbodies, sources of fecal contamination, and the expression of the 2012 RWQC.

The 2012 RWQC recommendations indicators for fresh water are the bacteria enterococci and *Escherichia coli (E. coli)* and for marine water are enterococci. Section 3.1 explains that EPA recommends culture-based methods be used to detect the presence of both indicators and quantitative polymerase chain reaction (qPCR) be used on a site-specific basis for enterococci enumeration for the purposes of beach monitoring. Because of the limited experience with this method, EPA recommends that States evaluate qPCR performance prior to developing new or revised standards based on this qPCR method. EPA will provide separate guidance on how to evaluate qPCR performance.

Section 3.2.1 provides a historical overview of how WQC have changed throughout the past century. Scientific advancements in microbiological, statistical, and epidemiological methods have demonstrated *E. coli* and enterococci are better indicators of health than the previous indicators, total coliforms (TC) and fecal coliforms (FC).

Section 3.2.2 discusses the various human health endpoints that EPA and others have examined in epidemiological studies. Additionally, two illness definitions are discussed. EPA's 1986 criteria correspond to a level of water quality that is associated with an estimated illness rate recommendations expressed in terms of the number of highly credible gastrointestinal illnesses (HCGI) per 1,000 recreators. EPA's National Epidemiological and Environmental Assessment of Recreational Water (NEEAR) studies used a more encompassing definition of gastrointestinal (GI) illness, referred to as NEEAR-GI (NGI). Because NGI is broader than HCGI (e.g., NGI includes diarrhea without the requirement of fever), more illness cases were reported and associated with aquatic recreation in the NEEAR studies.

Section 3.2.3 provides an overview of the epidemiological studies conducted by EPA as part of the NEEAR studies. Seven studies were performed at temperate beaches impacted by publicly owned treatment works (POTWs) discharging effluent from treated municipal sewage. Three study beaches were in marine water and four were in fresh water. Studies also were performed at two additional beaches: a temperate beach in Surfside, South Carolina impacted by urban run-off sources, and a tropical beach in Boquerón, Puerto Rico impacted by a POTW. EPA also considered epidemiological studies from other research efforts.

Section 3.2.4 describes the process EPA used to establish a comparable illness rate for culture and qPCR thresholds. EPA's recommended indicator density in the 2012 RWC would retain the same level of water quality established by the 1986 criteria (U.S. EPA, 1986), as determined by culturable levels of enterococci for both marine waters and fresh waters and *E. coli* levels for fresh water. The water quality level recommended in the 2012 RWQC for marine waters and fresh waters (as measured by enterococci) corresponds to a mean estimate of illness ranging from approximately 6 to 8 cases of HCGI per 1,000 recreators for both fresh and marine waters, based on the results from the NEEAR studies and studies conducted in support of the 1986 criteria. EPA derived a qPCR value for enterococci comparable to the culture-based value based on an illness rate of 8 HCGI per 1,000 recreators for both fresh and marine waters, computed from the combined NEEAR epidemiological regression model. The 2012 RWQC recommendations correspond to the same level of water quality associated with the previous 1986 criteria recommendations.

Section 3.3 discusses subpopulations that participated in recreational activities in the NEEAR studies. The sample sizes in the epidemiological data were not large enough to capture potential differences for persons over 55 years of age, pregnant women, and other subpopulations. Children aged 10 years and younger did show a difference from adults in fresh water, but the sample size for marine water exposures was too small to draw statistical conclusions for children. EPA is basing the 2012 RWQC on the general population, which includes children. Because children may be more exposed and more sensitive to pathogens in recreational waters, it is imperative that effective risk communication outreach be done to mitigate their exposure to contaminated waters effectively. Alerting families with children when the water quality does not meet the States' applicable WQS on a given beach day, in real time, will allow for better protection of children.

Section 3.4 describes EPA's review of the available information comparing coastal (including Great Lakes and marine) and non-coastal (including flowing and non-flowing inland) waters to evaluate whether EPA should recommend that States use the 2012 RWQC in developing recreational water quality standards (WQSs) in all waterbody types. Based on EPA's evaluation of the body of information described in section 3.4, EPA recommends the 2012 RWQC for use in both coastal and non-coastal waterbodies. While some differences may exist between coastal and non-coastal waters, WQS based on the recommended criteria in both waterbody types would constitute a prudent approach to protect public health. Therefore, EPA's §304(a) RWQC recommendations are national recommendations for all surface waters of the United States designated for swimming, bathing, surfing, or similar water contact activities (referred to throughout this document as "primary contact recreational use").

Section 3.5 describes EPA's evaluation of how different fecal sources may influence risks to human health. EPA's research indicates that the source of contamination is critical for understanding the human health risk associated with recreational waters and that there is variability in the amount of human health risk in recreational waters from the various fecal sources due to the wide-ranging environmental conditions that occur across the United States. Human pathogens, microorganisms that could cause disease, are present in animal fecal matter. Therefore, there is a level of risk from recreational exposure to human pathogens in animal-impacted waters. Quantifying that risk is difficult, however, and the methods necessary to distinguish between human and nonhuman sources, with the appropriate level of confidence, are still under development. EPA concluded that States adopting the 2012 RWQC would have WQS protective of public health, regardless of the source of fecal contamination. EPA is not developing separate national criteria for nonhuman sources. States interested in adopting different standards to address the potential human health risk differences from different sources of fecal contamination on a site-specific basis should refer to section 5 of this document for suggestions on approaches.

Section 3.6 describes the statistical expression of the RWQC. As part of the 2012 RWQC, EPA is recommending that the criteria be expressed using two components: the geometric mean (GM) and the 75th percentile Statistical Threshold Value (STV). EPA computed the STV based on the water quality variance observed during EPA's epidemiological studies. The STV corresponds to the 75th percentile of an acceptable water-quality distribution. Because fecal indicator bacteria (FIB; which refers to TC, FC, *E. coli* or *Enterococcus*) are highly variable in environmental waters, distributional estimates are more robust than single point estimates. EPA is including the STV in the 2012 RWQC, rather than the term "single sample maximum," to resolve previous inconsistencies in implementation. In addition, the 2012 RWQC are no longer recommending multiple "use intensity" values, in an effort to increase national consistency across bodies of water and ensure equivalent public health protection in all waters.

Section 4 presents EPA's recommended magnitude, duration, and frequency for *E.coli* and enterococci as measured by the culture method.. The designated use of primary contact recreation would be protected if the following criteria are adopted into State WQSs:

(a) For fresh waters, a criterion that measures *E. coli* using EPA Method 1603, or any other equivalent method that measures culturable *E. coli* at a GM of 126 colony forming units (cfu) per 100 milliliters (mL) and an STV of 235 cfu per 100 mL; a criterion for enterococci measured using EPA Method 1600 (U.S. EPA 2002b), or any other equivalent method that measures culturable enterococci at a GM of 33 cfu per 100 mL and an STV of 61 cfu per 100 mL; or both of the above criteria.

(b) For marine waters, a criterion that measures enterococci using EPA Method 1600, or another equivalent method that measures culturable enterococci at a GM of 35 cfu per 100 mL and an STV of 104 cfu per 100 mL.

For the purposes of beach monitoring, EPA is providing information to States for developing a site-specific criterion that measure enterococci using EPA *Enterococcus* qPCR Method A, at a GM of 475 calibrator cell equivalent (CCE) per 100 mL and an STV of 1,000 CCE per 100 mL.

Section 5 describes the tools that can be used to assess and manage recreational waters and derive site-specific criteria. The tools listed in section 5 will not only provide States with additional options for revising their WQS for primary contact recreation, but will also help States gain a better understanding of their surrounding watersheds. Section 5.1 describes sanitary surveys and provides an overview of predictive models. Section 5.2 provides an overview of how epidemiological studies, QMRA, and alternative fecal indicator/method combinations may be used to support the development of site-specific criteria. The use of alternative fecal indicators and methods may not be scientifically defensible or protective of the use for all CWA purposes. All of the tools described in section 5 will be further explained in technical support materials (TSM) that are being developed by EPA.

A series of appendices is also included. Appendix A provides additional information on indicators and enumeration methods, Appendix B describes data and information used to evaluate the linking of water quality and health, Appendix C contains information on sources of fecal contamination, and Appendix D provides additional information on supplemental tools.

1.2 EPA's Recommended §304(a) Water Quality Criteria

An important goal of the CWA is to protect and restore waters for swimming. Section 304(a) of the CWA directs EPA to publish and, from time to time, to revise the WQC to accurately reflect the latest scientific knowledge on the identifiable effects on health and welfare that might be expected from the presence of pollutants in any body of water, including groundwater. These recommendations are referred to as §304(a) criteria. Under §304(a)(9) of the CWA, EPA is required to publish WQC for pathogens and pathogen indicators based on the results of the studies conducted under §104(v) for the purpose of protecting human health in coastal recreation waters.

The 2012 RWQC recommendations are based on data and scientific conclusions on the relationship between FIB density and GI illness and do not reflect the economic impacts or technological feasibility of meeting the criteria. These criteria recommendations may be used by the States to establish WQS, and if adopted in State WQS, will ultimately provide a basis for controlling the discharge or release of pollutants and assessing water bodies. Additionally, the criteria also provide guidance to EPA when promulgating WQS for States under CWA §303(c), when such actions are necessary. Monitoring and sampling strategies are not included in the 2012 RWQC. The criteria recommendations do not address pollutants in sand, except to the degree that sand may serve as a source of FIB in recreational waters.

When adopting new or revised WQSs, the States must adopt criteria that are scientifically defensible and protective of the designated uses of the bodies of water. EPA's regulations stated in 40 CFR §131.11(b)(1) provide that "In establishing criteria, States should (1) Establish numerical values based on (i) 304(a) Guidance; or (ii) 304(a) Guidance modified to reflect site-specific conditions; or (iii) Other scientifically defensible methods." EPA's 2012 RWQC recommendations describe the desired ambient water quality conditions to support the designated use of primary contact recreation. WQS are used in various CWA programs to identify and address sources of pollution, with the ultimate goal of attaining standards. These CWA programs include National Pollutant Discharge Elimination System (NPDES) permitting, waterbody assessments, and the development of total maximum daily loads (TMDLs). In addition, the BEACH Act requires States with coastal waters to use WQS in beach monitoring and water quality notification programs funded by EPA grants.

EPA's current recommended criteria for protecting people who use recreational waters are based on fecal indicators of bacterial contamination. In the 1960s, the U.S. Public Health Service (U.S. PHS) recommended using fecal coliform as indicator bacteria and EPA revised the recommendation in 1976 (U.S. EPA, 1976). In the late 1970s and early 1980s, EPA conducted epidemiological studies that evaluated the use of several organisms as possible indicators, including FC, *E. coli*, and enterococci (Cabelli et al., 1983; Dufour, 1984). These studies showed that enterococci are good predictors of GI illnesses in fresh and marine recreational waters and *E. coli* is a good predictor of GI illnesses in fresh waters. As a result, EPA published *EPA's Ambient Water Quality Criteria for Bacteria – 1986* (hereafter referred to as "the 1986 criteria") for determining contamination levels in recreational waters. This document recommends the use of *E. coli* for fresh recreational waters (the criteria recommend a GM of 126 cfu per 100 mL) and enterococci for fresh and marine recreational waters (the criteria recommends a GM of 33 cfu per 100 mL in fresh water and 35 cfu per 100 mL in marine water) (U.S. EPA, 1986). The 1986 recommendations replaced the U.S. PHS previously recommended FC criteria of 200 cfu per 100 mL (US EPA, 1976). In 2004, EPA promulgated the1986 criteria as the WQSs for coastal recreational waters in the 21 States that had not yet adopted standards as protective of human health as EPA's 1986 criteria recommendations (U.S. EPA, 2004). Since the promulgation of the BEACH Act Rule, six States have adopted their own standards that are as protective of human health as EPA's 1986 criteria recommendations and therefore, they are no longer covered by the Federal standards.

Like past EPA recommendations for the protection of people using bodies of water for recreational uses, such as swimming, bathing, surfing, or similar water-contact activities, these criteria are based on an indicator of fecal contamination, which is a pathogen indicator because pathogens frequently occur with fecal contamination. A pathogen indicator, as defined in §502(23) of the CWA and amended by the BEACH Act, is defined as follows: "a substance that indicates the potential for human infectious disease." Most strains of *E. coli* and enterococci do not cause human illness (that is, they are not human pathogens); rather, they indicate the presence of fecal contamination. The basis for recommending criteria that use bacterial indicators of fecal contamination is that pathogens often co-occur with indicators of fecal contamination.

2.0 Applicability and Scope of the 2012 RWQC

EPA's 2012 RWQC recommendations supersede EPA's previous criteria recommendations to protect primary contact recreation, *Ambient Water Quality Criteria for Bacteria – 1986* (referred to as the "1986 criteria"). These recommendations are for all waters in the U.S. including coastal, estuarine, Great Lakes, and inland waters that are designed for swimming, bathing, surfing, or similar water-contact activities ("primary contact recreation"). When swimming, bathing, surfing, water skiing, tubing, skin diving, water play by children, or engaging in similar water-contact activities, immersion and ingestion are likely and there is a high degree of bodily contact with the water.

Since EPA last issued recommended RWQC in 1986, scientific advances have been made in the areas of epidemiology, molecular biology, microbiology, QMRA, and methods of analytical assessment. Adding these new scientific and technical advances in the development of the 2012 RWQC strengthens the scientific foundation of EPA's criteria recommendations to protect the designated use of primary contact recreation.

In accordance with §104(v) of the CWA, as amended by the BEACH Act, EPA developed and implemented a research plan to ensure that state-of-the-art science would be available to support the development of the 2012 RWQC recommendations. To facilitate the identification of research required to develop the 2012 RWQC, EPA held a 5-day scientific workshop in 2007 to obtain a broad range of external scientific input. Forty-three U.S. and international experts provided input on near-term research requirements that would be needed in the next 2–3 years to further develop the scientific foundation of new 2012 RWQC and implementation guidance. The report from this workshop, *Report of the Experts Scientific Workshop on Critical Research Needs for the Development of New or Revised Recreational Water Quality Criteria* (U.S. EPA, 2007a), included chapters from the seven breakout groups: (1) approaches to criteria development, (2) pathogens, pathogen indicators, and indicators of fecal contamination, (3) methods development, (4) comparing the risks of different contamination sources to humans, (5) acceptable risk, (6) modeling applications for criteria development and implementation, and (7) implementation realities.

The report from the *Experts Scientific Workshop* provided a core part of the information EPA used to develop the *Critical Path Science Plan for the Development of New or Revised Recreational Water Quality Criteria* (U.S. EPA, 2007b). The *Critical Path Science Plan*, which was peer reviewed, includes 32 projects that EPA completed for the development of the 2012 RWQC. All projects included in the *Critical Path Science Plan*, and any additional projects, were completed and considered during the process of developing the 2012 RWQC. These projects included epidemiological studies to provide data correlating illness with indicators, site-characterization studies to facilitate QMRA, indicator and methods development and validation, water quality modeling, literature reviews, and additional studies to support appropriate levels of public health protection. EPA also supported the Water Environment Research Foundation (WERF) workshop, *Experts Scientific Workshop on Critical Research and Science Needs for the Development of Recreational Water Quality Criteria for Inland Waters*, to consider the significance of the differences between inland and coastal recreational waters (WERF, 2009). As summarized or included in the appendices, these projects included efforts in the following areas:[1]

- Epidemiological Studies and QMRA
  - 2003–2004 Temperate Fresh water: four beach sites on the Great Lakes
  - 2005–2007 Temperate Marine: three beach sites: Alabama, Rhode Island, Mississippi
  - 2009 sites: Puerto Rico (tropical), South Carolina (urban runoff)
  - QMRA for fresh water impacted by agricultural animals
  - Technical support to the Southern California Coastal Water Research Project (SCCWRP) for epidemiological studies at the beaches of Doheny, Avalon, and Malibu
- Site Characterization Studies
  - Development of site characterization tool for QMRA applications

[1] EPA's RecreationalWater Quality Criteria website: http://water.epa.gov/scitech/swguidance/standards/criteria/health/recreation/

  - Expanded data collection at epidemiological study locations to support modeling and QMRA
  - Site selection evaluation for Puerto Rico and South Carolina epidemiological studies
  - Study to better understand spatial and temporal variability
  - Pilot sanitary survey in the Great Lakes
- Indicators/Methods Development and Validation Studies
  - Evaluate multiple indicator/method combinations to develop quantifiable relationships
  - Study the effects of sample holding time, storage, and preservation
  - Performance of qPCR signal in ambient water and wastewater (fate and transport)
  - Develop, refine, validate, and publish new ambient and wastewater methods
  - Publish a rapid test method that has been validated by multiple laboratories
  - Evaluate the suitability of individual combinations of indicators and methods for different CWA purposes
  - Develop new and/or evaluate previously published source-identifying assays
  - Evaluate genetic markers for human, bovine, chickens, and gulls
- Modeling
  - Pilot test Virtual Beach Model Builder
  - Refine and validate existing models for fresh water beaches
  - Refine and validate other existing models for marine beaches
  - Develop technical protocol for site-specific application of predictive models
- Appropriate Level of Public Health Protection
  - Evaluate 1986 recommendations for culturable *E. coli* and enterococci compared to data collected in EPA studies and non-EPA studies
  - Evaluate applicability of EPA Great Lakes epidemiological data to inland waters
  - Evaluate available children's health data
- Literature Reviews
  - State-of-the-science reviews of published studies to characterize relative risk from different fecal sources
  - State-of-the-science review on occurrence and cross-infectivity of specific pathogens associated with animals
  - Comparison and evaluation of epidemiological study designs of health effects associated with recreational water use

EPA epidemiological studies were conducted at U.S. beaches in 2003, 2004, 2005, 2007, and 2009, and as a group are referred to as the NEEAR studies. These studies enrolled 54,250 participants, encompassed 9 locations, and collected and analyzed numerous samples from a combination of fresh water, marine, tropical, and temperate beaches (Wade et al., 2008, 2010; U.S. EPA, 2010d).

In addition to its own studies, EPA considered independent research, based on a comprehensive search of the scientific literature, which was related to the development of the 2012 RWQC. These studies included epidemiological studies, research on the development of new and improved water quality indicators and analytical methods, approaches to QMRA, water quality predictive modeling, and microbial-source tracking. As of the date of the draft RWQC, EPA received data from SCCWRP, which were generally consistent with the NEEAR study findings. However, because results were preliminary in nature, they were not considered quantitatively. These scientific topics are discussed further in section 3 of this document.

3.0 Science and Policy Underlying the 2012 RWQC

To develop the 2012 RWQC, EPA considered indicators of fecal contamination, methods for detecting and enumerating such indicators, the relationship between the occurrence of FIB in the water and their human health effects, the populations to be protected by the 2012 RWQC, waterbody types, sources of fecal contamination, and how the 2012 RWQC should be expressed in terms of the magnitude, duration, and frequency of any excursions above the criteria values. For each aspect of the 2012 RWQC, the following variables are discussed: background related to the 1986 criteria, new scientific findings and information, and what EPA is proposing for the 2012 RWQC recommendations.

Indicators of fecal contamination and RWQC indicator organisms can be detected through different methods, thus information on both the indicator organism and the method of detection are important for RWQC. The important linkage between the organism and the method is captured throughout this document by the use of the term indicator/method to refer to the combination of both. EPA believes that addressing only the organism or only the method is not adequate for deriving RWQC because the organism and the detection method result in different units (see Section 3.1.1).

3.1 Indicators of Fecal Contamination

Public health agencies have long used FIB to identify potential for illness resulting from the engagement in recreational activities in surface waters contaminated by fecal pollution. EPA based its 1986 criteria for marine and fresh recreational waters on levels of bacterial indicators of fecal contamination, specifically *E. coli* and enterococci for fresh water and enterococci for marine water. Although generally not inherently pathogenic, these particular FIB demonstrate characteristics that make them good indicators of fecal contamination, and thus, indirectly indicate the potential presence of fecal pathogens capable of causing GI illnesses. As such, FIB are “pathogen indicators” as that term is defined by Section 502(23) –“a substance that indicates the potential for human infectious diseases” – even though they are not generally thought of as “pathogen indicators,” as that term is typically used by the scientific community as direct indicators of pathogens. EPA cannot publish criteria for “pathogens” at this time because the current state of the science is not sufficient to support this effort. In addition, there are numerous pathogens that cause the full range of illnesses associated with primary contact recreation. Many pathogen specific methods were not finalized at the time of the fresh and marine water epidemiology studies, and thus a health relationship was not established. For additional information on indicators, see Appendix A.3 and A.5.

Several microorganisms that are potential indicators of fecal contamination are normally present in fecal material. Not all of these indicators, however, have a clear relationship to illness levels observed in epidemiological studies. Two microorganisms that have consistently performed well as indicators of illness in epidemiological studies are enterococci in both fresh and marine water and *E. coli* in fresh water (see Section 3.2.3). Although EPA does not have recent epidemiological data on *E. coli* in fresh water, two independent epidemiological studies support the utility of *E. coli* as an indicator as recommended in the 1986 criteria (Marion et al., 2010, Wiedenmann, 2006). A meta-analysis of 27 studies also supports *E. coli* as an indicator in fresh water (Wade et al., 2003). See section 5.2.3 for discussion of alternative indicators that EPA has not specifically included in 2012 RWQC.

Some human pathogens, such as various species of *Vibrio*, *Legionella*, and the free-living amoeba *Naegleria*, occur naturally in the environment (Cangelosi et al., 2004; Pond, 2005). Other aquatic microbes, such as harmful algae, cyanobacteria, diatoms, and dinoflagellates, produce toxins that can cause human illnesses. These microbes were not the focus of the 2012 RWQC because adverse health effects that occur in humans from these microorganisms have not been associated with FIB.

3.1.1 Enumeration Methods in RWQC

FIB can be enumerated using various analytical methods including those in which the organisms are grown (cultured) and those in which their deoxyribonucleic acid (DNA) is amplified and quantified (qPCR). These different enumeration methods result in method-specific units and values. One culture method, membrane filtration (MF), results in the number of cfu that arise from bacteria captured on the filter per volume of water. One colony can be produced from one or several cells (clumped cells in the environmental sample). Another culture method, the defined substrate method, produces a most probable number (MPN) per volume. MPN analyses estimate the number of organisms in a sample using statistical probability tables, hence the “most probable number.” Bacterial densities are based on the combination of positive and negative test tube results that can be read from an MPN table (U.S. EPA, 1978). Culture-based approaches for the enumeration of FIB, such as MPN and MF, do not result in a direct count or concentration of the bacteria being enumerated but rather rely on probabilities and generate results following culturing of a particular microbe for 18–24 hours. Results from qPCR analysis are reported in CCE units that are calculated based on the target DNA sequences from test samples relative to those in calibrator samples that contain a known quantity of target organisms (Haugland et al., 2005, Wade et al., 2010).[2]

The results from each of these enumeration techniques depend on the method used. Each analytical technique focuses on different attributes of the fecal indicator and results in a “signal” specific to that technique. For example, culture-based methods fundamentally depend on the metabolic state (i.e., viability) of the target organisms for effective enumeration. Only the culturable members of the target population are detected using culture-based techniques. Alternatively, qPCR-based approaches detect specific sequences of DNA that have been extracted from a water sample, and results contain sequences from all members of the target population, both viable and nonviable. In the context of the 2012 RWQC, the results for enterococci determined using the culture

[2] Note that in some EPA NEEAR study publications, the term calibrator cell equivalents (CCEs) has been shortened to cell equivalents (CEs). EPA considers these terms to be synonymous and in all cases calibrator cells were used. EPA used the delta-delta comparative Ct calibration model for estimating CCE or CE in all NEEAR studies.

methods are not the same as the results for enterococci detected by qPCR methods. These results are not directly interchangeable and require an explanation of each method's results as they relate to the reported health effects (i.e., epidemiological relationships; see section 3.2).

FIB, such as *E. coli*, enumerated by culture-based methods have a demonstrated correlation with GI illness from exposure to ambient recreational water previously (Dufour 1984; Wade et al. 2003) and more recently (Marion et al., 2010,Wiedenmann et al., 2006), provide a historical association with previous water-quality data, and are scientifically defensible and protective of the primary contact recreation use when used for multiple CWA programs (beach monitoring and notifications, §303[d] listing, permits, TMDLs). Culture-based methods have a time lag of 24 hours or more between sample collection and results. This lag is less of an issue if monitoring is coupled with a calibrated predictive model (see section 5.1.2).

EPA is also providing information on how to use a more recently developed qPCR method as a site-specific criterion for the purposes of beach monitoring. This methodology showed a statistically significant correlation with GI illness among swimmers in both marine and fresh recreational waters impacted by human fecal contamination (Wade et al., 2006, 2008, 2010). The technical literature demonstrates that this enterococci enumeration technique can provide results more rapidly than culture-based methods, with results available the same day (Griffith and Weisberg, 2011). Thus, the strengths of the *Enterococcus* qPCR compared to the culture method include rapidity and demonstration of stronger and more sensitive health relationships in the NEEAR studies.

As with other methods, including culture methods, the qPCR methodology may be affected by unpredictable interference from substances in different environmental matrices such as surface waters. Interference is any process that results in lower quantitative estimates than expected or actual values. Unlike culture methods, the EPA *Enterococcus* qPCR method (U.S. EPA Method A, 2010h) has a sample processing control (SPC) assay that is performed on each sample to identify unacceptable levels of interference (defined as a 3-Ct unit shift compared to corresponding control samples).

While the fresh water NEEAR studies in the Great Lakes and four temperate marine beaches demonstrated minimal to no inhibition, EPA's overall testing of qPCR in ambient waters has been limited. EPA anticipates that there may be situations at a given location where the qPCR performance may be inconsistent with respect to sample interference. Given that there is limited information on the performance of EPA's *Enterococcus* qPCR method in inland and tropical marine waters, EPA recommends that States evaluate qPCR performance with respect to sample interference prior to developing new or revised standards relying on this method for the purposes of beach monitoring. EPA will provide guidance on how to evaluate performance with respect to sample interference at a particular site at a later date.

3.2 Linking Water Quality and Health

This section discusses the information that EPA considered during the course of evaluating the association between measures of water quality and potential human health effects from exposure to fecal contamination. There are many scenarios where fecal contamination can impact a waterbody, and the relationship between the presence of FIB and of the pathogens that cause illness can be highly variable. The following four subsections—historical perspectives in criteria development, human health endpoints, water quality and illness, and derivation of recommended numerical criteria values—describe the lines of evidence EPA used to support the association between the 2012 RWQC and human health protection. The historical perspectives subsection briefly discusses previous approaches to the development of WQC in the United States. The human health endpoint subsection explains how the definition of illness is important for understanding the meaning of the associated 2012 RWQC illness-rate levels. The water quality and illness subsection presents the results of epidemiological studies that EPA considered when developing the 2012 RWQC. The derivation subsection discusses the mathematical basis of the 2012 RWQC values.

3.2.1 Historical Perspectives in Criteria Development

EPA's previously recommended recreational water-quality criteria (the 1986 criteria) and the 2012 RWQC are based on the association between the density of FIB and observation of GI illnesses. FIB levels have long served as the surrogate measure of fecal contamination and thus the presence of pathogens that are commonly associated with fecal material.

In the 1960s, the U.S. PHS recommended using FC bacteria as the indicator of primary contact with FIB. Studies the U.S. PHS conducted reported a detectable health effect when TC density was about 2,300 per 100 mL (Stevenson, 1953). In 1968, the National Technical Advisory Committee (NTAC) translated the TC level to 400 FC per 100 mL based on a ratio of TC to FC, and then halved that number to 200 FC per 100 mL (U.S. EPA, 1986). The NTAC criteria for recreational waters were recommended again by EPA in 1976.

In the late 1970s and early 1980s, EPA conducted a series of epidemiological studies to evaluate several additional organisms as possible indicators of fecal contamination, including *E. coli* and enterococci. These epidemiological studies showed that enterococci are a good predictor of GI illnesses in fresh and marine recreational waters, and *E. coli* is a good predictor of GI illnesses in fresh waters (Cabelli et al., 1982; Cabelli, 1983; Dufour, 1984).

The 1986 criteria values represent the desired ambient condition of the water body necessary to protect the designated use of primary contact recreation. Those values were selected in order to further carry forward the same level of water quality associated with EPA's previous criteria recommendations to protect the primary contact recreation use, which were for FC (US EPA, 1976). For this effort, the enterococci and *E. coli* criteria values from the existing FC criteria were translated using the GM values for the FIB established in the previous epidemiological studies (see Text Box 1, below) (Dufour and Schaub, 2007). The SSM component of the 1986 criteria was computed using the GM values and corresponding observed variances in the FIB obtained from water quality measurements taken during the epidemiological studies from the 1970s and 1980s. The 1986 criteria values resulted in different values and corresponding illness rates for marine and fresh waters because the marine and fresh water epidemiological studies reported different GMs for the FIB associated with the level of water quality corresponding to EPA's FC criteria recommendations.

Text Box 1. Translation of 1960s criteria to 1986 criteria

The 1986 criteria values (A) were derived as follows

$$A = (B*C) / D$$

Where

B is the observed GM enterococci (from epidemiological studies)

C is the criterion for fecal coliform (200 cfu per 100 mL)

D is the observed GM fecal coliform (from epidemiological studies)

For example, using the equation in Text Box 1, the marine enterococci 1986 criterion was calculated as follows:

B = 20 cfu per 100 mL (observed GM enterococci)
C = 200 cfu per 100 mL (old FC standard)
D = 115 cfu per 100 mL (observed GM fecal coliforms)
Therefore, A = 35 cfu per 100 mL.

Using the observed relationships between the FIB densities and GI illness, EPA estimated in 1986 that the predicted level of illness associated with the criteria was 8 HCGI per 1,000 recreators in fresh water (see section 3.2.2) and 19 HCGI per 1,000 recreators in marine waters (U.S. EPA, 1986).

3.2.2 Human Health Endpoint

EPA's 1986 criteria values correspond to a level of water quality associated with an estimated level of illness that is expressed in terms of the number of HCGI. The HCGI case definition is "any one of the following unmistakable or combinations of symptoms [within 8 to 10 days of swimming]: (1) vomiting (2) diarrhea with fever or a disabling condition (remained home, remained in bed or sought medical advice because of symptoms), (3) stomachache or nausea accompanied by a fever."

EPA's NEEAR epidemiological studies used a different definition of GI illness, defining a case of GI illness as "any of the following [within 10 to 12 days after swimming]: (a) diarrhea (3 or more loose stools in a 24 hour period), (b) vomiting, (c) nausea and stomachache, or (d) nausea or stomachache and impact on daily activity." This illness definition is referred to as NGI and is the definition of illness associated with the 2012 RWQC. For additional information, see Appendix B.

The NGI case definition was broadened in that diarrhea, stomachache, or nausea is included without the occurrence of fever. Viral gastroenteritis does not always present with a fever, so including GI illness without fever incorporates more types of viral illnesses in this definition. Viruses are thought to be the etiologic agent responsible for most GI illnesses that are contracted in recreational waters impacted by sources of human fecal contamination (Cabelli, 1983; Soller et al., 2010a).

In addition, the NEEAR studies extended the number of days following the swimming event in which illness may have been observed to account for pathogens with longer incubation times. For example, the incubation of *Cryptosporidium* spp. can be up to 10 days, thus participants contacted after 8 days may not have developed symptoms. By calling participants after 10 days, the study design allowed for illness caused by pathogens associated with longer incubation periods to be included. Similar GI definitions are now widely used nationally and internationally (Colford et al., 2002, 2007; Payment, 1991, 1997; Sinigalliano et al., 2010; Wiedenmann et al., 2006).

Because the NGI definition is broader than HCGI, more illnesses qualify to be counted as “cases” in the epidemiological studies, than if the older HCGI definition were applied. Therefore, at the same level of water quality, more NGI illnesses will be observed than HCGI illnesses. The relative differences in rates of GI illness between the studies (i.e., HCGI versus NGI) are directly attributable to the changes in how illness was defined and not due to an actual increase in the incidence of illness among swimmers at a given level of water quality.

EPA estimated how the GI illness rate associated with the two GI illness definitions can be compared using the difference between (a) non-swimmer illness rates from the pre-1986 epidemiological data, and the (b) non-swimmer illness rates from the NEEAR studies (U.S. EPA, 2011a). The non-swimmer HCGI rate from pre-1986 epidemiological studies was 14 illnesses per 1,000 non-swimmer recreators, while the non-swimmer recreators NGI rate from the NEEAR studies was 63 illnesses per 1,000 non-swimmer recreators. Thus an illness level of 8 HCGI per 1,000 recreators is estimated to be equivalent with an illness level of 36 NGI per 1,000 recreators (estimated translation factor of 4.5 NGI per HCGI). For analyses presented in section 3.2.4, the HCGI illness rate metric was used, through this translation factor, in order to maintain comparability to the 1986 criteria.

Of all the adverse health effects considered, the NEEAR epidemiological studies found the strongest association with GI illnesses (see section 3.2.3). In addition to NGI illnesses, the NEEAR epidemiological studies evaluated other health endpoints that could have been caused by pathogens found in fecal matter. These included the following:

1. “Upper respiratory illness,” which was defined as any two of the following: sore throat, cough, runny nose, cold, or fever;
2. “Rash,” which was defined as a rash or itchy skin;

3. "Eye ailments," which were defined as either an eye infection or a watery eye;
4. "Earache," which was defined as ear pain, ear infection, or runny ears;
5. "Infected cut," which was defined as a cut or wound that became infected.

Results from the NEEAR studies and previous epidemiological studies indicate that criteria based on protecting the public from GI illness correlated with FIB will prevent most types of recreational waterborne illnesses. In general, these other illnesses occur at a lower rate than GI illness (Fleisher et al., 1998; Haile et al., 1999; McBride et al. 1998; Wade et al. 2008). For example, Wade et al. (2008) reported overall GI illness incidence of 7.3 percent, upper respiratory infection incidence of 5.7 percent, rash incidence of 2.7 percent, and eye irritations and infections of 2.9 percent. Kay et al. (1994) and Fleisher et al. (1998) reported 14.8 percent GI illness in swimmers and 9.7 percent in non-swimmers, 4.7 percent incidence of respiratory infection in swimmers and 3 percent in non-swimmers, and 4.2 percent incidence of ear ailments in swimmers and 4.8 percent and non-swimmers.

Non-EPA studies in waters not impacted by POTWs found correlations between other health endpoints and water quality. Sinigalliano et al. (2010) reported symptoms between one set of human subjects randomly assigned to marine water exposure with intensive environmental monitoring compared with other subjects who did not have exposure. Their results demonstrated an increase in self-reported GI, respiratory, and skin illnesses among bathers compared to non-bathers. Among the bathers, a relationship was observed between increasing FIB and skin illness, where skin illness was positively related to enterococci enumeration by culture methods.

3.2.3 Relationship Between Water Quality and Illness

The protection of the primary contact recreation use has always been the goal of bacterial WQCs in the United States. For decades, epidemiological studies have been used to evaluate how FIB levels are associated with health effects of primary contact recreation on a quantitative basis. The 1986 criteria recommendations are supported by epidemiological studies conducted by EPA in the 1970s and 1980s. In those studies, *E. coli* and enterococci exhibited the strongest correlation to swimming-associated gastroenteritis (specifically HCGI, as discussed in section 3.2.2). Because these indicators correlate with illness, EPA selected *E. coli* as the indicator to be measured in fresh water and enterococci as an indicator to be measured in both fresh water and marine water. Both indicators continue to be used in epidemiological studies conducted throughout the world, including in the European Union (E.U.) and Canada (EP/CEU, 2006; MNHW, 1992). In addition, the World Health Organization (WHO) recommends the use of these two organisms as water-quality indicators for recreational waters (WHO, 2003).

<u>EPA NEEAR epidemiological study design and conclusions.</u>
EPA conducted the NEEAR epidemiological studies at U.S. beaches in 2003, 2004, 2005, 2007, and 2009 and the results of these studies were reported in a series of research articles (Wade et al., 2006, 2008, 2010; U.S. EPA, 2010d). These NEEAR studies were

prospective cohort (PC) epidemiological studies that enrolled participants at the beach (the cohort) and followed them for an appropriate period of time to compare incidence of illness (i.e., NGI illness) between the exposed (swimmers) and unexposed groups. This type of study can also include exposure response analyses if varying degrees of exposure (such as water-quality data) are present (see Appendix B). The PC design used in NEEAR studies was a modification of the cohort design previously employed by Cabelli (1983), Dufour (1984), and numerous others (Calderon et al., 1991; Cheung et al., 1990; Colford et al., 2005; Corbett et al., 1993; Haile et al., 1999; McBride et al., 1998; Prieto et al., 2001; Seyfried et al., 1985; von Schirnding et al., 1992).

Investigators considered several different study designs, but only the randomized controlled trial (described below) and prospective designs were viewed as potentially viable methods to address the specific goals of the study. The cohort design adopted for these studies modified and improved the design used for studies in the development of the 1986 criteria (U.S. EPA, 1986). Attributes of the NEEAR studies' design include: (1) the studied population of beach-goers is representative of all beach-goers; (2) the ability to recruit many swimmers and nonswimmers; (3) the studies can be conducted over an entire season, capturing and observing variability in the water quality; (4) potentially sensitive groups who use the beach, such as children, the elderly, and the immunocompromised are represented in the sample; and (5) the matrix water-sampling design allows flexibility in determining monitoring options and allows short-term (hours) variability in water quality to be evaluated.

The criteria used to select the seven beaches studied between 2003 and 2007[3] include:

1. The beach is an officially designated recreational area near a large population center.
2. The beach has an attendance large enough to support an epidemiological study (e.g., 300–400 attendees/day).
3. The age range of the swimmers is broad (i.e., includes children, teenagers, and adults).
4. The beach generally meets the state or local WQSs with a range of concentrations.
5. The range of indicator concentration is related to occasional contamination by an identified human source of pollution (point-source).
6. The swimming season is at least 90 days long.

In addition to the above criteria, obtaining agreement and consent from the local community and beach or park management was necessary.

The enrollment goal was to approach and offer enrollment to all beach-goers between 11:00 AM and 5:00 PM. Interviewers approached beach-goers on weekends and holidays during the summer. The health survey was administered in three parts: enrollment, exit interview, and telephone interview. The beach interview included questions about demographics, swimming and other beach activities, consumption of raw or undercooked meat or runny eggs, chronic illnesses, allergies, acute health symptoms in the past 48

[3] Criteria for selecting urban run-off and tropical beaches included other selection criteria as well (see Appendix B.2).

hours, contact with sick persons in the past 48 hours, other swimming in the past 48 hours, and contact with animals in the past 48 hours. The telephone interview was conducted 10–12 days after the beach visit, and consisted of questions about health symptoms experienced since the beach visit and other swimming or water-related activities, contact with animals, and consumption of high-risk foods since the beach visit, among others.

The goal of the data analysis was to evaluate the relationship between novel and rapid measures of water quality and health effects and, by doing so, determine whether the new approaches to measuring water quality would be useful in protecting beach-goers health by accurately predicting swimming associated illness.

Regression models were the primary method used to determine the strength and the significance of the relationship between the indicator measures and health effects. The types of models used are an improvement over those used in the development of the 1986 criteria because they use individual-level data and do not rely on grouping of data points. Grouping of the 1986 data resulted in the loss of the ability to account for individual differences, such as age, sex, and other health conditions. The individual-level analysis results in better control over these and other factors that might differ among individuals (covariates or confounding factors). Nearly all the studies conducted in recent years have used similar models, usually logistic or log-linear models (Fleisher et al., 1993; Haile et al., 1999; Kay et al., 1994; McBride et al., 1998; Prieto et al., 2001; Seyfried et al., 1985). The models used for the NEEAR data analysis are similar, but include several modifications to the usual approach employed by these studies (Wade et al., 2008 and 2010).

Statistical tests were conducted using several approaches and models to assess whether the odds ratios for the different fresh water and marine beaches were statistically different. The regression models considered many potential covariates, including age, sex, race, contact with animals, contact with other persons with diarrhea, number of other visits to the beach, any other chronic illnesses (GI, skin, asthma), digging in sand, and consumption of raw or undercooked meat.

As a result of the statistical analyses, EPA concluded that epidemiological data from POTW-impacted temperate fresh waters and marine waters could be combined. A direct comparison of the slope parameters (the change in illness rate per unit change in enterococci CCE) shows no difference (p = 0.44) between the marine and fresh water beaches. There were no significant differences in risk estimates from separate models from marine and fresh water beaches separately or from the combined model. The results indicated that for the majority of the range of exposures observed there were no significant differences in the estimated risk levels for marine and fresh waters. Thus, based on these NEEAR epidemiological study results, the relationship between the *Enterococcus* qPCR levels and illness did not differ across POTW-impacted temperate fresh water and marine beach sites (U.S. EPA, 2011a). For additional information, see Appendix B.

As part of the NEEAR epidemiological study design, EPA collected data from seven POTW-influenced temperate fresh water and marine water beaches at intervals throughout the day at different water depths. EPA collected 18 water samples each day for each study. Water samples were collected three times daily (at 0800 hr, 1100 hr, and 1500 hr); two water samples were collected along each of three transects perpendicular to the shoreline, one in waist-high water (1 m deep) and one in shin-high water (0.3 m deep). The association between the qPCR average of the enterococci sample collected at 0800 hr and GI illness was nearly identical to the daily GM of all samples collected.[4] The GM of the 18 daily samples provided a single daily value for the health relationship analysis. For the four fresh water beaches and the three marine beaches, enterococci were positively associated with swimming-associated NGI illnesses (Wade et al., 2008, 2010).

A number of FIB were examined in the NEEAR studies (see Table 1). The occurrence of GI illness in swimmers was positively associated with exposure to levels of enterococci enumerated with EPA's *Enterococcus* qPCR method A in fresh waters and marine waters (Wade et al., 2008, 2010). GI illness in swimmers at marine waters was also associated with exposure to levels of anaerobic bacteria of the order *Bacteroidales* enumerated with EPA's *Bacteroidales* qPCR method (Wade, 2010). The correlation between GI illness and enterococci measured by culture in the NEEAR studies was positive, but not as strong as the qPCR relationship to illness. No associations between adverse health outcomes and any of the other fecal indicator organisms were observed in either the fresh water or marine beach studies. Culturable *E. coli* was not included in the NEEAR epidemiological studies because EPA had decided at the time to evaluate a single indicator that it could potentially recommend for use by States in both marine and fresh waters. Although cultured *E. coli* samples were not included in the NEEAR epidemiological studies, other researchers confirm that culturable *E. coli* remains a useful indicator of contamination in fresh waters (Marion et al., 2010).

Table 1. Fecal indicator organisms and enumeration methods tested in the NEEAR epidemiological studies.

EPA Epidemiological Study	**Indicator/Methods Tested in Study**
Great Lakes	*Enterococcus* measured by qPCR, enterococci measured by culture, *Bacteroidales* measured by qPCR
2007 Marine	*Enterococcus* measured by qPCR, enterococci measured by culture, *E. coli* measured by qPCR, *Bacteroides thetaiotamicro* (potentially human associated) measured by qPCR, *Bacteroidales*, male-specific coliphage measured by antibody assay, *Clostridium* spp. measured by qPCR
Tropical	Same as 2007 marine, but no coliphage
Urban Runoff	Same as 2007 marine, but no coliphage

[4] The association between the 0800-hr sample and health is potentially important from an implementation perspective. These results indicate that a sample taken at 0800 hr could be used for beach-management decisions on that day.

In addition to the seven temperate, POTW-influenced beaches, EPA conducted PC epidemiological studies at two other beaches in 2009: a temperate beach in Surfside, South Carolina that is impacted by urban run-off sources but has no POTW sources, and a tropical beach in Boquerón, Puerto Rico that is impacted by a POTW. Boquerón was selected as an epidemiological study site to specifically examine the health relationships of the indicators in a tropical setting. For both studies, the illness levels were found to be low and no correlation between illness and indicator levels was observed (significant inhibition, however, was reported for water samples measured by qPCR in the tropical beach study) (U.S. EPA, 2010d). The very low indicator levels are likely an important reason for the absence of a demonstrated relationship between FIB and health at both sites.

<u>Other Epidemiological Studies.</u>
Findings from epidemiological studies conducted by non-EPA researchers were also reviewed and considered during the development of the RWQC. Numerous epidemiological investigations have been conducted since the 1950s to evaluate the association between illness risk to recreational water users and the concentration of suitable fecal indicators (Reviewed in U.S. EPA, 2009b). These studies have been conducted in Australia, Canada, Egypt, France, Hong Kong, Israel, the Netherlands, New Zealand, Spain, South Africa, the United States, and the United Kingdom. Most of these studies investigated waters that were impacted or influenced by wastewater effluent. Several groups of researchers have compiled information and generated broad and wide-ranging inferences from these epidemiological studies (Prüss, 1998; Wade et al., 2003; Zmirou et al., 2003). For example, a systematic review and meta-analysis of 27 published studies evaluated the evidence linking specific microbial indicators of recreational water quality to specific health outcomes under non-outbreak (endemic) conditions and concluded that: (1) enterococci and *E. coli* are indicators of fecal contamination in fresh waters and demonstrated predictors of GI illness in fresh waters, and enterococci in marine waters, but FC are not; and (2) the risk of GI illness is considerably lower in studies with enterococci and *E. coli* densities below those established by EPA in 1986 (Wade et al., 2003).

As of the date of the draft RWQC, EPA received data from SCCWRP, which were generally consistent with the NEEAR study findings. However, because results were preliminary in nature, they were not considered quantitatively.

A PC epidemiological study at an Ohio reservoir (a fresh water inland beach) provided an indicator-illness relationship that agrees with EPA's earlier epidemiological studies conducted at fresh water beaches (Dufour, 1984; Marion et al., 2010). In this study, *E. coli* levels (EPA Method 1603; U.S. EPA, 2002a) were associated with HCGI in a statistically similar manner as in EPA's 1970s and 1980s epidemiological studies (U.S. EPA, 2010f; see Appendix A).

Several epidemiological studies have been conducted using study designs that differ from the NEEAR design, such as those referred to as randomized control trials (RCT) or randomized exposure trials (see below). The RCT is an epidemiological experiment in which the study subjects are randomly allocated to groups to receive an experimental procedure, manner, or intervention. For recreational water exposures, the groups are bathers and nonbathers (swimmers vs. nonswimmers). The bathers are instructed as to their time in the water and activities. Similar to a PC study, bathers and nonbathers must be followed for an appropriate time to assess illness incidence and the effect of other biases and potential confounders. Exposure-response analyses may be conducted for this purpose.

Among the purported merits of RCT study designs are that they (1) better account for the possibility that those who do not bathe choose not to do so based on factors other than water quality, (2) associate individuals and the incidence of illness with the water quality at the time and place of bathing, and (3) account for non-water-related risk factors (Kay, et al., 1994). One of the most significant limitations of RCT is that the exposures in the study are not necessarily representative of those experienced by the general population.

EPA reviewed and qualitatively considered the results from these studies, to the maximum extent possible. For example, the E.U. used epidemiological studies to support their WQSs (EP/CEU 2006). An RCT was conducted over four bathing seasons (summers) at a different marine beach each season in the United Kingdom. Trends in gastroenteritis (equivalent to GI illness) rate with increasing enterococci exposure were not significantly different between sites, and data from the four beaches were pooled (Kay et al., 1994). The source of FIB in this study was reported as domestic sewage. Gastroenteritis was defined as “all cases of vomiting or diarrhea or all cases of nausea, indigestion, diarrhea or vomiting that was accompanied by a fever”. Rates of gastroenteritis were significantly higher in the exposed group than the unexposed group and adverse health effects were identified when the FIB density exceeded 32 per 100ml (Kay et al., 1994; Fleisher et al., 1998). Another E.U. randomized control trial at five fresh water bathing sites in Germany recommended the following guidance values for water quality: 100 *E. coli* cfu per 100 mL and 25 enterococci cfu per 100 mL, based on the no observable adverse effects levels (NOAELs) for gastroenteritis (Wiedenmann et al., 2006).

Additionally, a randomized exposure epidemiological study at a Florida marine beach not impacted by a POTW found that those randomized to head immersion were approximately twice as likely to develop a skin rash when swimming in water with culturable enterococci levels greater than or equal to 40 cfu per 100 mL, than swimmers exposed to enterococci levels less than 40 cfu per 100 mL (Fleming et al., 2008; Sinigalliano et al., 2010).

Not all epidemiological studies show a clear correlation between indicator levels and health outcomes. For example, in a 1989 PC epidemiological study at marine beaches impacted by sewage outfalls and stormwater overflows in Sydney, Australia, gastrointestinal symptoms did not increase with increasing counts of FC or enterococci (Corbett et al., 1993). In a PC epidemiological study at Mission Bay, in California, where birds were the primary fecal source, only male-specific coliphage had a correlation with illness (Colford et al., 2005).

3.2.4 Establishing a Comparable Illness Rate for Defining Culture and qPCR Thresholds

The 2012 RWQC values for cultureable levels of enterococci for marine and fresh waters and *E. coli* for fresh waters, if adopted by a State in its WQSs, would correspond to the same level of water quality established by the 1986 criteria in terms of indicator density, if the State had WQS consistent with EPA's 1986 criteria recommendations (U.S. EPA, 1986). They assume this level of water quality would be determined by culturable levels of enterococci for marine waters and fresh waters and *E. coli* for fresh waters.

The NEEAR studies provided additional culturable enterococci data that EPA used to help estimate an illness rate associated with the recommended level of water quality. The NEEAR culture-based data were analyzed in several ways, some of which differed from the reported approach with the NEEAR qPCR-based data. EPA conducted these analyses to provide a comparison with the data analysis underlying the 1986 criteria for recreational waters. The following details describe EPA analytical approaches to evaluate the culture-based data. Taken together, these analyses indicate that the illness level associated with the 2012 RWQC water quality recommendations is approximately 6 to 8 cases of HCGI per 1,000 recreators in both fresh and marine waters. The HCGI illness rate metric was used in these analyses, rather than the NGI employed in the NEEAR studies, in order to maintain comparability to the 1986 criteria.

<u>Approach 1.</u>
As reported by Wade et al. (2008, 2010), culture-based measures of enterococci collected in the NEEAR studies were analyzed using the same rigorous statistical approach applied to the qPCR data (Wade et al., 2008, 2010). This approach did not result in a statistically significant illness association over the entire range of observed water quality measured by culturable enterococci using the fresh water, marine, or combined beach datasets (Wade et al., 2008, 2010). Therefore, EPA is not relying quantitatively on those exposure-response relationships because the regression coefficients would have little predictive value and may be misleading.

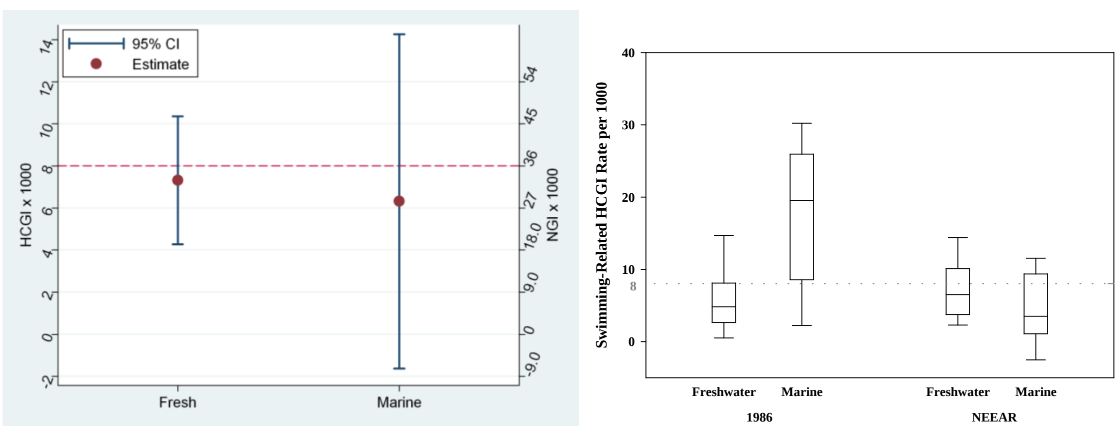
EPA's fresh water NEEAR studies, however, did indicate that swimmers exposed above the guideline value of 33 cfu per 100 mL had higher risks than nonswimmers or swimmers exposed below this value (Wade et al. 2008). Additionally, during EPA's marine water NEEAR studies, approximately 16 percent of the marine study days exceeded the enterococci GM value of 35 cfu enterococci per 100 mL. Similar to the fresh water NEEAR studies, odds of diarrhea, respiratory illness and earache were elevated among swimmers compared to non-swimmers on these study days (Wade et al., 2010).

<u>Approach 2.</u>
EPA also used the NEEAR study statistical approach (Wade et al., 2008, 2010) to compare the swimmer-associated risk on days when cfu per 100 mL was above and below 33 cfu per 100 mL and 35 cfu per 100 mL for fresh and marine sites, respectively

(Figure 1a). Those data indicate that (1) on days when the current GM guidelines values were exceeded, illness rates were similar at marine and fresh water sites, (2) illness rates at marine sites are likely less than the previously predicted 19 HCGI per 1,000, and (3) average illness rates in marine and fresh water were on the order of 6 to 8 HCGI per 1,000 recreators.

<u>Approach 3.</u>

EPA then compared the distributions of fresh water and marine swimming-associated HCGI rates observed in the NEEAR study to that of the corresponding 1986 illness rates. Results of this analysis indicate that the distribution of NEEAR fresh water swimming-associated HCGI rates was consistent with that observed in the earlier studies (Figure 1b). Boxes in Figure 1b represent the middle 50 percent of the data, which intersect over most of their range between these two fresh water data sets. (Note that the whiskers describe the 10th and 90th percentiles, while the lines within the boxes indicate the median values). In contrast, marine swimming-associated HCGI rates were considerably higher than fresh water rates in the 1980s, showing no commonality among the middle 50 percent. This observation explains the greater level of HCGI risk that was estimated for marine beaches in the 1986 criteria, at 19 cases per 1,000 in marine waters versus 8 cases per 1,000 in fresh water. Among the NEEAR beaches, however, the distribution of marine swimming-associated HCGI rates is similar to that of both the NEEAR and the 1986 fresh water rates, consistent with the results presented in Figure 1a.



a) b)

Figure 1. Swimming-associated HCGI Illness levels observed during EPA's epidemiological studies. a) risk on days with GM above 35 cfu at marine sites and above 33 cfu per 100 mL at fresh water sites. b) illness observed during 1986 and NEEAR studies

<u>Approach 4.</u>

EPA next attempted to compare the behavior of culturable data with respect to GI illness from the NEEAR studies to the results of the 1986 analyses (Cabelli, 1983; Dufour, 1984). EPA could not reanalyze the 1980s data using the newer and more rigorous NEEAR analytical approaches because the raw data from those earlier studies are no longer available. Therefore, EPA used the same analytical approaches employed in the

1980s studies to evaluate the comparability of the NEEAR data with the results from the 1980s.

In the 1986 criteria, quantitative relationships between the rates of swimming-associated illness and FIB densities were determined using regression analysis. Linear relationships were estimated from data grouped in two ways: (1) pairing the GM indicator density for a summer bathing season at each beach with the corresponding swimming-associated GI rate for the same summer (fresh water beaches), and (2) by trial days with similar indicator densities from each study location (marine beaches). The second approach, grouping by trial days with similar indicator densities, was not possible with the 1980s fresh water data because the variation of bacterial indicator densities in fresh water samples was not large enough to allow such groupings (U.S. EPA, 1986). For the 2012 RWQC, EPA evaluated both approaches with the NEEAR culture-based enterococci data (seasonal and days of similar water quality) to estimate the illness associated with the recommended level of water quality.

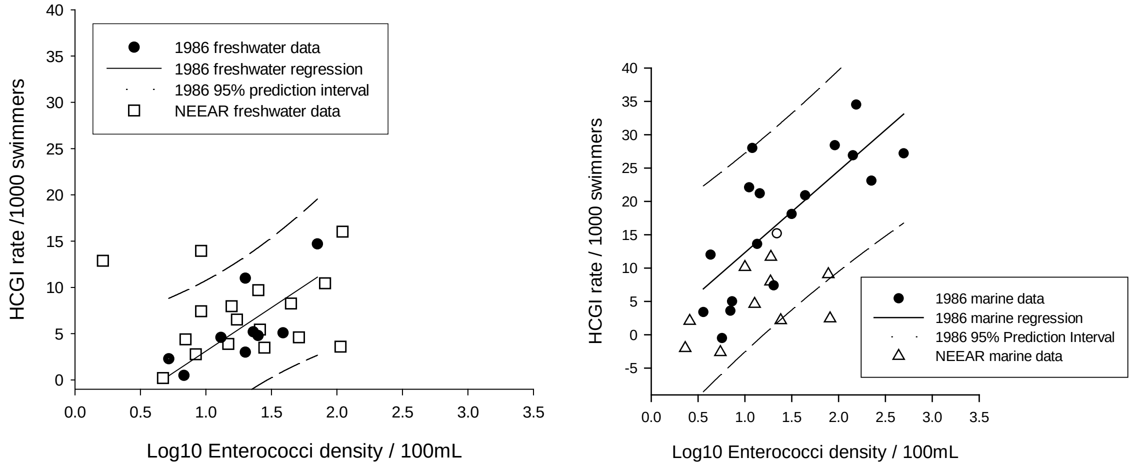
Using the NEEAR culture-based enterococci data, the first analyses summarized each NEEAR beach as a seasonal GM of water quality and its average seasonal illness rate estimate, using the entire body of culturable enterococci data from the NEEAR studies. Illness rates were translated from NGI case definition to the older HCGI case definition to be able to compare NEEAR epidemiological results to 1986 results (U.S. EPA, 2011a). These data points generally fell within the predicted range of the published epidemiological regressions (Cabelli, 1983; Dufour, 1984). However, this analysis proved to be insufficient to estimate NEEAR study illness estimates, because only seven data points—one for each of the NEEAR beaches—were available.

EPA then examined the NEEAR culture-based enterococci data consistent with the analytical approach utilized for the marine water studies in the 1986 criteria by aggregating days of similar water quality (bins) for each beach (Cabelli, 1983; U.S. EPA 1986). The NEEAR data were sorted by the observed GM for each beach day and the data for each beach were grouped according to natural breaks in these data. Bins of beach days were established from these data to balance, to the extent feasible, the existence of natural breaks of days with similar culturable enterococci GM and the number of study participants represented in each bin (Table 2). The binned data for all seven NEEAR beaches resulted in more data points per beach for both fresh water and marine beaches (Figures 2 and 3), which provided a greater level of resolution to the data compared to the seasonal-level fresh water analysis described above. Illness rates were also translated into HCGI equivalents.

EPA compared both fresh water and marine culture-based NEEAR indicator data to the corresponding 1986 regressions using the binned data. Results of this analysis indicate the vast majority of these data points fall within the 95^{th} percentile prediction intervals derived from the 1986 regression models (Figure 2). The prediction intervals can be used to assess whether the additional data fall within an expected range based on the 1986 data. While, the NEEAR marine culture-based data cluster at the lower end of the water quality and illness distribution described by the 1986 marine regression, they occur in a similar range of water quality and illness that was observed in the fresh water studies (Figure 3). Because this analysis does not take into account the individual and beach-level factors that may affect the association, EPA is only using this analysis to describe the potential range of illness associated with the water quality level recommended in the 2012 RWQC for marine and fresh waters, ($\log_{10}$ of 35 = 1.54 and $\log_{10}$ of 33 = 1.52, respectively). Based on this analysis, the corresponding mean estimate of illness ranged approximately from 6 to 8 cases of HCGI per 1,000 recreators for both fresh waters and marine waters (Figure 3).

Table 2. NEEAR culture-based enterococci and illness rate data for each of the seven beaches.

Beach	Daily geometric mean Enterococcus density (CFU/100 mL)	Total number interviewed	Number reporting no water contact	Number reporting immersion	Number NGI cases no contact	Number NGI cases immersion	Excess HCGI swimmers (#/1000), beach average non-swimmer illness rate
West Beach (fresh)	1.6	1122	360	556	21	60	12.9
	9.2	726	144	468	2	39	7.4
	25.1	463	101	299	8	28	9.7
	110.4	553	117	344	5	42	16.0
Huntington Beach (fresh)	4.7	731	426	186	43	18	0.2
	9.2	733	391	208	27	33	14.0
	15.7	526	251	167	31	22	8.0
	81.1	850	467	196	46	28	10.5
Silver Beach (fresh)	7.0	864	220	490	16	37	4.4
	14.8	2203	603	1215	36	89	3.9
	25.8	3128	900	1720	54	138	5.5
	51.3	2525	808	1281	46	98	4.6
	106.6	2152	843	945	36	68	3.6
Washington Park Beach (fresh)	8.4	722	198	398	15	30	2.8
	17.2	789	171	488	10	45	6.5
	27.9	1368	364	764	23	60	3.5
	44.6	1465	524	710	31	71	8.3
Edgewater Beach (marine)	2.3	555	135	173	10	13	-2.0
	10.0	239	66	77	7	10	10.1
	18.9	441	152	139	13	19	11.7
	77.7	108	27	40	2	5	9.1
Fairhope Beach (marine)	5.5	494	261	120	27	9	-2.6
	12.7	541	200	186	19	20	4.6
	24.1	351	126	114	5	11	2.2
	81.0	629	266	225	23	22	2.4
Goddard Beach (marine)	2.6	2433	1322	596	58	33	2.1
	18.8	535	262	183	15	15	8.0



a) b)

Figure 2. NEEAR studies culture data aggregated by similar water quality and 1986 criteria data for (a) fresh water beaches and (b) marine water beaches.

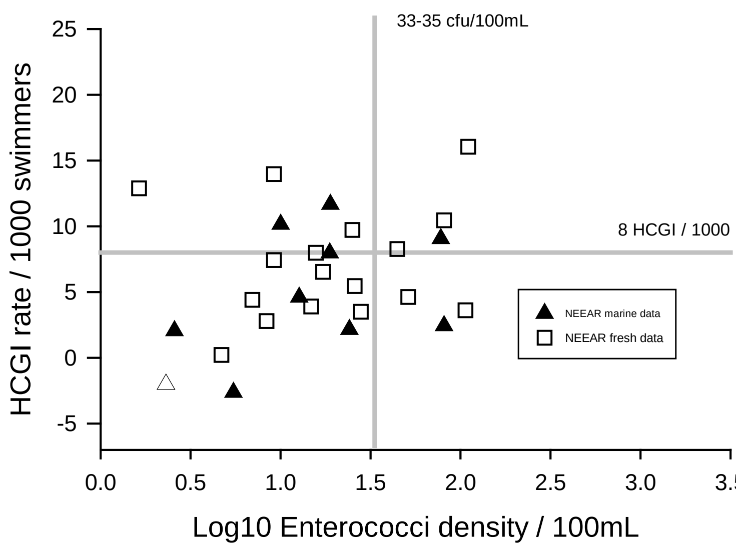


Figure 3. NEEAR marine water and fresh water culture-based enterococci and illness rate data aggregated by days of similar water quality.

EPA also conducted several additional analyses that were not used directly to derive new criteria, but nevertheless support the underlying basis. For example, EPA conducted a water quality translation of the NEEAR water quality data in a manner parallel to that used to derive the 1986 criteria (Text Box 1, see section 3.2.1). The translation indicated that the estimated illness level associated with the 1986 criteria is in the 6- to 8-HCGI per 1,000 recreators range. Another set of analyses indicated that salinity was not the primary factor for predicting culturable enterococci levels at NEEAR beaches (see Appendix B.7).

Conclusion.

Taken together, the set of approaches described above provide lines of evidence to refine the illness rate estimate associated with the recommended marine criterion for enterococci (i.e., 19 HCGI per 1,000 recreators was the best mean estimate available at the time in 1986, but it was accompanied by a wide range of uncertainty) and indicates that the recommended 2012 RWQC values are similarly protective of public health in both marine waters and fresh waters.

Derivation of an equivalent qPCR value.

EPA then derived a value for enterococci measured by qPCR value comparable to the culture-based value based on an illness rate of 8 HCGI per 1,000 recreators for both fresh waters and marine waters computed from the combined NEEAR epidemiological regression model (Figure 4) (U.S. EPA, 2011a). This model was used rather than separate models for marine waters and fresh waters because EPA's analysis indicated that there was little evidence for differences in illness rate estimates obtained from separate models from marine and fresh water beaches and because the beach-specific separate models showed no statistical improvement over a single combined model (U.S. EPA, 2011a). Furthermore, results from the marine water and fresh water studies are sufficiently similar to allow combining the NEEAR marine water and fresh water data to give a single relationship between health effects and water quality measured with a new rapid method (U.S. EPA, 2011a). The relationship between swimming-associated illness in terms of NGI per 1,000 recreators and water quality developed from the combined marine and fresh water data is defined as follows:

Swimming associated NGI illness = -27.3 + 23.64 (mean Log_{10} qPCR CCE/100 mL)

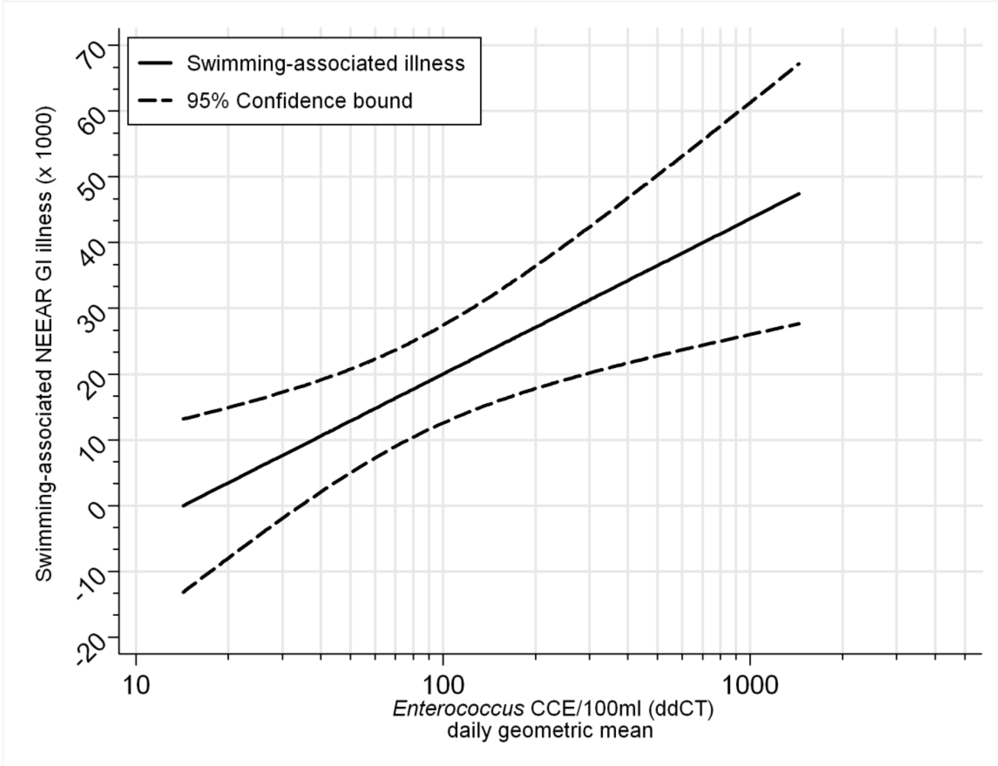


Figure 4. Swimming-associated NGI illness and daily average *Enterococcus* qPCR CCE. All subjects, marine and fresh water beaches combined (Intercept= -0.0273, Slope= 0.02364).

The illness level of 8 cases of HCGI per 1,000 recreators corresponds to an estimated 36 cases of NGI per 1,000 recreators based on a translation of the definition of NGI to HCGI using a factor of 4.5 (U.S. EPA, 2011a). Thus, a qPCR-based GM value of 475 CCE enterococci per 100 mL corresponds to 36 cases of NGI per 1,000 recreators. Based on the regression model, the following equation was used to derive the qPCR value:

$$\text{qPCR Value} = 10^{\frac{4.5 * HCGI + 27.3}{23.64}}$$

where:

qPCR = qPCR value in units of CCE per 100 mL

HCGI = HCGI illness rate[5] in illnesses per 1,000 recreators

This approach to derive a comparable qPCR-based recommended value for enterococci allows EPA to use all the data collected during the NEEAR studies, demonstrates a consistent level of protection for enterococci enumerated with culture-based methods, and provides a qPCR value for States that desire a more rapid enumeration technique for beach monitoring.

<u>Summary.</u>

EPA's 2012 RWQC recommendations, if adopted into State WQSs, will correspond to the same level of water quality associated with the previous 1986 criteria

[5] See U.S. EPA (2011) for translation information of HCGI illness rate into the NEEAR illness rate.

recommendations. The analyses conducted with the NEEAR culture-based enterococci data allowed for a refined estimate of illness associated with the current level of water quality described by 35 cfu enterococci per 100 mL in marine waters and 33 cfu enterococci per 100 mL in fresh waters. Furthermore, the refined illness rate estimate range of 6 to 8 HCGI per 1,000 recreators applies to both fresh and marine waters. The illness rate of 8 HCGI per 1,000 recreators was used as the basis for developing a qPCR-based enterococci value. Visual representations of the separate fresh water and marine water health relationships can be found in Wade et al. 2008 and Wade et al. 2010.

3.3 Scope of Protected Population

EPA's 1986 criteria recommendations are supported by epidemiological studies that were conducted in the late 1970s and 1980s. Those studies enrolled participants according to the following criteria: "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" (Dufour, 1984). This enrollment strategy ensured that children were highly represented in those epidemiological studies. When EPA published the 1986 recommended criteria values, EPA related the water-quality level to the associated illness-rate level derived in the epidemiological studies conducted in the 1970s and 1980s. Thus, the illness rates corresponding to the 1986 criteria recommendations are based on the epidemiological relationship for the general population that includes children. EPA is proposing a similar approach for deriving illness levels for the 2012 RWQC.

As in the previous EPA epidemiological studies, children were well represented in EPA's NEEAR studies population. The proportions of individuals in the under 5-year and 5-to11-year age categories that were enrolled in the epidemiological studies were greater than those present in the U.S. demographic. For example, at West Beach the proportion of children aged 10 years and under made up 20 percent of the study sample. A similar over-representation of children is true for the other beaches, including Huntington (20 percent of the study sample), Washington Park (22 percent), Silver Beach (22 percent), Edgewater (17 percent), Fairhope (30 percent), and Goddard (20 percent). According to the U.S. Census data for 2009, children younger than 10 years of age make up approximately 14 percent of the U.S. population (Census, 2010). Based on national demographics, the NEEAR epidemiological studies included an over-representation of children.

EPA conducted statistical analyses of the data from each of EPA's epidemiological studies at fresh water, marine, and tropical beaches to evaluate whether children at these sites were at an increased risk of illness following exposure to recreational waters. The results for children were compared to adults and other age groups. The age groups used for comparison included the following: 10 years and under, 11 to 55 years, and over 55 years of age. Other age groups for children were not separately analyzed due to small sample sizes. Data for children (i.e., 10 years and under) were specifically analyzed to evaluate whether their behavior and/or physiology results in different illness rates compared to the general population.

In the NEEAR fresh water epidemiological studies, the association between GI illness and water quality, as measured by EPA's *Enterococcus* qPCR method A, was stronger among children (age 10 years and under) compared with the NEEAR general population, which also included children. Relative to body size, children breathe more air and ingest more food and water than adults (U.S. EPA, 2003). Children also exhibit behaviors that increase their exposure to environmental contaminants, including increased head and body immersion in recreational waters (Wade et al., 2006, 2008; U.S. EPA, 2010d) and hand-to-mouth contact (Xue et al., 2007). The immature immune systems of children can also leave them particularly vulnerable to the effects of environmental agents (Pond, 2005). A higher proportion of children immerse their heads in shallow water compared with adults. Children also stay in the water longer than adults (Wade et al., 2006, 2008) and ingest more water (Dufour et al., 2006). These characteristics supported the hypothesis that a significant difference in GI illness in children in comparison to the general population could have been observed in the epidemiological studies.

In the NEEAR fresh water studies, however, there was considerable overlap in the confidence intervals associated with the estimated mean illness responses between children and the general population. The confidence intervals for the children's curve were wider than the confidence intervals for the general population. When health effects were compared with water quality, as measured by cultured enterococci, differences between children (age 10 years and under) and the general population were not observed (Wade et al., 2008). Swimmers exposed to water qualities above densities of 33 cfu per 100 mL had an elevated risk of developing GI illness compared with non-swimmers and swimmers exposed to water having densities less than 33 cfu per 100 mL. Both cohorts, including children (age 10 years and under) and the general population, demonstrated similar responses to water having more than 33 cfu per 100 mL.

In the NEEAR marine epidemiological studies, there was insufficient evidence of increased illness among children corresponding to water quality as measured by qPCR. As with the fresh water sites, a higher proportion of children age 5 to 10 years (75 percent) would immerse their bodies or head in the water compared with adults over age 55 years (26 percent) (Wade et al., 2010). Elevated GI illness levels were observed among swimmers of all age groups compared with non-swimmers on days that exceeded the enterococci GM value of 35 cfu per 100 mL (Wade et al., 2010).

The epidemiological studies conducted by EPA in tropical regions (Boquerón Beach, Puerto Rico) and temperate marine waters that were impacted by urban runoff (Surfside Beach, South Carolina) showed no evidence of increased illness in children that corresponded to exposure to FIB in the recreational waters (U.S. EPA, 2010d).

EPA considered children's unique physiological and behavioral characteristics when developing these criteria. The collective results of the NEEAR epidemiological studies, however, provide inconclusive evidence that children (age 10 years and under) exhibited a significantly different illness response given the range of water qualities measured in these studies.

Another subpopulation of participants, those over the age of 55 years, was also present but at levels too low to be evaluated separately. For example, in the fresh water studies, this subgroup represented 7 percent of the study population. This small sample size did not allow EPA to make any conclusions about risk in the subpopulation over 55 years of age. EPA's NEEAR studies were also not designed to evaluate the effects on groups with compromised immune systems or other vulnerable subpopulations.

EPA considered all the demographic data and results presented above and concluded that the robustness of the estimates for the general population data provide a significant advantage over the more uncertain and smaller sample set that consisted only of children. Importantly, the general population data are weighted to include children in a robust manner. Thus, the general population data provide an appropriate basis for deriving EPA's recommended values for the 2012 RWQC.

The 2012 RWQC document includes information for States on an additional protective option for children through implementation of qPCR for site-specifically, which would allow families to make real-time decisions to protect their children. In contrast to the "rapid" methods, such as qPCR, traditional culture methods provide estimates of water quality a day or two after the actual exposure. qPCR can be performed in 2–6 hours and has been shown to be successful when implementing same-day health-protective decisions (Griffith and Weisberg, 2011). Predictive models will also be available for rapid notification with these new criteria for the measurement of *E. coli* and enterococci by culture and qPCR as presented in section 5.1.2. These models have been demonstrated to be useful tools for implementing beach monitoring programs in the Great Lakes (Francy, 2009; Frick et al., 2008; Ge and Frick, 2009). Because children may be more exposed and more sensitive to pathogens in recreational waters, it is imperative that effective risk communication and health outreach be done to effectively mitigate exposure to contaminated waters. Alerting families with children to the level of water quality on a given beach day, in real time, will allow for better protection of children.

3.4 Waterbody Type

EPA's 2012 RWQC national recommendations are for all surface waters of the United States designated by a State for swimming, bathing, surfing, or similar water contact activities. Historically, the scientific evidence used to generate criteria recommendations has been based on data collected mostly from coastal, temperate and Great Lakes freshwaters. The stakeholder community has asked EPA to consider whether EPA's criteria recommendations could be used to develop State WQSs for other types of waters.

In response, EPA conducted a review of the available information comparing coastal (including Great Lakes and marine) and non-coastal (including flowing and non-flowing inland waters, such as streams, rivers, impoundments, and lakes) waters to evaluate whether EPA should include recommendations in the 2012 RWQC for all waterbody types (U.S. EPA, 2010g). Additionally, EPA considered the WERF Inland Water Workshop report (WERF, 2009) and subsequent meeting report publication (Dorevitch et al., 2010), which concluded that the inclusion of non-coastal waters in the 2012 criteria will result in public health protection, by preventing illnesses associated with exposure to non-coastal waters if States adopt WQS based on EPA's 2012 RWQC recommendations. Additionally, outbreaks from exposure to non-coastal waters indicate a need for public health protection in such settings. FIB monitoring can be used as a way to reduce the occurrence of outbreaks of severe illness, as well as the sporadic cases of illness that occur among swimmers. Overall, the distinction of non-coastal waters versus coastal waters is of less importance than more fundamental variables such as the source of fecal contamination, scale of the body of water, and the effects of sediment, which translate into differences in the densities, transport, and fate of indicators and pathogens (Dorevitch et al., 2010). The next two subsections describe the scope of the currently available data that EPA considered supporting the revision of criteria that include both coastal and non-coastal waters. For additional information on the EPA report, see Appendix B.6.

Waterbody type and sources of fecal contamination.

EPA's literature review identified the source of fecal pollution as one of the most important factors when considering the potential differences between EPA epidemiological study sites and non-coastal waters (U.S. EPA 2010g). More information specifically concerning the source of fecal contamination is found in section 3.5. Sources of fecal contamination are discussed in this section only insofar as they potentially impact FIB in coastal versus non-coastal settings.

All surface waters receive FIB from point sources, diffuse sources (which may consist of point source and non-point source pollution), direct deposition, and resuspension of FIB contained in sediments. Loadings and hydrodynamics of FIB in POTW-impacted coastal and non-coastal waters are generally similar. POTW discharges, which are known sources of human-derived pathogens and indicators from fecal pollution, are relatively steady. Differences exist in FIB loadings between POTW-impacted coastal and non-coastal waters, and non-coastal waters impacted by sources other than treated sewage effluent due to differences in the physical and biological characteristics that influence FIB survival compared to pathogen survival. Some of the characteristics include potential and extent of shading, hydrodynamics, potential for sedimentation, and microbial ecology.

Differences can exist between coastal and non-coastal waters that could affect the relationship between FIB levels and adverse health effects, including the type of fecal source impacting the waterbody and the differences in fate and transport of pathogens and FIB in the receiving waters. For example, POTW effluents are a continual loading event, whereas fecal contamination from other sources, particularly non-point sources, occurs primarily during precipitation events. Pathogens and FIB in rain event-driven fecal loadings could be affected by the different transport characteristics in coastal versus non-coastal waters.

Epidemiological studies in non-coastal waters.
EPA also evaluated the available epidemiological evidence in non-coastal waters. Only a handful of studies have been conducted in small lakes and even fewer in inland flowing waters. Among those, one of the epidemiological sites for earlier EPA studies (Dufour 1984) was a small inland lake in Oklahoma, which helped provide the basis for the 1986 criteria.

Ferley et al. (1989) conducted a retrospective study in the French Ardèche basin to assess the relationship between swimming-related morbidity and the bacteriological quality of the recreational water. Tourists (n = 5737) in eight holiday camps were questioned about the occurrence of illness and their bathing habits during the week preceding the interviews. GI illness was higher in swimmers than in non-swimmers. Fecal streptococci (FS) were best correlated to GI illness. Direct linear regression models and FC did not predict risk as well. The concentration of FS above which bathers exhibited higher illness rates than non-bathers was as 20 FS per 100 mL.

A series of RCT epidemiological studies was conducted in Germany to establish the association of illness with recreational use of designated fresh recreational waters (four lakes and one river) (Wiedenmann et al., 2006). All study sites were considered to be in compliance with the European standards for total coliform and FC for at least the three previous bathing seasons. Sources of fecal contamination at the study sites included treated and untreated municipal sewage, non-point source agricultural runoff, and fecal contamination from water fowl. Based on the water quality measured as levels of *E. coli*, enterococci, somatic coliphages, or *Clostridium perfringens*, and observed health effects, the authors recommended guideline values for each of these fecal indicator organisms. They noted that these values for *E. coli* and enterococci were consistent with EPA's 1986 criteria for recreational water recommendations.

Epibathe, a public health project funded under E.U. Framework Programme 6 to produce "science support for policy" began in December 2005 and ended in March 2009. The imperative for this research effort was the relative paucity of E.U. data describing the health effects of controlled exposure (head immersion) in E.U. fresh waters and Mediterranean marine waters. Both aquatic environments provide important recreational resources throughout the E.U. (European Commission-Epibathe, 2009). Epibathe comprised a series of marine and fresh recreation water epidemiological studies conducted in 2006 and 2007 in Spain and Hungary, respectively. Four riverine recreational sites were assessed in Hungary and four coastal sites were assessed in Spain. All sites were in compliance with the European standards specified in the E.U. bathing Water Directive (EP/CEU, 1976). For E.U. marine waters (Spain and the U.K. RCT studies), the clearest trend in increasing risk of illness with decreasing water quality was evident using enterococci as an indicator of water quality. For fresh waters (German and Hungary RCT studies), the clearest indicator-illness relationship between GI symptoms and water quality was seen with *E. coli*. Both analyses (fresh waters and marine waters) suggest elevations in GI illness in the controlled exposure (head immersion) cohorts. The authors concluded that the empirical field studies and combined data analysis suggested that the WHO or E.U. water quality standard recommendations did not need to be revised. Additionally, EPA concluded that these results provide further evidence that the E.U.-recommended *E. coli* and enterococci guidelines values are consistent with the 1986 criteria for recreational waters.

A PC study was recently conducted at a small inland lake in Ohio (Marion, 2010). The study was undertaken to examine the illness rates among inland recreational water users. It also evaluated the effectiveness of *E. coli* as an effective predictor of GI illness risk among recreators. Human health data were collected during the 2009 swimming season at East Fork Lake, Ohio and adverse health outcomes were reported 8–9 days post-exposure. The authors concluded that *E. coli* was significantly associated with elevated GI illness risk among swimmers compared to non-swimmers. The risk of illness increased among swimmers with increasing densities of *E. coli*. The results of this study were consistent with prior fresh water beach studies used by EPA to develop the 1986 criteria for recreational waters.

Based on the best available information, which is summarized above, EPA has determined that the 2012 RWQC recommendations are applicable to coastal and non-coastal waterbodies. Although some differences may exist between coastal and non-coastal waters, application of the recommended criteria in both water types would constitute a prudent approach to protect public health. States wishing to address site-specific conditions or local waterbody characteristics in their WQS should refer to section 5 of this document for suggestions on approaches.

3.5 Sources of Fecal Contamination

In the 1986 criteria, EPA recommended:

> "the application of these criteria unless sanitary and epidemiological studies show the sources of the indicator bacteria to be nonhuman and that the indicator densities are not indicative of a health risk to those swimming in such waters. EPA is sponsoring research to study the health risk of non-point source pollution (NPS) from rural areas on the safety of water for swimming. Definitive evidence from this study was not available at the time of preparation of this criterion, but will be incorporated into subsequent revisions."

Section 303(i)(2)(A) required EPA to promulgate criteria for States as protective of human health as EPA's 1986 criteria where States had failed to do so for their coastal and Great Lakes waters. When EPA promulgated WQSs for those States based on the 1986 criteria in 2004, EPA evaluated the scientific understanding of the human health risks associated with nonhuman sources of fecal contamination and concluded that although "[the] EPA's scientific understanding of pathogens and pathogen indicators has evolved since 1986, data characterizing the public health risk associated with nonhuman sources is still too limited for the [EPA] to promulgate [WQSs for States based on] another approach." Thus, the federally promulgated criteria values in the Rule were considered applicable regardless of origin unless a sanitary survey shows that the sources of the indicator bacteria are nonhuman and an epidemiological study shows that the indicator densities are not indicative of a human health risk. In addition, in evaluating whether

State standards were as protective of human health as EPA's 1986 criteria, EPA concluded that State WQSs with exemptions for non-human sources were not as protective of human health as EPA's 1986 criteria (See 69 FR at 67228).

EPA has continued to examine the potential for illness from exposure to nonhuman fecal contamination compared to the potential for illness from exposure to human fecal contamination. One of the key topics discussed at the *Experts Scientific Workshop on Critical Research Needs for the Development of New or Revised Recreational Water Quality Criteria* (U.S. EPA, 2007a) was different sources of FIB, including human sources and a variety of nonhuman sources (such as animals and the environment). EPA further investigated this topic in *Review of Published Studies to Characterize Relative Risks from Different Sources of Fecal Contamination in Recreational Waters* (U.S. EPA, 2009b) and *Review of Zoonotic Pathogens in Ambient Waters* (U.S. EPA, 2009a). EPA recognizes the public health importance of waterborne zoonotic pathogens. However, the state of the science has only recently allowed for the characterization of the potential health impacts from recreational exposures to zoonotic pathogens relative to the risks associated with human sources of fecal contamination. Overall, however, the aforementioned reviews indicate that both human and animal feces in recreational waters pose potential threats to human health, especially in immunocompromised persons and subpopulations. For additional information, see Appendix C.

Humans can become ill from exposure to zoonotic pathogens in fecal contamination originating from animal sources. Livestock and wildlife carry both human pathogens and FIB, and can transmit these microbes to surface waters and other bodies of water (CDC, 1993, 1996, 1998, 2000, 2002, 2004, 2006, 2008; USDA, 2000). Additionally, many documented outbreaks of potential zoonotic pathogens, such as *Salmonella*, *Giardia, Cryptosporidium*, and enterohemorrhagic *E. coli* O157:H7, could be of either human or animal origin, although providing proper source attribution for these outbreaks can be quite difficult. U.S. Centers for Disease Control and Prevention (CDC) reports have documented instances of *E. coli* O157:H7 infection resulting from exposure to surface waters, but the source of the contamination is not specified (CDC 2000, 2002). Other studies have linked recreational water exposure to outbreaks caused by potentially zoonotic pathogens, but the sources of fecal contamination in these waters were not identified (Valderrama, 2009; Roy, 2004; U.S. EPA 2009a). Although formal surveillance information is not comprehensive, Craun et al. (2005) estimated that 18 percent of the 259 recreational water outbreaks reported to the CDC from 1970 to 2000 were associated with animals.

One study documenting a 1999 outbreak of *E. coli* O157:H7 at a lake in Vancouver, Washington suggested that duck feces were the source of the pathogen causing the outbreak (Samadpour, 2002). More than 100 samples of water, soil, sand, sediment, and animal feces were collected in and around the lake and tested. *E. coli* O157:H7 was detected in both water and duck fecal samples. Genetic analyses of the *E. coli* isolates demonstrated similar results in the water, duck feces, and patient stool samples. Duck feces could not be confirmed as the primary source of the zoonotic pathogens, however, because the ducks could have been infected by the same source of contamination that was present in the lake. Other notable outbreaks are discussed in the EPA's *Review of Published Studies to Characterize Relative Risks from Difference Sources of Fecal Contamination in Recreational Water* (Appendix C and U.S. EPA, 2009b).

Fecal contamination from nonhuman sources can transmit pathogens that can cause GI illnesses, such as those reported in EPA's NEEAR and other epidemiological studies. The potential human health risks from human versus non-human fecal sources, for a given level of water quality as measured by FIB, can be different, with certain non-bovine fecal sources potentially posing less risk (Soller et al. 2010b. and Schoen and Ashbolt, 2010).

Although EPA's research indicates that the source of contamination is critical for understanding the human health risk associated with recreational waters, there is variability in the amount of human health risk in recreational waters from the various fecal sources due to the wide-ranging environmental conditions that occur across the United States. EPA and others have documented human health impacts in numerous epidemiological studies in fresh waters and marine waters primarily impacted by human sources of fecal contamination (see sections 3.2 and 3.4 for a discussion of these studies). The cause of many of the illnesses, particularly those resulting from exposure to POTW effluent, is thought to be viral (USEPA, 1986, Soller et al., 2010a, Bambic et al., 2011).

While human sources of fecal contamination are fairly consistent in the potential human health risks posted during recreational exposure, non-human sources of fecal contamination, and thus the potential human health risks, can vary from site-to-site depending on factors such as: the nature of the non-human source(s), the fecal load from the non-human source(s), and the fate and transport characteristics of the fecal contamination from deposition to the point of exposure. Nonhuman fecal sources can contaminate recreational bodies of water via direct fecal loading into the body of water, and indirect contamination can occur via runoff from the land. The fate and transport characteristics of the zoonotic pathogens and FIB present under these conditions can be different (e.g., differences in attachment to particulates or differences in susceptibility to environmental parameters affecting survival) (see Appendix C.4). For more information on pathogenic risks from nonhuman sources, see *Review of Zoonotic Pathogens in Ambient Waters* (U.S. EPA, 2009a). EPA did not develop nationally applicable criteria values that adjust for the source of the fecal contamination, for non-human sources. Rather, EPA recommends that States use these nationally applicable criteria in all waters designated for primary contact recreation.

Few epidemiological studies have been conducted in waters impacted by nonhuman sources of fecal contamination resulting in an ambiguous understanding of the relationship between swimmer-associated illness and any of the conventionally enumerated FIB in those types of waters. For example, Calderon (1991) found a lack of a statistical association between swimmers' illness risk and FIB levels in a rural fresh waterbody impacted by animal fecal contamination; however, other researchers have commented that this lack of statistical association was likely due to the small study size and not a lack of potential human health risks (McBride, 1993). Another epidemiological study conducted at a nonhuman, nonpoint source impacted beach at Mission Bay, California documented an increase in diarrhea and skin rash in swimmers versus non-swimmers, but the incidence of illness was not associated with any of the traditional FIB levels tested (Colford, 2007). The few studies conducted in non-POTW-impacted waters that also report significant health effects (McBride et al., 1998; Cheung, 1990; and Wiedenmann 2006) have (1) been conducted in highly animal-impacted scenarios, and (2) epidemiological data from beaches with nonhuman fecal source impacts combined with data from beaches impacted by human fecal contamination sources. McBride et al. (1998) conducted a separate analysis of the impact on human sources versus the impact of animal sources on beach sites in addition to evaluating the effects of both human and animal sources combined and concluded that illness risks posed by animal versus human fecal material were not substantially different. Thus, waterbodies with substantial animal inputs can result in potential human health risks on par with those that result from human fecal inputs.

Microbial risk assessment approaches are available to assist in characterizing potential human health risks from nonhuman sources of fecal contamination (Till and McBride, 2004, Roser et al., 2006, Soller et al., 2010b, Schoen and Ashbolt, 2010). For example, New Zealand, where roughly 80 percent of the total notified illnesses are zoonotic and potentially waterborne, recently updated its recreational fresh water guidelines based on a risk analysis of campylobacteriosis (accounting for over half of the reported total notifiable disease burden in that country) and using *E. coli* as a pathogen indicator (Till and McBride, 2004). Since those waters were highly impacted by fecal contamination, in this case from agricultural sources, a predictable relationship between the pathogen and the FIB was able to be developed. The correlation between the occurrence of *Campylobacter* and *E. coli* may not hold in all waters, but this relationship was demonstrated in New Zealand, particularly in waters with high levels of *Campylobacter* and *E. coli*. Water quality guidelines based on this work resulted in values for *E. coli*, which when compared at similar estimated illness levels, are consistent with the 2012 RWQC recommendations.

EPA determined that the current scientific understanding of the human health risks associated with the wide variation of exposures to nonhuman fecal contamination is insufficient to support development of separate nationally applicable 2012 RWQC for waterbodies impacted by nonhuman sources. The risk presented by fecal contamination from nonhuman sources varies and, has been shown in some cases, to be potentially less significant than the risk presented by fecal contamination from human sources (Soller et al., 2010a,b; Schoen and Ashbolt, 2010, Bambic et al., 2011). The number of cases where animals are suspected as being the likely cause of the contamination and resulting illness, however, present a strong case for not neglecting these sources altogether. EPA's research indicates that some nonhuman fecal sources (cattle in particular) may pose risks comparable to those risks from human sources; not all animal fecal material, however, presents the same level of risk (see Appendix C for additional details; Soller et al., 2010a,b; U.S. EPA, 2010a). Human pathogens are present in animal fecal matter, and there is, therefore, a potential risk from recreational exposure to human pathogens in animal-impacted waters. EPA feels that the state of the science is not developed sufficiently for quantifying potential human health risks from non-human fecal contamination on a national basis given the site-to-site variability. For waters predominated by non-human sources and in the absence of site-specific criteria, EPA recommends that the national criteria should be used to develop WQS.

For these reasons, EPA has concluded that States adopting the 2012 RWQC, regardless of the source of fecal contamination, would result in WQSs protective of public health. EPA is not developing separate national criteria for nonhuman sources. States interested in addressing the potential human health risk differences from different sources of fecal contamination on a site-specific basis should refer to section 5.2.2 of this document for suggestions on approaches.

3.6 Expression of Criteria

In 1986, EPA recommended criteria for enterococci and *E. coli* that contain two components: a GM and an SSM. The 1986 criteria values were derived from separate beach water quality datasets that were averaged over the entire summer swimming season, as part of EPA's epidemiological studies conducted during the 1970s and 1980s. The GM is calculated as the antilog of the arithmetic mean of the log-transformed densities (Wymer and Wade, 2007). The SSM densities are based on the upper percentiles of the water quality distribution around the GM. Together, the GM and SSM describe a water quality distribution that would be protective of primary contact recreation, based on the epidemiological studies conducted at that time. Because the GM and SSM are components of the same water quality distribution, they are anchored to the same illness rate (e.g., 8 HCGI per 1,000 recreators).

The two components, however, serve different purposes for different CWA programs. For beach management, the SSM is given as a value that should not be exceeded, allowing States to determine when to make timely public notifications (i.e., advisories or closings). The 1986 criteria expression contains four different SSM values, corresponding to the 75th, 82th, 90th, and 95th percentile confidence levels. EPA recommended using different SSM percentiles based on a waterbody's use intensity. For NPDES or State permitting programs, water quality-based effluent limitations (WQBELs) for dischargers are to be calculated in accordance with 40 CFR §122.45, which requires WQBELS for continuous dischargers to be expressed as short-term (such as daily or weekly) and long-term (monthly) limits. These effluent limitations would be derived from the State's WQS which, if it is consistent with EPA's recommendations would include both a GM and an SSM value. When identifying those waters for which existing effluent limitations are not stringent enough to meet recreational WQS (i.e., determining attainment status) states, with standards consistent with EPA's 2012 RWQC recommendations, would use both the GM and SSM. Two clarifications to the 1986 criteria expression for determining attainment status for CWA §303(d) and §305(b) purposes using the GM and SSM are described below.

First, the 1986 criteria GM was meant to be compared to the calculated GM of the waterbody being assessed, using at least five samples taken over a 30-day period. As stated in the preamble to EPA's promulgation of WQS for States in 2004 the GM is the more relevant value for protecting water quality because it is a more reliable measure and more directly linked to the underlying studies on which the 1986 criteria are based. However, the 2004 preamble also states that "EPA intends that States and Territories should retain discretion to use single sample maximum values as they deem appropriate in the context of Clean Water Act implementation programs other than beach notification and closure, consistent with the Clean Water Act and its implementing regulations (U.S. EPA, 2004)."

Secondly, if SSM's values are interpreted to be "never to be exceeded" values for assessing a waterbody, the resulting water-quality standard is much more stringent than needed to protect the designated use of primary contact recreation if the GM were used. For example, a marine body of water that is in compliance with the 1986 criteria for enterococci (i.e., GM = 35 cfu per 100 mL; estimated 75th percentile = 104 cfu per 100 mL) would have a water-quality distribution such that 25 percent of the samples taken would be higher than 104 cfu per 100 mL. For a body of water to meet 104 cfu per 100 mL as a "never to be exceeded" value, the GM of that body of water would need to be extremely low.

In the 2012 RWQC, to ensure public health protection and to minimize inconsistencies in the interpretation or application of the statistical construct, EPA is recommending that the criteria magnitude be expressed using two components: the GM and the estimated 75th percentile STV. The recommended GM and STV (essentially the STV represents a renaming of the previous SSM) values are described below.

The GM for a waterbody should be calculated in the same way it was calculated for the 1986 criteria: 1) take the $\log_{10}$ of the samples under consideration,[6] 2) average those values, and 3) raise that average to the power of 10. It is important to note that EPA' recommendations no longer include a recommendation to calculate the GM criterion over a period of 30 days. Epidemiological data, from which these criteria are derived, were evaluated on a seasonally basis. Thus, EPA recommends States to select a duration for both the GM and the STV between 30 days and 90 days. The duration for calculating the GM and associated STV should not exceed 90 days. The duration should be explicitly included in the State's WQS, as it is a component of the WQS. Including more samples in calculation of the GM and STV improves the accuracy of the characterization of water quality. If States decide to use a duration that is shorter than 90 days for the purposes of calculating waterbody GMs, please be aware that smaller number of samples increases the chance of misclassification and careful consideration will be needed to properly interpret multiple GM estimates (see Section 3.6.3).

Identical to the derivation of the SSM in the 1986 criteria document, the STV corresponds to an upper percentile (e.g., 75th percentile) of a water-quality distribution around the 2012 RWQC's GM. EPA is recommending the STV in the 2012 RWQC, rather than an SSM, to resolve previous inconsistencies in implementation and to ensure

[6] For data points reported below detectable limits, the GM calculation should based on the assumption that those observations were present at the detection limit.

that both components of the 2012 RWQC (i.e., the GM and STV) are equivalently stringent. Since FIB are highly variable in environmental waters and generally are well represented by a $\log_{10}$ normal distribution (Bartram and Rees, 2000, Wyer et al., 1999, Kay et al., 2004), distributional estimates are more robust than single point estimates. In addition, EPA is no longer recommending multiple "use intensity" values to ensure equivalent public health protection in all waters. This section clarifies how a WQS that includes a GM and STV should be used and evaluated for various CWA purposes. EPA believes that in order to be consistent with EPA's recommended criteria; the criteria in a State WQS need to include both the GM and STV.

The STV represents the estimated 75th percentile of a distribution of water quality as measured by FIB. For the 2012 RWQC, EPA computed the STV based on the observed pooled variance of the FIB data reported in EPA's epidemiological studies. The computed pooled variances represent a wide range of weather conditions because the monitoring was conducted over the full course of the set of epidemiological studies. In computing the observed pooled variance, EPA stratified the data from the epidemiological studies by beach and water depth, since these are known to differ systematically in their respective distributions of FIB (Wade et al., 2008), and computed the variances within each of the resulting strata. The pooled variances from these 14 subsets of the data in effect represent an overall mean variance. For the qPCR method, the pooled variance resulted in a log standard deviation (the standard deviation of the base 10 logarithms of the data) of 0.49 and the pooled variance estimates for culturable FIB that were reported previously (U.S. EPA, 1986). For the STV, EPA selected the estimated 75th percentile to align the beach notification decision-making process with the water-quality attainment criteria (i.e., the 1986 SSM was based on the estimated 75th percentile and beach-management decisions were based on this value).

3.6.1 Use of the STV for Beach Notification

The estimated 75th percentile STV is the recommended value for beach notification purposes (such as advisories and closings). Any single sample above the estimated 75th percentile STV should trigger beach notification until another sample that is below the estimated 75th percentile STV is collected. Additionally, a short-term GM can be useful in the beach advisory context.

3.6.2 Criteria Magnitude, Duration, and Frequency for other CWA Purposes

- Magnitude: GM and the estimated 75th percentile STV regardless of the sample size.
- Duration: For calculating the GM and associated STV, EPA recommends a duration between 30 days and 90 days. The duration for calculating the GM and associated STV should not exceed 90 days. The duration is a component of a water quality criterion and as such would need to be explicitly included in the State's WQS. Sampling of waterbodies should be representative of meteorological conditions (e.g., wet and dry weather). If a State is not sampling during or immediately after a rain event, the State should advise the public to the risks of primary contact recreation.
- Frequency of exceedance:

GM: The GM of a body of water over the duration specified in the standard for calculating a GM should not be higher than the recommended GM criteria value. Therefore, EPA recommends a frequency of exceedance of zero - i.e., no "excursions" – of the GM over the duration specified in the State standard. Like duration, the frequency of exceedance is a component of a water quality criterion and as such would need to be explicitly included in a State's WQS.

STV: EPA recommends that no more than 25 percent of the observations exceed the STV over the duration specified for calculating the STV. This should be computed by multiplying the total number of observations by 0.25. The number of observations above the STV is the whole-number portion of this quotient.

A State's recreational WQS should include a clearly articulated magnitude, duration, and frequency. States may adopt more stringent criteria into their WQSs. For example, it may be appropriate for States to establish a lower frequency of exceedances of the STV based on regional or site-specific circumstances or studies.

NPDES permitting purposes

The NPDES regulations at 40 CFR 122.44(d) require the development of water quality-based effluent limitations (WQBELs) as necessary to attain water quality standards. Under §122.45(d), permit limits for continuous dischargers must include both short- and long-term WQBELs unless there is a specific finding of "impracticability." To derive the required short-term (maximum daily or average weekly) permit limits, EPA recommends that permitting authorities use the more stringent derivation values between the GM and STV. To derive the required long-term (average monthly) permit limits, EPA recommends that permitting authorities use the GM. Once established, pathogen limits for continuous dischargers are applied and enforced in a manner consistent with all other water quality parameters.

For non-continuous or episodic discharges, by comparison, 40 CFR 122.45(e) requires WQBELs to reflect the frequency of discharge; total mass; maximum discharge rate; and prohibition or limitation of specified pollutants by mass, concentration, or other measure. Combined sewer overflows (CSOs) are a key example of these types of discharges. As the paragraph below discusses, EPA's longstanding CSO Policy has recommended various approaches for addressing CSO discharges. The statistical framework underlying EPA's revised water quality criteria recommendations recognizes that a certain number of excursions from the STV criteria value may be permissible. Therefore, in permitting episodic discharges, such as CSOs, it may be appropriate for a permitting authority to authorize a limited number of discharge events that could exceed the STV as long as the permitting authority could demonstrate that the applicable criteria for primary contact uses (STV and geometric mean values) would be maintained in the stream. (As mentioned above, CSOs are episodic discharges that pose particular challenges for water quality-based permitting due to the extreme variability in the volume and quality of overflows. For this reason the 1994 CSO Control Policy (also see section 402(q) of the CWA) provides for expression of WQBELs as performance standards based on average design conditions (e.g., a maximum number of overflow events per year or a minimum percentage capture of combined sewage). The CSO Policy also recommends WQS review and revision, as appropriate, to reflect the site-specific wet weather impacts of CSOs. This review should be coordinated with the development, implementation, and post-construction monitoring associated with an approved long-term CSO control plan. WQS review could involve a use attainability analysis (40 CFR 131.10(g)) and subsequent modification of a designated use -- for example, adoption of a partial or time-limited use for a defined period of time when primary contact recreation does not exist.

Detailed approaches for deriving WQBELs to meet WQS based on EPA's final 2012 RWQC will be further explained in the TSM.

Identification of Impaired and Threatened Waters

Under §303(d) of the CWA and EPA's implementing regulations (40 CFR 130.7), states, territories, and authorized tribes (hereafter referred to as states) are required to develop lists of impaired and threatened waters that require Total Maximum Daily Loads (TMDLs). Impaired waters are those that do not meet any applicable WQS. EPA recommends that states consider as threatened those waters that are currently attaining WQS, but which are expected not to meet WQS by the next listing cycle (every two years). Consistent with EPA recommendation, many states consolidate their §303(d) and §305(b) reporting requirement into one "integrated" report.

For making these water quality attainment determinations, a State that adopts WQSs consistent with the 2012 RWQC, would evaluate all readily available data and information to determine whether a waterbody meets the WQS (i.e., whether the waterbody is in attainment). A WQS that is consistent with EPA's recommended criteria would include both a GM and an STV, and all three components of a WQS (e.g., magnitude, duration, and frequency) for both the GM and the STV. Both the GM and the STV apply independently and would need to be evaluated to determine whether or not water quality in a given waterbody meets the WQS for primary contact recreation. The waterbody condition would need to be evaluated based on all existing and readily available data and information for the specified duration. EPA's regulations define "all existing and readily available water quality related data and information" at 40 CFR 130.7(b)(5). EPA expects that water quality attainment determinations would include water quality monitoring data collected as part of a beach monitoring program, as well as information regarding beach closures and advisories.

3.6.3 Practical Considerations for Applying the Criteria

The number of samples is not an approvable element of a WQS, therefore states should not include a minimum sample size as part of their criteria submission. The recommendations and information provided in this section can be used when identifying sampling frequency as part of a state's monitoring plan.

Typically, a larger dataset will more accurately characterize the water quality in a waterbody, resulting in more meaningful attainment determinations (Table 3 and Figure 5). Therefore, EPA is recommending that states conduct weekly sampling to calculate a

GM over a 30 to 90 day period. This recommendation is consistent with global recommendations for recreational water management (WHO, 2003; E.U. 2007; MFE 2003). EPA's analysis indicates increasing the number of samples when calculating a GM from the typical monthly regime of 4 or 5 samples to the recommended 90 day basis of 12 to 15 samples will reduce waterbody misclassification from both Type I (false positive) and Type II (false negative) errors with respect to attainment status based on the computed GM (Table 3 and Figure 5). For example, compared to GMs based on four samples (logsd=0.7), the predicted level of waterbody misclassification for 15 samples is reduced by 50 percent for a simulated waterbody with GM of 30 cfu per 100 mL (from 34 percent to 17 percent) and 98 percent for a simulated waterbody with GM of 60 cfu per 100 mL (from 10 percent to 0.2 percent). Although waterbody misclassification can occur even with large datasets (e.g., 60 samples or more), the likelihood of waterbody misclassification is highest when the GM is based on a small number of samples (Figure 5).

Table 3. Sample size influences the likelihood of misclassification.[1]

Number of Samples	Actual Geometric Mean[2] (cfu enterococci per 100 ml)			
	25	30	45	60
4	20.3%	34.6%	25.0%	10.0%
5	14.0%	31.0%	21.1%	4.0%
12	5.3%	22.0%	9.7%	0.2%
15	3.4%	17.4%	8.6%	0.2%

[1]Falsely being determined as above or below the limit (35 GM), when in fact the true GM is below (GM=25 and 30) or above (GM=45 and 60).
[2] Actual GM is the GM of a simulated waterbody (with logsd=0.7).

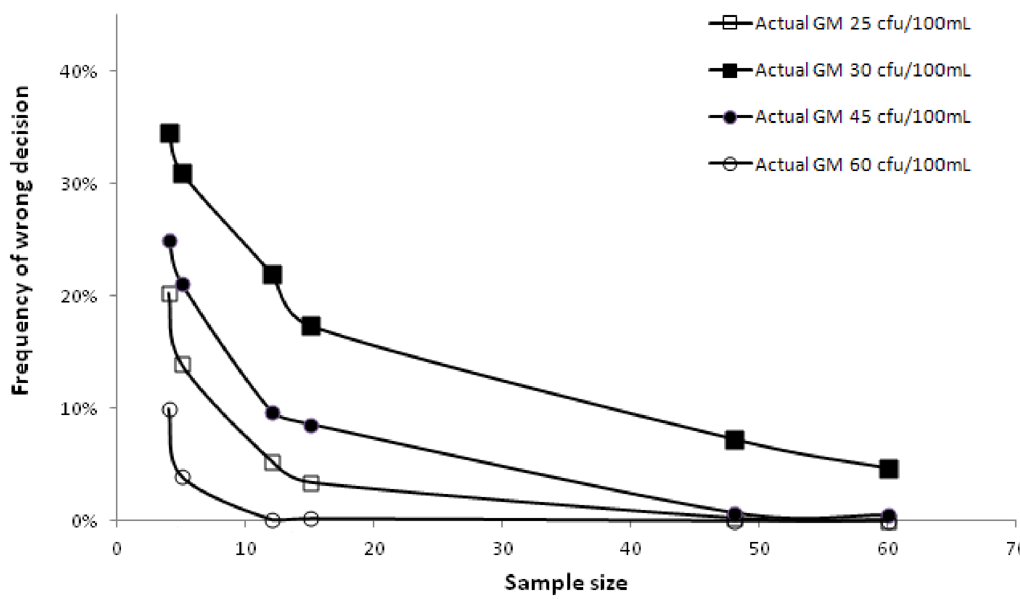


Figure 5. Likelihood of misclassification as a function of sample size.
(Graphical representation of data in Table 3**)**

4.0 Recreational Water Quality Criteria

EPA evaluated the available data and determined that the designated use of recreation would be protected if the following criteria were adopted into State WQS:

(a) <u>Fresh water criteria</u>

Magnitude: Culturable *E. coli* at a GM of 126 cfu per 100 mL and an STV of 235 cfu per 100 mL measured using EPA Method 1603, or any other equivalent method that measures culturable *E. coli*; culturable enterococci at a GM of 33 cfu per 100 mL and an STV of 61 cfu per 100 mL measured using EPA Method 1600 (U.S. EPA, 2002b), or any other equivalent method that measures culturable enterococci; or both of the above criteria. EPA believes that in order to be consistent with EPA's recommended criteria, the criteria in a State WQS need to include both the GM and STV.

Duration: For calculating the GM and associated STV, EPA recommends a duration between 30 days and 90 days. The duration for calculating the GM and associated STV should not exceed 90 days. The duration is a component of a water quality criterion, and as such, would need to be explicitly included in the State's WQS. Sampling of waterbodies should be representative of meteorological conditions (e.g., wet and dry weather). If a State is not sampling during or immediately after a rain event, the State should advise the public to the risks of primary contact recreation.

Frequency: EPA recommends a frequency of zero exceedances of the GM and ≤ 25 percent exceedance of the STV, over the duration specified for calculating the GM and STV. The frequency of exceedance is a component of a water quality criterion, and as such, would need to be explicitly included in State's WQS.

(b) <u>Marine criteria</u>

Magnitude: Culturable enterococci at a GM of 35 cfu per 100 mL and an STV of 104 cfu per 100 mL measured using EPA Method 1600, or any other equivalent method that measures culturable enterococci. EPA believes that in order to be consistent with EPA's recommended criteria, the criteria in a State WQS need to include both the GM and STV.

Duration: For calculating the GM and associated STV, EPA recommends a duration between 30 days and 90 days. The duration for calculating the GM and the associated STV should not exceed 90 days. The duration is a component of a water quality criterion, and as such, would need to be explicitly included in the State's WQS. Sampling of waterbodies should be representative of meteorological conditions (e.g., wet and dry weather). If a State is not sampling during or immediately after a rain event, the State should advise the public to the risks of primary contact recreation.

Frequency: EPA recommends a frequency of zero exceedances of the GM and ≤ 25 percent exceedance of the STV, over the duration specified for calculating the GM and STV. The frequency of exceedance is a component of a water quality criterion, and as such, would need to be explicitly included in State's WQS.

EPA has also developed a qPCR method to detect and quantify enterococci more rapidly than the culture method. Enterococci as measured by EPA *Enterococcus* qPCR method A has shown a strong relationship to GI illness in the recent EPA NEEAR epidemiological studies compared to other methods tested (Wade et al., 2008; U.S. EPA, 2010d). Introduction of EPA *Enterococcus* qPCR method A is anticipated also to provide increased public health protection by permitting timely notification[7] to swimmers of levels of FIB that exceed the site-specific criteria value. While the fresh water Great Lakes and temperate marine water NEEAR studies resulted in minimal to no inhibition, it is EPA's goal to publish RWQC recommendations that can be recommended nationally. Given the current state of knowledge regarding the performance of qPCR methods under varied waterbody conditions and the limited experience of its use in the field, EPA encourages a site-specific assessment of the method's performance before it is adopted into State WQS for implementation in beach monitoring programs.

For the purposes of beach monitoring, alternative site-specific criteria could be adopted into State standards measured by EPA's *Enterococcus* qPCR method A based on a site-specific performance characterization. This method is not recommended for NPDES permitting. A "site" may be a beach, a waterbody, or a particular watershed that is anticipated to have uniform qualities throughout. As States adopt water-quality standards for enterococci, as measured by EPA's *Enterococcus* qPCR method A, they will gain experience with the qPCR method and better understand how this method performs in their waters. Considerations for determining how qPCR could be used to develop site-specific criteria will be provided in additional TSM. For States interested in adopting a value for enterococci using EPA's *Enterococcus* qPCR method A into their WQS, EPA recommends a GM criterion of 475 CCE per 100 mL and an STV criterion of 1,000 CCE per 100 mL in freshwaters and marine waters based on its epidemiological study data.

Because this document only includes supplementary information about how States may adopt water-quality standards on a site-specific basis for enterococci as measured by qPCR, the 2012 RWQC recommendations are not "applicable" to that pathogen indicator (i.e., enterococci as measured by qPCR). Therefore, the inclusion of qPCR-related information in this document does not trigger the requirement in CWA §303(i) that States adopt water-quality standards "for all pathogens and pathogen indicators to which the new or revised WQC are applicable" for their coastal recreational waters.

[7] See section 5.2.1 for a discussion on the use of predictive models as an additional approach for achieving timely notification.

5.0 Tools to Support States and Tribes in Managing Recreational Waters and for Considering Alternate Water Quality Criteria

EPA's implementing regulations for §303 of the CWA provide that "states must adopt those WQC that protect the designated use. Such criteria must be based on sound scientific rationale and must contain sufficient parameters or constituents to protect the designated use." (40 CFR §131.11(a)). EPA's regulations stated in 40 CFR §131.11(b)(1) provide that "In establishing criteria, States should (1) Establish numerical values based on (i) 304(a) Guidance; or (ii) 304(a) Guidance modified to reflect site-specific conditions; or (iii) Other scientifically defensible methods." WQS can be established for waterbodies, or a portion of a water body and therefore they could be established for a specific site, such as a waterbody adjacent to a beach or the entire water body that is anticipated to have uniform qualities throughout. When EPA reviews State WQSs for approval or disapproval under the CWA, EPA must ensure that the WQC in the standard (regardless of whether they are "site-specific") are scientifically defensible and protective of the designated use.

The tools discussed in this section fall into two main categories: (1) tools that States can use to enhance public health protection when implementing state WQS for primary contact recreation; and (2) tools that can be used by States in the development of WQC that differs from EPA's recommended criteria ("alternate criteria"). Alternate criteria could be developed to reflect site-specific conditions, or they could be developed using different indicators and analytical methods. State WQS that include alternate criteria would need to be scientifically defensible and protective of the use. These tools reflect currently available scientific information, can be utilized to assist in the assessment and management of recreational waters (see section 5.1), and have the potential to be used in the development of site-specific criteria (see section 5.2). Site-specific criteria are based in part on assumptions regarding the current state of a watershed such as current land uses, and should be revisited no less frequently than triennially to ensure the site-specific criteria remains protective of the primary contact recreation use. This section does not provide details on how to implement these tools. Additional, detailed information on these tools will be provided in TSM.

The tools discussed below (and the corresponding subsections) are (1) sanitary surveys (5.1.1); (2) predictive models (5.1.2); (3) epidemiological studies (5.2.1); (4) quantitative microbial risk assessment (QMRA) (5.2.2); and (5) approaches for developing criteria using alternative fecal indicators and/or methods (5.2.3).

5.1 Tools for Assessing and Managing Recreational Waters

EPA recognizes that advancements have been made since the publication of the 1986 criteria in the area of managing recreational waters. This section discusses tools that States can use to enhance public health protection. These tools can aid in the identification of days of poor water quality on a site-specific basis. Specifically, this section discusses the use of sanitary surveys as a tool for identifying sources of fecal contamination and identifying and prioritizing clean-up/remediation actions for a specific body of water and the use of predictive models for timely beach notification. EPA encourages the use of sanitary surveys and predictive models, specifically by beach managers, to better understand and potentially control sources of fecal contamination and pathogens. EPA also encourages the use of predictive models to supplement a sound monitoring program that has the potential to prevent human exposure on days of poor water quality. Together, the tools in this section have the potential to allow a State or locality to assess and communicate the risks associated with fecally contaminated recreational waters. These tools are not a part of the adopted WQSs and do not result in different numerical criteria value(s).

5.1.1 Sanitary Survey

Beach managers often use sanitary surveys to assess beaches for fecal contamination and to prioritize clean-up and remediation efforts. Beach sanitary surveys involve collecting information at the beach, as well as in the surrounding watershed. Information collected at the beach may include the following: proximity to septic systems, number of birds at the beach, slope of the beach, location and condition of bathrooms at beach facilities, and amount of algae on the beach. Information collected in the watershed may include the following: land use, location of storm water outfalls, surface water quality, and residential septic tank information.

Sanitary surveys are a “snapshot” of the conditions at a beach, which can change due to factors including those listed above. Sanitary surveys help State and local beach program managers and public health officials identify sources of beach water pollution, assess the magnitude of pollution, and designate priority locations for water testing. In conjunction with monitoring to determine whether a waterbody is meeting State WQS for recreation, they can use sanitary survey data (such as bacteria levels, source flow, turbidity, and rainfall) to develop models to predict bathing beach water quality using readily available data. Other information, such as source tracking and watershed information may be needed to effectively delineate sources within the watershed.

EPA has developed documents on sanitary surveys for the purpose of supplementing the 2012 RWQC recommendations. These documents are available on the website: http://water.epa.gov/type/oceb/beaches/sanitarysurvey_index.cfm, as well as in *Great Lakes Beach Sanitary Survey User Manual* (U.S. EPA, 2008). EPA plans to include detailed information on developing and using sanitary surveys in its upcoming beach guidance and other TSM (see Appendix D).

5.1.2 Predictive Models

EPA recognizes that, at some locations and under some conditions, implementation of a rapid enumeration methodology, such as the qPCR-based method described previously in this document, is not feasible or is unlikely to provide sufficiently timely information for making a same-day beach notification decision (for example, in locations where water samples cannot be transported to the appropriate laboratory facilities for analysis in a timely manner). EPA is therefore providing an approach that may supplement the current culture-based analytical results to facilitate same-day public health decisions. EPA encourages the use of predictive models in these situations to allow timely notification at beaches. Typically, States would use these and site-specific predictive models, such as statistical models, rainfall threshold levels, and notification protocols (U.S. EPA, 2010b, 2010c), to supplement monitoring using culture-based methods. The models would not themselves be a part of State' WQS.

Predictive models that are currently employed in areas such as the Great Lakes have proven to be effective. These models draw on existing culture-based monitoring data bases, are inexpensive to use, and allow for a rapid, proactive beach management decisions (U.S. EPA, 2010b,c). They provide a means to supplement monitoring and support rapid notification.

EPA has conducted research and published a two-volume report to advance the use of predictive models (U.S. EPA, 2010b,c). Volume I summarizes the current uses of these predictive tools to provide model developers with the basic concepts for developing predictive tools for same-day beach notifications at coastal marine waters, the Great Lakes, and inland waters (U.S. EPA, 2010b). Volume II provides the results of research conducted by EPA on developing statistical models at research sites. It also presents Virtual Beach, a software package designed to build statistical multivariate linear regression predictive models (U.S. EPA, 2010c; see Appendix D). EPA is also expanding the Virtual Beach tool so that it will include other statistical approaches besides multiple linear regression. Techniques such as recursive partitioning (especially a technique called the Gradient Boosting Method [GBM] that involves usage of multiple decision trees) are promising. Artificial neural networks, binary logistic regression, and partial least-squares techniques also are being added. Beyond these improvements in Virtual Beach, other efforts such as linking watershed and statistical models, Cyterski's temporal synchronization approach to incorporate time lags, and process-based transformations are being pursued to improve predictive modeling efforts.

The types of predictive tools that can be used to make beach notification decisions fall into the following categories: statistical regression models, rainfall-based notifications, decision trees or notification protocols, deterministic models, and combinations of tools.

- A statistical regression model is a general term for any type of statistical modeling approach used to predict beach water quality. A statistical correlation (for example, one established using multivariate linear regression techniques) is observed between FIB and environmental and water quality variables that are easier to measure than FIB. Typical variables include meteorological conditions (such as solar radiation, air temperature, precipitation, wind speed and direction, and dew point), water quality (such as turbidity, pH, conductivity/salinity, and ultraviolet [UV]/visible spectra), and hydrodynamic conditions (such as flows of nearby tributaries, magnitude and direction of water currents, wave height, and tidal stage).
- Rainfall-based notifications are based on a rain threshold level, which is a predictive tool that can be used when a connection exists between the

concentration of FIB at a beach and the amount of rain received in nearby areas. That relationship can be quantified as the amount or intensity of rainfall (i.e., the threshold level) that is likely to cause an exceedance of the WQSs at a beach, and the length of time over which the standards will be exceeded.

- Decision trees or notification protocols are a series of questions that can also be used to consider factors such as rainfall to guide beach notifications. Such evaluations use water quality sampling, rainfall data, and other environmental factors that could influence FIB levels (such as proximity to pollution sources, wind direction, visual observations, or other information specific to the region or beach). This process is referred to as developing a notification protocol.
- Deterministic models use mathematical representations of the processes that affect bacteria densities to predict exceedances of WQSs. They include a range of simple to complex modeling techniques.

There are various considerations for developing each of these model types for beaches and each has its own set of challenges (Boehm et al., 2007). To be effective, these predictive models should be sufficiently calibrated to reflect site-specific conditions and account for inter-seasonal variations, if applicable. Predictive models are intended for use as a rapid beach notification tool only. They do not replace the need for a sound monitoring program, and the development of predictive models requires monitoring data both for establishing and maintaining statistical relevance. A State using a site-specific predictive model would still need to evaluate the waterbody in order to determine whether it meets the WQS for purposes of CWA §303(d) listing.

5.2 Tools for Use in Developing Alternative Criteria

As described above, EPA's regulations provide that "States must adopt those water quality criteria that protect the designated use. Such criteria must be based on sound scientific rationale and must contain sufficient parameters or constituents to protect the designated use." 40 CFR 131.11(a). EPA's regulations at 40 CFR §131.11(b)(1) provide that in establishing criteria, States should (1) establish numerical criteria based on (i) EPA's CWA §304(a) guidance; (ii) §304(a) guidance modified to reflect site-specific conditions or, (iii) other scientifically defensible methods. States could adopt site-specific modifications of a §304(a) criterion to reflect local environmental conditions and human exposure patterns. A "site" may signify beach, a waterbody, or a particular watershed, that is anticipated to have uniform qualities throughout. Such site-specific criteria may be adopted into a state WQS as long as the resulting site-specific WQS are scientifically defensible and protective of the use. For example, alternative WQSs may involve the adoption of different numerical value(s) that are based on: (1) the results of an epidemiological study; (2) the results of a quantitative QMRA to account for different sources of FIB; or (3) a different FIB-method combination. To be used for CWA purposes, site-specific criteria would need to be adopted into State WQS and reviewed and approved under CWA §303(c).

EPA believes that the recommended 2012 RWQC, which are derived from and informed by the preponderance of epidemiological evidence in human fecal-impacted waters, would be protective of primary contact recreation. EPA recognizes, however, that the conditions studied in the temperate fresh waters and marine waters by the NEEAR studies (i.e., waters primarily impacted by secondary-treated and disinfected POTW effluent) may not be representative of all possible fecal contamination combinations that could impact recreational bodies of water in the United States. Therefore, this section describes the tools available to support States considering alternate WQS based on other data such as: (1) epidemiological studies, (2) QMRA, and (3) novel fecal indicators and analytical methods.

5.2.1 Epidemiological Studies

EPA's NEEAR epidemiological studies were conducted in water primarily impacted human fecal contamination, including temperate fresh water, temperate marine water, and tropical marine water sites, as well as one temperate marine water site that was impacted by urban runoff (Wade et al., 2006, 2008, 2010; U.S. EPA, 2010d). Statistically significant associations between water quality, as determined using *Enterococcus* measured by qPCR, and reported illness were observed in the temperate marine water and fresh water POTW-impacted beaches. No associations between FIB, enumerated with either culture-based or qPCR-based methods, and reported illness were observed at the beach impacted by urban runoff in Surfside, SC or at the tropical beach in Boquerón, PR.

Local and/or State agencies have conducted, or are considering conducting, epidemiological studies of health risks and water quality at recreational beach sites. For example, epidemiology studies of recreational water exposures have been conducted recently in Southern California (SCCWRP,personal communication, 2010), south Florida (Fleming, 2006; Sinigalliano, 2010), and Ohio (Marion et al., 2010). These studies could be used to confirm EPA's 2012 criteria or to develop site-specific criteria.

Several factors can influence the potential epidemiological relationship between indicator density and relative human health risk. Some of the potentially important factors include the source of fecal contamination, age of the fecal contamination, intensity of solar radiation that the fecal contamination is exposed to, water salinity, turbidity, dissolved organic matter, water temperature, and nutrient content. Numerous factors also affect the occurrence and distribution of FIB and the pathogens from the source of contamination to the receptor location that include, but are not limited to, the following: predation of bacteria by other organisms; differential interactions between microbes and sediment, including the release and resuspension of bacteria from sediments in the water column; and differential environmental effects on indicator organisms versus pathogens. For additional information, see Appendix B.

States or local agencies may choose to conduct epidemiological studies in their waterbodies and use the results from those studies to derive site-specific criteria. To derive scientifically defensible site-specific WQC for adoption into state standards, the epidemiological studies should be of similar quality and of comparable scientific rigor as EPA's NEEAR water studies. The epidemiological information underlying the recommended 2012 RWQC was produced using a study design called "prospective cohort." EPA is unsure at the current time how results from alternate epidemiological study designs can inform site-specific criteria. Significant differences in the study designs, data collection, and analysis methods, exposure, and health outcome measures pose a major challenge to the ability to quantitatively compare the illness rate and water quality relationships in epidemiological studies with significant design differences to the NEEAR studies.

Epidemiological studies are resource intensive and logistically difficult, although the results can provide the data necessary for a scientifically defensible basis to allow the adoption of WQS based on fecal indicator/methods that are not part of EPA's national §304(a) recommendations. First, site-specific epidemiological studies can take into account the characteristics of local waterbodies to support the derivation of a site-specific criteria value based on the fecal indicator/methods that are part of EPA's national §304(a) recommendations. Second, such studies may support the development and adoption of alternative criteria based on different health endpoints, such as respiratory illnesses, than EPA has used in its current recommendations (i.e., GI illnesses). Where the studies demonstrate a statistically significant correlation between levels of water quality measured using particular FIB(s) and adverse health outcomes, they may be scientifically defensible and as such, could be used to develop and adopt alternate criteria.

If a State wishes to develop alternative criteria using their own epidemiological studies, EPA recommends that the studies also be of the PC design, to facilitate the evaluation of the resultant alternative criteria. EPA's TSM will provide additional information on the use of epidemiological studies in development of site-specific criteria.

5.2.2 Quantitative Microbial Risk Assessment and Sanitary Characterization

If a particular waterbody is believed to be predominantly impacted by nonhuman sources, a site-specific criterion may be worth investigating. EPA's research indicates that understanding the predominant source of fecal contamination is critical for characterization of the human health risks associated with recreational water exposure. Various epidemiological investigations, including EPA's have documented human health effects in waters impacted by human fecal contamination. Additionally, QMRA studies have demonstrated that the potential human health risks from human and non-human fecal sources can be different due to the nature of the source, the type and number of pathogens from any given source, as well as, variations in the co-occurrence of pathogens and fecal indicators associated with different sources (Till and McBride, 2004, Roser et al, 2006, Schoen and Ashbolt, 2010, Soller et al., 2010b, Bambic et al, 2011). While human sources of fecal contamination pose similar health risks regardless of location, the differences in predicted human health risks from recreational water exposure to non-human fecal contamination are dependent on local characteristics that will vary from site-to-site. EPA is not recommending nationally-applicable criteria values for recreational waters that account for non-human sources of fecal contamination due to this variability. EPA's nationally applicable criteria values can be used for such waters. However, EPA is making available TSMs for QMRA to assist States in developing equivalent site-specific criteria to account for local scale, non-human sources.

Any alternative WQSs must be scientifically defensible and protective of the use. QMRA is one tool that has been identified as potentially useful for developing alternative criteria by enhancing the interpretation and application of new or existing epidemiological data (Boehm et al., 2009; Dorevitch et al., 2011). Recreational water epidemiological studies describe the risks associated with exposure to fecal contamination as measured by FIB. QMRA can supplement new or existing epidemiological results by characterizing various exposure scenarios, interpreting potential etiological drivers for the observed epidemiological results, and accounting for differences in risks posed by various types of fecal sources. EPA is working to anchor the QMRA framework to existing epidemiological relationships as part of the TSMs.

QMRA applies risk-assessment principles (NRC, 1983) to approximate the consequences from exposure to selected infectious pathogens. To the greatest possible extent, the QMRA process includes the evaluation and consideration of quantitative information; qualitative information, however, is also used when appropriate (WHO, 1999). QMRA can be initiated for a variety of reasons, including, but not limited to, the following:

- to assess the potential for human risk associated with exposure to a known pathogen;
- to determine critical points for control, such as watershed protection measures;
- to determine specific treatment processes to reduce, remove, or inactivate various pathogens;
- to predict the consequences of various management options for reducing risk;
- to determine appropriate criteria (regulatory) levels that will protect individuals and/or populations to a specified risk level or range
- to identify and prioritize research needs; and
- to assist in interpretation of epidemiological investigations.

QMRA methodologies have been applied to evaluate and manage pathogen risks for a range of scenarios, including from food, sludge/biosolids, drinking water, recycled water, and recreational waters. Moreover, risk assessment in general has been used extensively by EPA for decades to establish human health criteria for a wide range of pollutants in water and other media, and microbial risk assessment has been used to inform EPA's policy making for microbiological pollutants in drinking water and biosolids, and by other U.S. and international governmental agencies (e.g., U.S. Department of Agriculture [USDA], U.S. Food and Drug Administration, WHO) to protect public health from exposure to microbiological pollutants in food and water.

For recreational waters, QMRA incorporates a site-specific sanitary characterization and maybe used to determine if a particular waterbody/watershed is predominantly impacted by a source other than human fecal contamination and whether lower relative risk is associated with the contributing source(s) of fecal contamination in that waterbody or watershed (Soller et al., 2010a,b). Site characterization tools (similar to an enhanced sanitary survey) can provide detailed information on the source(s) of fecal contamination in a waterbody and whether the sources are human or nonhuman. EPA developed a

QMRA-specific application of the sanitary survey, hereafter referred to as a site characterization, to capture information directly applicable for the conduct of a QMRA. This site-specific sanitary characterization process will be described in detail in the QMRA TSM.

Where sanitary site characterization work indicates that the predominant source is human, the 2012 RWQC recommendations are scientifically defensible and protective of primary contact recreation. Also, when sources are predominately nonhuman, EPA has concluded the 2012 RWQC would be scientifically defensible and protective of primary contact recreation. Where the sources of fecal contamination are predominantly nonhuman or non fecal, QMRA is a tool that is less resource intensive and more broadly applicable than epidemiological studies. Epidemiological studies have reported ambiguous results in scenarios impacted by nonhuman sources and are impractical in infrequently used waterbodies. However, EPA's QMRA framework, anchored with the newer reported epidemiological relationships, will help facilitate the risk characterization on a site-specific basis.

EPA's recent QMRA research provides new information on fecal contamination from nonhuman sources which, under some circumstances, may be less risky to human health than contamination from human sources (Schoen and Ashbolt, 2010; Soller et al., 2010a,b; U.S. EPA, 2010a). For additional information and case studies of QMRA for recreational waters, see Appendix C. This research demonstrates that different pathogens are expected to cause illness in recreational waters impacted by different sources of fecal contamination. For example, in human-impacted recreational waters, human enteric viruses are expected to cause a large proportion of illnesses (Soller et al., 2010a). In recreational waters impacted by gulls and agricultural animals, such as cattle, pigs, and chickens, other pathogens (such as bacteria and protozoa) would be expected to be the etiologic agents that cause human illness (Roser et al., 2006, Soller et al., 2010b; Schoen and Ashbolt, 2010). Other research also supports the utility of QMRA, such as QMRA conducted for a tropical waterbody (Viau et al., 2011) and the use of QMRA to establish recreational WQC in New Zealand (MFE, 2003).

Moreover, the relative level of predicted human illness in recreational waters impacted by nonhuman sources can vary depending on whether the contamination is direct or via runoff due to a storm event (U.S. EPA, 2010a). For example, when considering a direct contamination scenario in which FIB was assumed to be present at the 1986 criteria levels, predicted GI illness risks associated with exposure to recreational waters impacted by fresh cattle feces were not substantially different from waters impacted by human sources (Soller et al., 2010b). Predicted illness levels in bodies of water that contain FIB at the 1986 criteria levels from land-applied fecal material from cattle (with microbial loading due to runoff from a storm event), however, were approximately 20 times lower than the risk associated with human-impacted water (U.S. EPA, 2010a). These results highlight the potential power of QMRA to inform site-specific criteria.

To derive site-specific criteria that are considered scientifically defensible and protective of the use, QMRA studies should follow accepted practices, rely on scientifically defensible data, and be well documented (Haas et al., 1999; Soller et al., 2004; Schoen and Ashbolt, 2010; MFE, 2003). EPA plans to provide additional guidance on conducting QMRA for the purpose of assessing differences in risk and for the possible derivation of site-specific criteria in a TSM.

5.2.3 Developing Alternative Criteria Based on Novel Indicators or New Analytical Methods, without Site-Specific Epidemiological Studies

EPA anticipates that scientific advancements will provide new technologies for quantifying fecal pathogens or fecal contamination indicators. These newer technologies may provide alternative ways to address methodological considerations, such as rapidity, sensitivity and specificity, and method performance in site-specific situations, but may not be appropriate for all CWA purposes. As new or alternative indicator and/or enumeration method combinations are developed, States may want to consider using them to develop WQC on a site-specific basis. EPA would approve them if the resulting criteria are scientifically defensible and protective of the recreational use. One way such alternate criteria may be demonstrated to be scientifically defensible would be a consistent and predictable demonstration of the enumeration method performance for a proposed site-specific criterion.

Previously, EPA has used the relative performance of enumeration methods to describe a common level of water quality. For example, derivation of the 1986 criteria was fundamentally based on the comparison of enumeration methods for FC, enterococci, and *E. coli*. In that specific case, those comparisons were made among membrane filtration methods specific to each target organism. Another example of this occurred when EPA approved the use of the IDEXX-based methods for the detection of enterococci and *E. coli*. In this comparison, results from a membrane-filtration method were compared to another method that relied on substrate-utilization and MPN enumeration. Use of already available rapid methods, such as qPCR methods for *E. coli,* has been demonstrated (Lavender and Kinzelman, 2009), on a site-specific basis.

Examples of other reported methodologies for quantifying of FIB include the following: immunomagnetic separation/adenosine triphosphate (IMS/ATP), propidium monoazide (PMA) qPCR, reverse transcriptase (RT) PCR, covalently linked immunomagnetic separation/adenosine triphosphate (COV-IMS-ATP), and transcription mediated amplification (TMA-RNA)

Also, additional indicator organisms can be used with existing methodologies similar to those recommended by the 2012 RWQC. Examples of possible alternative indicators include but are not limited to, *Bacteroidales*, *Clostridium perfringens,* human enteric viruses, and coliphages. For example, in one case, *Bacteroidales* measured by qPCR were highly correlated with *Enterococcus* and *E. coli* when either traditional, cultivation dependent, or qPCR methods were used (WERF, 2011). Norovirus GI and GII have also shown to be predictors of the presence of other pathogens like Adenovirus, *Giardia,* and *Cryptosporidium* measured by qPCR (WERF, 2011). *E. coli* and *Enterococcus* measured by qPCR may also be a possible indicator and method in fresh water. For organism and enumeration methodology combinations that are different from the 2012 RWQC, EPA would review technical information on incorporating alternative indicator organisms and enumeration methods provided by the State.

To facilitate consideration, States could gather water quality data over a recreational season for both an EPA-approved method and the proposed alternative indicator-method combination. A robust relationship need not necessarily be established between EPA’s recommendation and alternative indicator(s) for the whole range of indicator densities observed, as EPA’s recent research highlights these difficulties and limitations (U.S. EPA, 2010e). It is, however, important that a consistent and predictable relationship exist between the enumeration methods and an established indicator-health relationship in the range of the criteria. A State WQS using a different indicator or analytical method would need to be scientifically defensible and protective of the primary contact recreational use. Information on demonstrating the relationship between two-indicator method combinations can be found in TSM.

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