OFFICE OF WATER 820-F-12-058

Recreational Water Quality Criteria

NOTICES

This document has been drafted and approved for publication by the Health and Ecological Criteria Division, Office of Science and Technology, United States (U.S.) Environmental Protection Agency (EPA), and is approved for publication. Mention of trade names or commercial products does not constitute endorsement or recommendation for use.

FOREWORD

Under §304(a)(l) of the Clean Water Act (CWA) of 1977 (P.L. 95-217) the Administrator of the EPA is directed to develop and publish water quality criteria (WQC) that accurately reflect the latest scientific knowledge on the kind and extent of all identifiable effects on health and welfare that might be expected from the presence of pollutants in any body of water, including groundwater. CWA §304(a)(9) directs the Administrator to publish new or revised WQC for pathogens and pathogen indicators (including a revised list of testing methods, as appropriate), based on the results of the studies conducted under §104(v) of the CWA, for the purpose of protecting human health in coastal recreation waters. Coastal recreation waters (“coastal waters”) are defined under §502(21) of the CWA as the Great Lakes and marine coastal waters (including coastal estuaries) that are designated by a state for use for swimming, bathing, surfing, or similar water contact activities. This document includes WQC recommendations for pathogens and pathogen indicators based on the results of the studies conducted under §104(v) of the CWA for both coastal recreational waters and other waters designated for primary contact recreation (“non-coastal waters”). As such this document is published pursuant to §304(a)(1) and §304(a)(9) of the CWA and it includes EPA’s recommended final recreational water quality criteria (RWQC) for the protection of primary contact recreation in both coastal and non-coastal waters, based upon consideration of all available information relating to the effects of fecal contamination on human health, including the studies conducted under CWA §104(v).

The term "water quality criteria" is used in two sections of the CWA: §304 (i.e., §304(a)(1) and 304(a)(9)) and §303(c)(2). The term has a different program impact in each section. CWA §304 criteria are developed by EPA based on the latest scientific information on the relationship that the effect of a constituent concentration has on particular aquatic species and/or human health. They are a non-regulatory, scientific assessment of effects on human health or aquatic life. The criteria recommendations presented in this document are such scientific assessments. The term “criteria,” as used in §303(c)(2), refers to elements of state water quality standards (WQS), expressed as constituent concentrations, levels, or narrative statements, representing a quality of water that supports a particular use. When criteria are met, water quality will generally protect the designated use. If WQC uses are adopted by a state or promulgated by EPA WQS under §303, they become the relevant standard for developing permit limits, assessing waters, and developing total maximum daily loads (TMDLs) for waters that do not meet the WQS. It is not until their adoption as part of state WQS that 303(c) criteria have a regulatory impact.

In establishing WQC for adoption in WQS, states could establish numerical values based on EPA’s §304(a) recommendations, or the 304(a) recommendations modified to reflect site-specific conditions, or other scientifically defensible methods. In all cases, the criteria adopted by states must be scientifically defensible and protective of designated uses. Guidelines to assist in modifying the criteria recommendations presented in this document are contained in the Water Quality Standards Handbook (U.S. EPA, 2012a). This handbook and additional guidance on the development of WQS and other water-related programs of this agency have been developed by EPA.

The contents of this final document include only EPA recommendations and additional information for use by states in developing or implementing RWQC. This document does not establish or affect legal rights or obligations. It does not establish a binding norm and cannot be finally determinative of the issues addressed. Agency decisions to approve or disapprove WQC adopted into state WQS in any particular situation will be made by applying the CWA and EPA regulations on the basis of specific facts presented and currently available scientific information.

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Acronyms

BAV	beach action value
BEACH	Beaches Environmental Assessment and Coastal Health
cce	calibrator cell equivalent
CDC	U.S. Centers for Disease Control and Prevention
cfu	colony forming units
CI	confidence interval
CSO	combined sewer overflow
Ct	cycle threshold
CWA	Clean Water Act
DNA	deoxyribonucleic acid
E. coli	*Escherichia coli*
EPA	Environmental Protection Agency
E.U.	European Union
FIB	fecal indicator bacteria, which includes fecal coliforms, *E. coli*, enterococci, or *Enterococcus* spp.
GI	gastrointestinal
GM	geometric mean
HCGI	highly credible gastrointestinal illness
mL	milliliters
MPN	most probable number
NEEAR	National Epidemiological and Environmental Assessment of Recreational Water
NGI	NEEAR-GI illness
NOAEL	no observed adverse effect level
NPDES	National Pollutant Discharge Elimination System
PC	prospective cohort
PCR	polymerase chain reaction
QMRA	quantitative microbial risk assessment
qPCR	quantitative polymerase chain reaction
RCT	randomized control trial
RT	reverse transcriptase
RWQC	recreational water quality criteria
SCCWRP	Southern California Coastal Water Research Project
SSM	single sample maximum
States	states, tribes, and territories of the United States
STV	statistical threshold value
TMDL	total maximum daily load
TSM	technical support material
U.S.	United States
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(s)
WWTP	wastewater treatment plant

1.0 Executive Summary

The CWA, as amended by the Beaches Environmental Assessment and Coastal Health (BEACH) Act in 2000, requires the U.S. EPA under §104(v) and §304(a)(9) to conduct studies associated with pathogens and human health and to publish new or revised WQC recommendations for these 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 from studies EPA conducted pursuant to CWA §104(v) and after public notice and comment on the 2011 draft RWQC. This document provides EPA's recommended CWA §304(a) RWQC for states, lays out the science related to the 2012 RWQC, describes how these scientific findings were used during the development of the 2012 RWQC, and describes the water quality methods associated with the 2012 RWQC. It also includes information for states that would prefer to adopt WQC that differ from EPA's 2012 RWQC recommendations. The additional information is intended to assist those states in developing alternative WQC that are scientifically defensible and protective of the primary contact recreational use.

1.1 Contents of this Document

Section 1 provides an executive summary and introductory information regarding the history of EPA's WQC recommendations and the CWA.

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

- The 2012 RWQC consists of both a geometric mean (GM) and a statistical threshold value (STV).
- The 2012 RWQC are now comprised of a magnitude, duration, and frequency of excursion for both the GM and STV.
- The 2012 RWQC were developed based on the studies utilized in creating the 1986 WQC as well as more recent scientific information including the National Epidemiological and Environmental Assessment of Recreational Water (NEEAR) data.
- EPA is including two sets of recommended criteria values that protect the designated use of primary contact recreation.
- The criteria recommendations for marine and fresh waters are no longer based on different illness rates.
- There are no longer different criteria recommendations for different use intensities.
- EPA is providing information for states that want to adopt WQS based on a quantitative polymerase chain reaction (qPCR) method that EPA has developed and validated.
- EPA is providing states with Beach Action Values (BAVs) for use in notification programs.
- EPA is providing additional information on tools for assessing and managing recreational waters, such as predictive modeling and sanitary surveys.
- EPA is providing information on tools for developing alternative RWQC on a site-specific basis, such as epidemiological studies in both marine and fresh waters and quantitative microbial risk assessment (QMRA).

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 (U.S. EPA 2010a, 2010b; see appendices A, B, and C). The projects align into the following major categories: epidemiological studies, 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 science that was considered during the development of the 2012 RWQC. This includes 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.

In the 2012 RWQC, EPA recommends using the fecal indicator bacteria (FIB) enterococci and *Escherichia coli (E. coli)* as indicators of fecal contamination for fresh water and enterococci for marine water. Section 3.1 explains that EPA recommends culture-based methods be used to detect the presence of either indicator and that states adopt standards for these indicators as measured by culture methods, expressed in colony forming units (cfu). Section 3.1 also includes information and recommendations for states that would like to adopt standards for *Enterococcus* spp., as measured by a rapid qPCR method. Because of the limited experience with this method and concerns with interference, EPA recommends that states evaluate qPCR performance in ambient waters in which it would be employed prior to developing new or revised standards based on the qPCR method. EPA will provide separate guidance on how to evaluate qPCR performance.

Section 3.2.1 provides a historical overview of how WQC that protect the designated use of primary contact recreation have changed throughout the past century. Scientific advancements in microbiological, statistical, and epidemiological methods have demonstrated that culturable enterococci and *E. coli* are better indicators of fecal contamination than the previously used general indicators, total coliforms and fecal coliforms. Fecal contamination in recreational waters is associated with an increased risk of gastrointestinal (GI) illness and less often identified respiratory illness. As such, fecal contamination and its indicators are considered “pathogen indicators,” as defined by §502(23) of the CWA.

Section 3.2.2 discusses the various human health endpoints that EPA and others have examined in epidemiological studies. Additionally, EPA’s two different GI illness definitions are discussed. EPA’s 1986 criteria recommendations correspond to a level of water quality that is associated with an estimated illness rate expressed in terms of the number of highly credible gastrointestinal illnesses (HCGI) per 1,000 primary contact recreators. EPA’s NEEAR study used a more comprehensive definition of GI illness, referred to as NEEAR-GI (NGI). Because NGI is broader than HCGI (i.e., NGI includes diarrhea without the requirement of fever), more illness cases were reported and associated with aquatic recreation in the NEEAR study using the NGI definition of illness, at the same level of water quality observed using the previous illness definition (i.e., HCGI).

Section 3.2.3 provides an overview of the epidemiological studies conducted by EPA as part of the NEEAR study. Seven studies were performed at temperate beaches primarily impacted by wastewater treatment plants (WWTPs) discharging effluent from treated municipal sewage. Three of those beaches were marine water and four were fresh water. Studies also were performed at two additional beaches: a temperate beach in Surfside, South Carolina impacted by urban runoff sources, and a tropical beach in Boquerón, Puerto Rico. EPA also considered epidemiological studies from other research efforts in developing these recreation criteria.

Section 3.2.4 describes the process EPA used to derive the culturable enterococci criterion value and comparable illness rates for *E. coli* measured by culture and *Enterococcus* spp. measured by qPCR thresholds. Based on the selected illness rates, EPA derived qPCR values for *Enterococcus* spp. comparable to the culture-based values for both marine and fresh waters, computed from the regression model derived from the NEEAR epidemiological study in marine and fresh waters.

Section 3.3 discusses subpopulations that participated in recreational activities in the NEEAR study. Children aged ten years and younger showed a higher rate of illnesses than adults in fresh water, but did not for marine water exposures. The sample sizes in the epidemiological data were not large enough to evaluate potential differences for persons over 55 years of age, pregnant women, or other vulnerable individuals. EPA's 2012 RWQC recommendations are based on the general population, which includes children. Because children may be more exposed and/or more sensitive to pathogens in recreational waters, it is important to have effective risk communication outreach to mitigate their exposure to contaminated recreational waters. EPA is also providing BAVs that are the 75th percentile value of a water quality distribution based on these new criteria. These values, while not recommended for determining use attainment, are provided for states to use as a precautionary tool to provide an early alert to beachgoers, including families with 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 WQS 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, the recommended indicators, enumeration methods, and criteria values are scientifically defensible and protective of the primary contact use in coastal and non-coastal waters. Therefore, EPA's 2012 RWQC recommendations are national recommendations for all waterbody types 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. Human pathogens are often present in animal fecal matter, and thus, there are risks associated with recreating in animal-impacted waters. However, quantifying that level of risk associated with animal fecal material is difficult, and the methods necessary to distinguish between human and nonhuman fecal sources, with the appropriate level of confidence, are still under development. Thus, EPA believes that the 2012 RWQC are protective of public health, regardless of the source of fecal contamination. EPA is not developing recommendations that take source of fecal contamination into account. Rather, states interested in adopting different standards to address the variability in human health risks associated with different sources of fecal contamination on a site-specific basis should refer to section 6, where EPA describes methods for developing site-specific standards.

Section 3.6 describes the statistical expression of the 2012 RWQC. As part of the 2012 RWQC, EPA is recommending criteria expressed using two components: the GM and the STV. For each of the sets of criteria values, EPA computed the STV based on the water quality distribution observed during EPA's epidemiological studies. The STV approximates the 90th percentile of the water quality distribution and is intended to be a value that should not be exceeded by more than 10% of the samples used to calculate the GM. Because densities of FIB are highly variable in ambient waters, distributional estimates are more robust than single point estimates.

Section 4 presents EPA's recommended WQC consisting of the magnitude, duration, and frequency of excursions for enterococci and *E. coli* as measured by culture-based methods. EPA provides two sets of recommended criteria, each of which correspond to two different illness rates. The designated use of primary contact recreation would be protected if either set of criteria recommendations in section 4.0 are adopted into state WQS and approved by EPA.

Section 5 provides additional elements for states' use to enhance public health protection. These elements include BAVs and values for *Enterococcus* spp. as measured by qPCR.

Section 6 describes the additional tools that can be used to manage recreational waters and derive site-specific criteria. The tools listed in section 6 will not only provide states with additional tools for revising their WQS for primary contact recreation, but will also help states gain a better understanding of their surrounding watersheds and of appropriate management strategies. Section 6.1 describes sanitary surveys and provides an overview of predictive models. Section 6.2 provides an overview of options for states to develop site-specific criteria. Tools described in section 6 will be further developed and explained in technical support material(s) (TSM) that are being developed by EPA. EPA will publish multiple TSM focusing on these tools as they are available.

Appendices are also included that describe data and information used to evaluate the linking of water quality and health. Appendix A provides a translation of the illness rates associated with the1986 criteria to equivalent illness rates for use with new health data developed using rapid methods for measuring water quality. Appendix B includes a comparison of NEEAR culturable water quality and health effects to EPA's epidemiological studies from the 1980s. Appendix C is an analysis of the NEEAR marine and fresh water data for culturable enterococci.

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, 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, which are defined as marine and Great Lakes waters designated under CWA §303(c) for use for swimming, bathing, surfing, or similar water contact activities (referred to throughout the document as primary contact recreation).

CWA §304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water. The 2012 RWQC recommendations are based on data and scientific conclusions on the relationship between FIB density and GI illness. These criteria recommendations may be used by the states to establish WQS, and if adopted in state WQS and approved by EPA, will ultimately provide a basis for controlling the discharge or release of pollutants and assessing waterbodies. Additionally, the criteria also provide guidance to EPA when promulgating WQS for states under CWA §303(c), when such actions are necessary.

When states adopt new or revised WQC into WQS, they must be scientifically defensible and protective of the designated uses of the waterbodies. EPA's regulation 40 CFR §131.11(b)(1) provides 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.

EPA has a long history of using FIB for protecting people who use recreational waters. In the 1960s, the U.S. Public Health Service recommended using fecal coliform as FIB, and EPA recommended fecal coliform bacteria 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 of fecal contamination, including fecal coliform, *E. coli*, and enterococci (Cabelli et al., 1983; Dufour, 1984). These studies showed that enterococci are good predictors of GI illnesses in marine and fresh recreational waters, and *E. coli* are good predictors 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"). The 1986 criteria document includes EPA recommendations to use enterococci for marine and fresh recreational waters (a GM of 33 enterococci cfu per 100 mL in fresh water and 35 enterococci cfu per 100 mL in marine water) and *E. coli* for fresh recreational waters (a GM of 126 *E. coli* cfu per 100 mL) (U.S. EPA, 1986). The 1986 recommendations replaced EPA's previously recommended fecal coliform criteria of 200 fecal coliform cfu per 100 mL (U.S. EPA, 1976). In the 2004 BEACH Act Rule, EPA promulgated WQS 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).

Like past EPA recommendations for primary contact recreational uses, the 2012 criteria are based on indicators of fecal contamination. A pathogen indicator, as defined in §502(23) of the CWA, as amended by the BEACH Act, is defined as follows: "a substance that indicates the potential for human infectious disease." Most strains of enterococci and *E. coli* 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.

EPA recommends that states make a risk management decision regarding illness rate which will determine which set (based on illness rate selected) of criteria values are most appropriate for their waters. The designated use of primary contact recreation would be protected if either set of criteria (including a GM and related STV) shown in Table 1 is adopted into state WQS and approved by EPA. EPA recommends states apply this risk management decision statewide. Note that criteria for either enterococci or *E. coli* can be used for fresh waters. Selecting a mixture of the GM and STV that are associated with different illness rates is not scientifically defensible since the STV is derived from the water quality distribution as defined by the GM.

Table 1. Recommended 2012 RWQC.

Criteria Elements	**Estimated Illness Rate (NGI): 36 per 1,000 primary contact recreators**			**Estimated Illness Rate (NGI): 32 per 1,000 primary contact recreators**	
	Magnitude			**Magnitude**	
Indicator	GM (cfu/100 mL)[a]	STV (cfu/100 mL)[a]	OR	GM (cfu/100 mL)[a]	STV (cfu/100 mL)[a]
Enterococci – marine and fresh	35	130		30	110
OR					
E. coli – fresh	126	410		100	320
Duration and Frequency: The waterbody GM should not be greater than the selected GM magnitude in any 30-day interval. There should not be greater than a ten percent excursion frequency of the selected STV magnitude in the same 30-day interval.					

[a] EPA recommends using EPA Method 1600 (U.S. EPA, 2002a) to measure culturable enterococci, or another equivalent method that measures culturable enterococci and using EPA Method 1603 (U.S. EPA, 2002b) to measure culturable *E. coli*, or any other equivalent method that measures culturable *E. coli.*

EPA is also providing information for developing site-specific criteria that measure enterococci using EPA's *Enterococcus* spp. qPCR Method 1611 (U.S. EPA, 2012b). For the purposes of beach notification, EPA encourages the use of a BAV, which approximates the 75th percentile of a water-quality distribution based on the desired GM. See section 5.1 and 5.2 for 'Supplemental Elements.'

2.0 Applicability and Scope of the 2012 RWQC

EPA's 2012 RWQC are for all waters in the United States including marine, estuarine, Great Lakes, and inland waters that are designated for primary contact recreation. Primary contact recreation typically includes activities where immersion and ingestion are likely and there is a high degree of bodily contact with the water, such as swimming, bathing, surfing, water skiing, tubing, skin diving, water play by children, or similar water-contact activities.

Since EPA last published recommended RWQC in 1986, scientific advances have been made in the areas of epidemiology, molecular biology, microbiology, QMRA, and methods of analytical assessment. EPA's evaluation and consideration of 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 five-day scientific workshop in 2007 to obtain a broad range of external scientific input. Forty-three domestic and international experts provided input on near-term research requirements that would be needed in the next two to three 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, including: (1) approaches to criteria development, (2) pathogens, pathogen indicators, and indicators of fecal contamination, (3) methods development, (4) comparison of 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*, were completed and considered during the process of developing the 2012 RWQC. 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 the recommended criteria values and associated level of public health protection. EPA specific-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
- Site Characterization Studies
    - Development of site characterization tool for QMRA applications
    - 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

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

    - 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
- Recommended Level of Public Health Protection
    - Evaluate 1986 recommendations for culturable enterococci and *E. coli* 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 conducted epidemiological investigations at U.S. beaches in 2003, 2004, 2005, 2007, and 2009, and as a group these investigations are referred to as the NEEAR study. The NEEAR study enrolled 54,250 participants, encompassed nine locations, and collected and analyzed numerous samples from a combination of fresh water, marine, tropical, and temperate beaches (U.S. EPA, 2010a; Wade et al., 2008, 2010).

EPA provided assistance and technical support to several additional projects: 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); and the Southern California Coastal Water Research Project (SCCWRP) for epidemiological studies at the California beaches of Doheny (Colford et al., 2012), Avalon, and Malibu.

Finally, EPA also considered other research and studies relevant 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. EPA considered all available data from the open literature and water quality data received from SCCWRP on studies they conducted with technical support from EPA at Doheny, Avalon, and Malibu beaches. These SCCWRP studies were generally consistent with the NEEAR study findings. These studies are discussed further in section 3 of this document.

3.0 Basis of 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 a magnitude, duration, and frequency. EPA also considered all of the comments received on the December 2011 draft RWQC document (EPA, 2011). EPA's responses to comments will be available separately. In response to comments asserting that the allowable illness rate in the 2011 draft RWQC was too high, EPA conducted additional analyses of the NEEAR data. These analyses and EPA's recommendations are presented in sections 3.0 and 4.0.

3.1 Indicators of Fecal Contamination

Public health agencies have long used FIB to identify potential for illness resulting from recreational activities in surface waters contaminated by fecal pollution. EPA based its 1986 criteria for recreational marine and fresh waters on observed illness levels in swimmers and corresponding levels of bacterial indicators of fecal contamination, specifically enterococci and *E. coli* for fresh water and enterococci for marine water. Although most strains of FIB are not pathogenic, they demonstrate characteristics that make them good indicators of fecal contamination (i.e., often of fecal origin and simple methods of detection) 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 CWA §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 is not publishing criteria for "pathogens" because the state of the science was not sufficient at the time of completion of these RWQC. In addition, there are numerous pathogens that cause the full range of illnesses associated with primary contact recreation. Pathogen-specific enumeration methods for environmental waters were not available at the time of the NEEAR study, and thus health relationships with specific pathogens were not established (U.S. EPA, 2010c, 2010d).

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 rates observed in epidemiological studies. As discussed in section 3.2.3, two microorganisms that have consistently performed well as indicators of illness in sewage-contaminated waters during epidemiological studies are enterococci in both marine and fresh water and *E. coli* in fresh water measured by culture (Prüss, 1998; Wade et al., 2003; Zmirou et al., 2003). Additionally, two recent epidemiological studies also demonstrate the utility of *E. coli* as an indicator as recommended in the 1986 criteria (Marion et al., 2010; Wiedenmann, 2006). Together the available body of information supports EPA's 2012 RWQC recommendations to use enterococci and *E. coli* as indicators of fecal contamination. See section 6.2.3 for discussion of the use of alternative indicators, such as *E. coli* measured by qPCR, which EPA has not specifically included in the 2012 RWQC.

3.1.1 Enumeration Methods in RWQC

Indicators of fecal contamination are detected and enumerated using a variety of methods. Thus, the chosen indicator and method combination is critical for determining a criterion value. 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 this combination.

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 extracted from an environmental sample, amplified, and quantified (using qPCR). These different enumeration methods result in method-specific units and values. One culture-based method, membrane filtration, results in the number of colonies that arise from bacteria captured on the membrane filter per volume of water filtered. One colony can be produced from one or several cells (clumped cells in the environmental sample). Another culture-based 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 term “most probable number.” Bacterial densities MPN 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 membrane filtration, generate results following the culturing of a particular microbe for 18–24 hours, and in the case of MPN do not result in a direct count or concentration density of the bacteria being enumerated but rather rely on probabilities. Results from qPCR analyses are reported in 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 (i.e., culture and qPCR) 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 and activity) of the target organisms for effective enumeration. Only the culturable sub-set of the target indicator is 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 both viable and non-viable forms of the targeted indicator. In the context of the 2012 RWQC, the results for enterococci determined using the culture-based methods are not the same as the results for EPA’s *Enterococcus* spp. qPCR Method 1611 (U.S. EPA, 2012b). 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).

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[2] Note that in some EPA NEEAR study publications, the term calibrator cell equivalent (cce) has been shortened to cell equivalent (ce). EPA considers these terms to be synonymous and in all cases calibrator cells were used. EPA used the delta-delta comparative cycle threshold (Ct) calibration model for estimating cce or ce in all NEEAR study data (U.S. EPA, 2012b).

FIB, such as enterococci and *E. coli*, enumerated by culture-based methods, have an association with GI illness from exposure to ambient recreational water as demonstrated previously (Cabelli et al., 1982; Cabelli, 1983; Calderon et al., 1991; Dufour 1984; Marion et al., 2010; Wade et al., 2003, 2006, 2008, 2010; Wiedenmann et al., 2006). Wade et al. (2008, 2010) did not show a statistically significant correlation of illness rates with culturable enterococci as was shown in the studies conducted in the 1980s. However, the NEEAR study did reaffirm an association with health as indicated by increased illness above the 1986 criteria values. The early and more recent studies conducted by EPA and others therefore support the establishment of WQC based on culturable indicators (see section 3.2.4). Thus, culturable indicators are scientifically defensible and are retained as the basis for the 2012 RWQC. FIB enumerated by culture-based methods also provide a historical association with previous water-quality data in states that already have WQS based on those indicators.

EPA is also providing information on how to use a more recently developed qPCR method. Enterococci measured by EPA's *Enterococcus* spp. qPCR Method (U.S. EPA, 2012b) showed a statistically significant correlation with GI illness among primary contact recreators in both marine and fresh recreational waters impacted by human fecal contamination (Wade et al., 2006, 2008, 2010). The technical literature demonstrates that enumeration of enterococci using this technique can provide results more rapidly than culture-based methods with results available the same day (Griffith and Weisberg, 2011).

As with other methods, the qPCR methodology may be affected by interference[3] from substances in different environmental matrices such as surface waters. Mitigation approaches discussed in EPA's *Enterococcus* spp. qPCR Method 1611 have been identified that show promise for reducing the effects of interference in particularly problematic water samples, including those that occurred in the tropical marine NEEAR study (Haugland et al., 2012; U.S. EPA, 2012b). Although the fresh water NEEAR study sites in the Great Lakes and four temperate marine beaches demonstrated minimal to no interference, EPA's overall testing of this qPCR method with different types of ambient waters and use by other laboratories has been limited.

Kinzelman et al. (2011) reported minimal incidences of unacceptable interference with EPA *Enterococcus* spp. qPCR Method 1611 in Great Lakes coastal waters using a more stringent definition of interference; however, increased incidences were observed in some inland water locations. The highest frequency of incidences was seen at sites that were dominated by non-point source pollution. Mitigation techniques, such as purification of the sample or follow-up sample extract dilution, were able to resolve the interference in some of the samples; however, these additional steps resulted in an increase in the amount of time necessary to generate results. Other researchers have also reported inhibition or other types of interference in samples using non-EPA qPCR methodologies (Noble et al., 2010).

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[3] Interference is any process that results in lower quantitative estimates than expected or actual values. Interference can result from sample inhibition of the polymerase or binding of substances to the DNA, which prevents either the primers from binding or polymerase function. EPA *Enterococcus* spp. qPCR Method 1611 (U.S. EPA, 2012b) has a sample processing control 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).

EPA believes that overall testing of the qPCR method with different types of ambient waters, and by different laboratories, remains limited and anticipates that there may be situations at some locations where the performance of the qPCR method may be inconsistent. EPA therefore suggests that states evaluate the qPCR method with respect to laboratory performance and sample interference in their prospective waters prior to developing new or revised standards relying on this method. EPA will provide additional guidance on how to evaluate qPCR method performance at a later date.

3.2 Linking Water Quality with GI Illness 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 human-derived fecal contamination can impact a waterbody. The relationship between the presence of FIB and any of the enteric pathogens that cause illness in humans can be highly variable, but has been described mathematically as used in QMRA (Schoen and Ashbolt, 2010). The following four subsections describe the lines of evidence EPA used to derive recommended criteria levels. The historical perspectives subsection briefly discusses previous approaches to the development of WQC in the U.S. 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 criteria values development subsection discusses the basis of the 2012 RWQC values.

3.2.1 Historical Perspectives in Criteria Development

EPA's previously recommended RWQC (i.e., the 1986 criteria) and the 2012 RWQC are based on the observed association between the density of FIB and 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. Public Health Service recommended using fecal coliform bacteria as the indicator of primary contact with FIB. Studies conducted by the U.S. Public Health Service reported a detectable health effect when total coliforms density was about 2,300 per 100 mL (Stevenson, 1953). In 1968, the National Technical Advisory Committee translated the total coliform level to 400 fecal coliforms per 100 mL based on a ratio of total coliforms to fecal coliforms and then halved that number to 200 fecal coliforms per 100 mL (U.S. EPA, 1986). The National Technical Advisory Committee criteria for recreational waters were recommended 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 represented the desired ambient condition of the waterbody 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 fecal coliform (U.S. EPA, 1976). For that effort, the enterococci and *E. coli* criteria values from the existing fecal coliform 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 single sample maximum (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 late 1970s and early 1980s. Four different SSM values (recommended to be used with different recreational use intensities) were provided and corresponded to different percentiles of the water quality distribution around the GM.

The 1986 criteria values resulted in different water quality values and associated 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 fecal coliform 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 fecal coliform criterion)
D = 115 cfu per 100 mL (observed GM of 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 primary contact recreators in fresh water (see section 3.2.2) and 19 HCGI per 1,000 primary contact 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 illness rate 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 eight to ten 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 and updated definition of GI illness, defining a case of GI illness as "any of the following [within ten to 12 days after swimming]: (a) diarrhea (three 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" (U.S. EPA, 2010a). This illness definition is referred to as NGI and is the definition of illness associated with the 2012 RWQC.

The NGI case definition was broadened in that diarrhea, stomachache, or nausea is included without requiring the occurrence of fever. Viruses are thought to be the etiologic agent responsible for most of the GI illnesses that are contracted in recreational waters impacted by sources of human fecal contamination (Cabelli, 1983; Sinclair et al., 2009; Soller et al., 2010a) and viral gastroenteritis does not always present with a fever. Thus a GI illness case definition that does not require fever should allow studies to more accurately capture cases caused by viruses.

In addition, the NEEAR study 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 ten days, thus participants contacted after eight days may not have developed the case definition symptoms. By calling participants after ten to 12 days, the study design allowed for illness caused by pathogens associated with longer incubation periods to be included as cases. 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 will be observed than HCGI illnesses. The relative increase in rates of GI illness between the studies (i.e., HCGI versus NGI) is directly attributable to the changes in how illness was defined and not due to an actual increase in the incidence of illness among primary contact recreators 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 study (U.S. EPA, 2011). The mean non-swimmer HCGI rate from pre-1986 epidemiological studies was 14 illnesses per 1,000 non-swimmer recreators, while the non-swimmer recreators mean NGI rate from the NEEAR study was 63 illnesses per 1,000 non-swimmer recreators. Thus an illness rate of 8 HCGI per 1,000 primary contact recreators is estimated to be equivalent with an illness rate of approximately 36 NGI per 1,000 primary contact recreators (estimated translation factor of 4.5 NGI per HCGI[4]). See Appendix A for more information.

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[4] 8 HCGI/1,000 primary contact recreators x 4.5 HCGI / 1 NGI = 36 NGI/1,000 primary contact recreators

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, 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; and
5. "Infected cut," which was defined as a cut or wound that became infected.

Results from the NEEAR study, and previous epidemiological studies, indicate that criteria based on protecting the public from GI illness via the use of FIB will prevent most types of recreational waterborne illnesses. In general, these other illnesses occur at a lower rate than GI illness (as defined by any widely accepted definition) (Fleisher et al., 1998; Haile et al., 1999; McBride et al., 1998; Wade et al., 2008). For example, Wade et al. (2008) reported a mean 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 three 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 WWTPs reported correlations between other health endpoints and water quality. For example, Sinigalliano et al. (2010) reported symptoms of human subjects randomly assigned to marine water exposure with intensive environmental monitoring, and compared them against other subjects who were not exposed. Their results demonstrated an increase in 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-based methods.

3.2.3 Relationship Between Water Quality and Illness

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 late 1970s and early 1980s. In those studies, enterococci and *E. coli* exhibited the strongest correlation to swimming-associated gastroenteritis (specifically HCGI, as discussed in section 3.2.2). Because enterococci and *E. coli* correlate with illness, EPA recommended *E. coli* as the indicator to be measured in fresh water and enterococci as the indicator to be measured in both marine and fresh 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). The World Health Organization (WHO) recommends the use of enterococci as water-quality indicators for recreational waters (WHO, 2003). Meta-analyses and systematic reviews of epidemiological studies conducted worldwide indicate that these indicators generally provided substantial improvements over the indicators that were favored previously, such as total and fecal coliforms (Prüss, 1998; Wade et al., 2003; Zmirou et al., 2003).

EPA NEEAR epidemiological study design and conclusions.

EPA conducted the NEEAR epidemiological studies at U.S. beaches in 2003, 2004, 2005, 2007, and 2009 and reported the results in a series of research articles (U.S. EPA, 2010a; Wade et al., 2006, 2008, 2010). The NEEAR study was a prospective cohort (PC) epidemiological study that enrolled participants at the beach (the cohort) at a number of study sites and followed them for an appropriate period of time to compare incidence of illness (i.e., NGI) between the exposed (swimmers) and unexposed groups. This type of study can also include exposure response analyses if varying degrees of exposure are present. The PC design used in the NEEAR study was an enhancement 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, 2012; 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).

EPA investigators considered several different epidemiological study designs, but only the randomized controlled trial (described below) and PC designs were viewed as potentially viable methods by EPA’s external expert advisory panel to address the specific goals of the study. The goals of the study were to obtain and evaluate a new set of health and water quality data at a number of beaches for the new rapid, state-of-the-art methods and to use the results to support the development of new or revised criteria for the protection of primary contact recreation. The NEEAR PC design enhanced and improved upon the PC design used for studies employed in the development of the 1986 criteria (U.S. EPA, 1986).

Characteristics of the NEEAR study’s design were used to establish criteria to select the seven beaches studied between 2003 and 2007:

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

For more information about the beach selection criteria, enrollment, administration of the health survey, and other details on the study design, please see Wade et al. (2006; 2008; 2010).

Wade et al. (2008, 2010) also described the details on the statistical models used for the NEEAR analysis. Statistical tests were conducted using several approaches and models to determine whether the odds ratios for the different fresh water and marine beaches were statistically different. Covariate analyses are discussed in U.S. EPA (2010a). Additionally, regression models were used to determine the strength and the significance of the relationship between the indicator measures and health effects. Nearly all the studies conducted in recent years have used similar statistical models, usually logistic or log-linear models (Colford et al., 2012; Fleisher et al., 1993; Haile et al., 1999; Kay et al., 1994; McBride et al., 1998; Prieto et al., 2001; Seyfried et al., 1985).

As a result of the statistical analyses, EPA concluded that the *Enterococcus* spp. levels measured by qPCR using EPA Method 1611 (U.S. EPA, 2012b) and GI illness data from the NEEAR epidemiological studies of WWTP-impacted marine and temperate fresh water study sites could be combined. A direct comparison of the slope parameters shows no significant difference (p = 0.44) between the marine and fresh water beaches. The results indicated that for the majority of the range of exposures observed, there were no statistically significant differences in the estimated risk levels for marine and fresh waters (see Appendix C; U.S. EPA, 2011).

For the NEEAR epidemiological study design, EPA collected data from seven WWTP-influenced marine and temperate fresh water beaches at intervals throughout the day at different water depths, resulting in 18 daily samples. The GM of the daily samples provided a single daily water quality value for the health relationship analysis (U.S. EPA, 2010a). The association between the GM of enterococci samples collected at 0800 hours and GI illness was nearly identical to the daily GM of all samples collected. This association is important from an implementation perspective because the results indicate that a sample taken at 0800 hours could be used for beach-management decisions on that day.

A number of FIB were examined in the NEEAR study (see Table 2). The occurrence of GI illness in swimmers was positively associated with exposure to levels of enterococci enumerated with EPA's *Enterococcus* spp. qPCR Method 1611 in marine and fresh water (U.S. EPA, 2012b; Wade et al., 2008, 2010). GI illness in swimmers at marine water beaches was also associated with exposure to levels of anaerobic bacteria of the order *Bacteroidales* enumerated with EPA's *Bacteroidales* qPCR method (Wade et al., 2010).

The association between GI illness and enterococci measured by culture in the NEEAR study 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 focused on evaluating a single indicator that could be used by states in both marine and fresh waters. Although culturable *E. coli* samples were not included in the NEEAR epidemiological studies, other researchers confirm that culturable *E. coli* is associated with GI illness, and remains a useful indicator of contamination in fresh waters (Prüss, 1998; Marion et al., 2010; Wiedenmann et al., 2006).

In addition to the seven temperate, WWTP-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 runoff sources but has no WWTP sources, and a tropical beach in Boquerón, Puerto Rico. 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 FIB levels and illness rates were found to be low (U.S. EPA, 2010a). Results from EPA studies at the urban-runoff and tropical beaches are consistent with NEEAR study results from other geographical areas and other sources are consistent with EPA's understanding of risk associated with fecal indicators (i.e., low illness rate and low FIB counts). Thus, EPA believes these criteria recommendations are scientifically defensible and protective of the use regardless of source or climate.

Table 2. Fecal indicator organisms and enumeration methods tested in the NEEAR epidemiological studies.

EPA Epidemiological Study	Indicator/Methods Tested in Study
Great Lakes	*Enterococcus* spp. measured by qPCR, enterococci measured by culture, *Bacteroidales* measured by qPCR
Marine (2007)	*Enterococcus* spp. 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 indicator/methods as 2007 marine, but no coliphage or *Clostridium* spp.
Urban Runoff	Same indicator/methods as 2007 marine, but no coliphage or *Clostridium* spp.

Other Epidemiological Studies.

Findings from epidemiological studies conducted by non-EPA researchers were also reviewed and considered to the maximum extent possible during the development of the 2012 RWQC, including all available data from the open literature, as well data from SCCWRP's epidemiological studies in Southern California (see below for description of these studies). Numerous epidemiological investigations have been conducted since the 1950s to evaluate the association between illness rate 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 U.S, 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. These studies concluded that: (1) good indicators of fecal contamination and demonstrated predictors of GI illness in fresh waters are enterococci and *E. coli*, and enterococci in marine water, but not fecal coliform; and (2) the risk of GI illness is considerably lower in studies where enterococci and *E. coli* densities were below levels established by EPA in 1986 (Wade et al., 2003).

Recently, SCCWRP conducted a series of PC epidemiological studies in Southern California, at Doheny, Avalon, and Malibu beaches. Many specific characteristics of the SCCWRP studies were designed to be similar to prior EPA and SCCWRP studies (Colford et al., 2007; Wade et al., 2006, 2008, 2010). EPA received the data for the analysis conducted at Doheny beach (Colford et al., 2012), a recreational marine beach impacted by urban runoff. The Doheny beach study evaluated health-risk relationships between GI illness and enterococci using qPCR-based (three different qPCR assays analyzed) and culture-based enumeration methods. Results indicated that when urban runoff with potentially containing human enteric viruses flowed freely into the marine water (berm open), the results were comparable and consistent with NEEAR marine WWTP-impacted beaches. Additionally, when the FIB source was more diffuse (berm closed), the relationship between enterococci and GI illness was not as strong as the relationship observed when the berm was open. These diffuse source results are similar to those observed in the NEEAR Surfside beach study (U.S. EPA, 2010a).

A PC epidemiological study at an Ohio reservoir (a fresh water inland beach) provided an indicator-illness relationship for *E. coli* (Marion et al., 2010). In this small-scale study, *E. coli* levels (EPA Method 1603; U.S. EPA, 2002b, 2010e) were associated with GI illness in a statistically significant manner. As indicated previously, *E. coli* demonstrated a statistically significant association with HCGI in EPA's epidemiological studies in the late 1970s and early 1980s (Cabelli, 1983; Dufour, 1984).

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 study in which the study subjects are randomly allocated to groups to receive an experimental procedure or intervention. For recreational water exposures, the groups are bathers and non-bathers (swimmers vs. non-swimmers). The bathers are given instructions detailing their time in the water and specific activities, such as immersing their heads in the water. Similar to a PC study, bathers and non-bathers must be followed for an appropriate time to evaluate illness incidence and to determine the potential effect of other biases and potential confounders. Exposure-response analyses may then be conducted.

RCT study designs are preferred by some researchers because they are intended to (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, potentially reducing misclassification bias; 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 considered the results from these RCT studies to the maximum extent possible. For example, the WHO and European Union (E.U.) used RCT epidemiological studies to support their recommended water quality values (EP/CEU 2006; WHO, 2003). The RCT studies were conducted over four bathing seasons (summers) at a different marine beach each season in the United Kingdom. Trends in the gastroenteritis (equivalent to GI illness) rate with increasing enterococci exposure were not significantly different between sites, and thus 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 fecal streptococci, of which enterococci are a subgroup, density exceeded 32 per 100 mL (Fleisher et al., 1998; Kay et al., 1994). Another E.U. randomized control trial at five fresh water bathing sites in Germany recommended guidance values based on the no observable adverse effects levels (NOAELs) for gastroenteritis of 100 *E.*

coli cfu per 100 mL or 25 enterococci cfu per 100 mL (average values) (Wiedenmann et al., 2006).

Additional RCT studies evaluated include Epibathe, a public health project funded under E.U. Framework Programme 6 to produce “science support for policy,” which began in December 2005 and ended in March 2009. The imperative for this research effort was to improve 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 evaluated in Hungary and four coastal sites were evaluated 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 United Kingdom RCT studies), the clearest trend in increasing illness rate with water quality was evident using enterococci measured by culture. For fresh waters (German and Hungary RCT studies), the clearest indicator-illness relationship between GI symptoms and water quality was seen by a threshold density of *E. coli* measured by culture. Both analyses (marine and fresh water) 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. WQS recommendations did not need to be revised.

Finally, an RTC epidemiological study at a Florida marine beach not impacted by a WWTP was considered. In this study, investigators found that swimmers 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 levels less than 40 enterococci cfu per 100 mL (Fleming et al., 2008; Sinigalliano et al., 2010).

Not all epidemiological studies show clear or consistent correlations between indicator levels and health outcomes. For example, in a 1989 PC epidemiological study at high-energy (surfing) marine beaches impacted by sewage outfalls and stormwater overflows in Sydney, Australia, GI, symptoms did not increase with increasing counts of fecal coliform or enterococci, however, swimmers did exhibit increasing respiratory, ear, and eye symptoms with increasing levels of FIB (Corbett et al., 1993). In a second independent study, respiratory and GI illnesses increased with increasing densities of enterococci (Harrington et al., 1993). In a PC epidemiological study at Mission Bay, California, impacted by non-point sources of fecal contamination, only male-specific coliphage had a correlation with illness (Colford et al., 2005).

3.2.4 Developing Enterococci Measured by Culture Criteria and Comparable Values for Culturable *E. coli* and *Enterococcus* spp. Measured by qPCR

The 2012 RWQC values for culturable levels of enterococci for marine and fresh waters and *E. coli* for fresh waters, if adopted in state WQS and approved by EPA, would be protective of the primary contact recreational use. The NEEAR study provided data to establish RWQC values for culturable enterococci and to help estimate an illness rate associated with those values. The NEEAR -based data were analyzed in several ways, some of which differed from the reported

NEEAR qPCR-based approach. EPA conducted these analyses, in part, to provide a comparison with the data analysis underlying the 1986 criteria for recreational waters.

The illness definition used in these analyses is consistent with those reported in the NEEAR study (i.e., NGI), rather than the illness definition (i.e., HCGI) used with the 1986 criteria (refer to section 3.2.2). To facilitate comparisons between the results from 1986 and the 2012 criteria, illness rates from 1986 (in terms of HCGI per 1,000 primary contact recreators) were translated to NGI rates using a translation (factor of 4.5) of the definition of NGI to HCGI (U.S. EPA, 2011). See section 3.2.2.

The following is a description of EPA's analytical approaches to develop recommended criteria values for enterococci measured by culture and comparable values for culturable *E. coli* and *Enterococcus* spp. measured by qPCR using EPA Method 1611 (U.S. EPA, 2012b). EPA was constrained to criteria values above the level of quantification (i.e., 20 cfu per 100 mL for culturable methods) (ASTM, 2012). Approach 1 analyzed the association between health and water quality for culturable enterococci using the NEEAR regression analysis. A statistically significant illness-exposure response relationship was not observed across the full range of exposures (Wade et al., 2008, 2010). Approach 2 evaluated NEEAR swimming-associated illness rates for exposures above and below the 1986 GM criteria values. These results indicated that illness rates were higher when the criteria were exceeded compared to when those criteria were not exceeded. Approach 3 compared the NEEAR study illness rates to those from 1986. This analysis confirmed that swimming-associated illness rates in NEEAR marine and fresh water studies were similar to each other and to those from the 1986 fresh water studies. Approach 4 analyzed the NEEAR data using the 1986 analytical approach. The results provided a linkage between NEEAR culturable enterococci data and GI illness. Approach 5 extended Approach 2 to consider whether there are significant differences in GI illness rates at enterococci densities lower than the 1986 criteria. The results indicate that water quality in the range of 30 to 35 enterococci cfu per 100 mL are the lowest water quality values reported to show statistically significant differences in swimming-associated illness rates.

Taken together, these approaches along with the level of water quality described by the 1986 criteria provide the lines of evidence EPA is using to recommend either the culturable enterococci GM criteria values of 30 or 35 cfu per 100 mL. The mean illness rates associated with the 2012 RWQC water quality recommendations are approximately 32 cases of NGI per 1,000 primary contact recreators for a culturable enterococci GM criterion of 30 cfu per 100 mL and 36 cases of NGI per 1,000 primary contact recreators for a culturable enterococci GM criterion of 35 cfu per 100 mL, in both marine and fresh water. These illness rates were used to estimate equivalent criteria values for culturable *E. coli* and supplemental water quality values for enterococci using EPA's *Enterococcus* spp. qPCR Method 1611 (U.S. EPA, 2012b).

<u>Approach 1.</u>

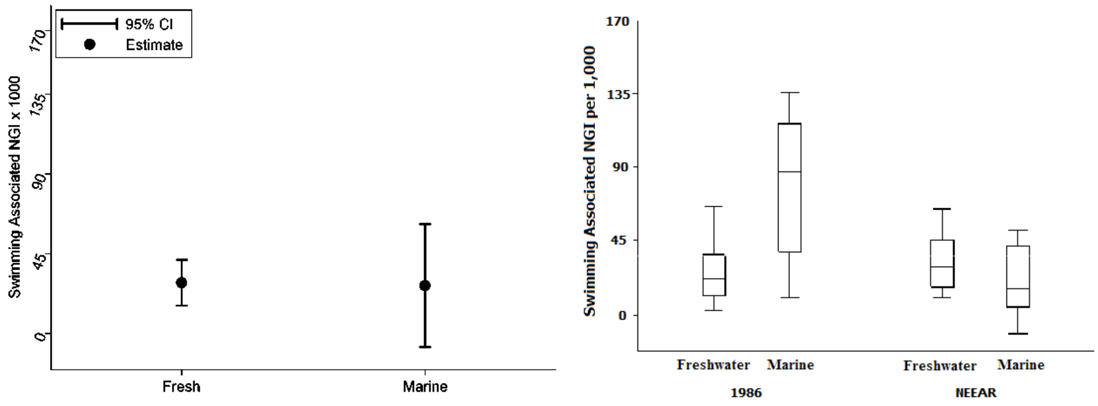
Culture-based measures of enterococci collected in the NEEAR study were analyzed using the same rigorous statistical approach applied to the qPCR data (Wade et al., 2008, 2010). Although a weak association between illness and water quality for culturable enterococci was observed using this approach, the exposure-response relationship was not statistically significant over the entire range of observed water quality measured by culturable enterococci using the marine and fresh water beach datasets (Wade et al., 2008, 2010). Therefore, EPA is not relying quantitatively on those exposure-response relationships for the 2012 RWQC because the regression coefficients would not have sufficient predictive value.

Approach 2.

EPA evaluated illness rates when swimmers are exposed to water quality levels either above or below the 1986 criteria values. Data from EPA's fresh water NEEAR study sites indicated that swimmers exposed above the 1986 criteria value of 33 cfu per 100 mL had higher risks than non-swimmers or swimmers exposed below this value (Wade et al., 2008). At EPA's marine water NEEAR study sites, approximately 16 percent of the marine study days exceeded the 1986 criteria enterococci GM value of 35 cfu enterococci per 100 mL. On those study days, the odds of diarrhea, respiratory illness and earache were elevated among swimmers compared to non-swimmers (Wade et al., 2010). EPA used the NEEAR study results (Wade et al., 2008, 2010) to compare the swimming-associated risk on days when enterococci levels were above and below 33 cfu per 100 mL and 35 cfu per 100 mL for fresh and marine sites, respectively. Those data also indicate that on days when the 1986 criteria GM values were exceeded, illness rates were similar at marine and fresh water sites (Figure 1a).

Approach 3.

EPA compared the full distribution of marine and fresh water swimming-associated illness rates observed in the NEEAR study to that of the corresponding 1986 criteria illness rates. The NEEAR study data (right side of Figure 1b) suggest that the marine swimming-associated illness rate and fresh water swimming-associated illness rate are similar to each other and to the 1986 fresh water rate. In contrast, the 1986 marine swimming-associated illness rate was considerably higher than the 1986 fresh water illness rate (left side of Figure 1b).



a) b)

Figure 1. Swimming-associated illness rates observed during EPA's epidemiological studies. a) risk on days with GM above 35 cfu per 100 mL at marine sites and above 33 cfu per 100 mL at fresh water sites; b) swimming-associated illness observed during 1986 and NEEAR study. Note**:** Boxes in Figure 1b represent the 25th to the 75th percentiles, the lines within the boxes indicate the median values, and the whiskers represent the 10th and 90th percentiles**.**

EPA then evaluated whether culturable enterococci data from the marine and fresh water NEEAR sites could be combined. The observed culturable enterococci data for each NEEAR beach were plotted and analyzed (Figure 2). There was substantial overlap in the densities of enterococci observed at beaches, even though there were statistically significant differences between beaches. However, statistically derived beach groups (represented by variations in shading in Figure 2) were not aligned strictly by their salinity classification, supporting the finding that there is not a compelling distinction between marine and fresh water (see Appendix C). The literature is consistent with this finding and indicates that of the factors influencing enterococci fate in the environment, there is evidence that sunlight, temperature and predation are more important in controlling enterococci concentrations than salinity (Noble et al., 2004).

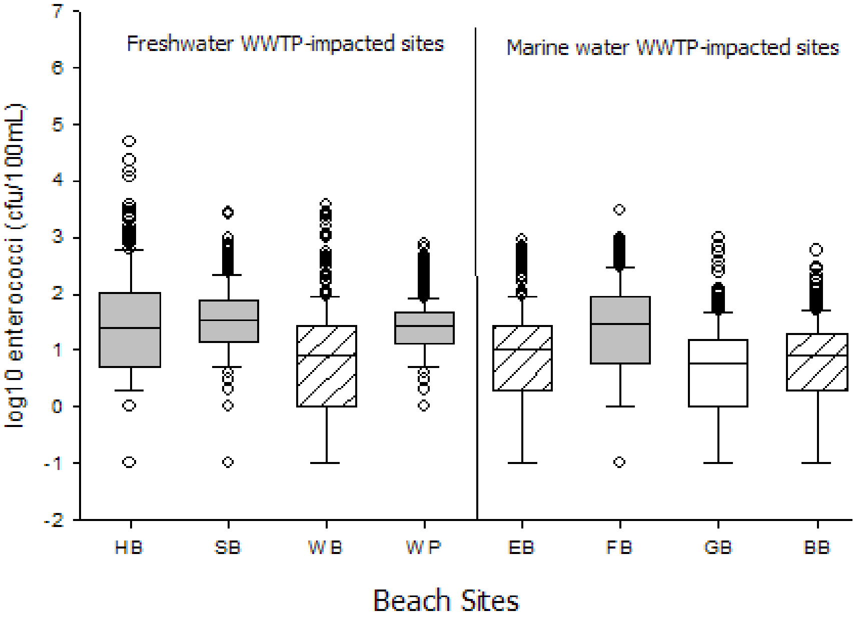


Figure 2. NEEAR marine and fresh water culturable water quality results. White, grey, and hatched boxes represent statistically different groups. Fresh water beach sites are Huntington Beach (HB), Silver Beach (SB), West Beach (WB), Washington Park (WP); marine water beach sites are Edgewater Beach (EB), Fairhope Beach (FB), Goddard Beach (GB), Boquerón Beach (BB). Note**:** Boxes in Figure 1b represent the 25th to the 75th percentiles, the lines within the boxes indicate the median values, and the whiskers represent the 10th and 90th percentiles.

Approach 4.

EPA conducted another analysis to develop a culture-based linkage between the NEEAR and 1986 studies. EPA could not reanalyze the 1980s data using the NEEAR statistical approaches because the raw data from those earlier studies are no longer available. Therefore, EPA analyzed the NEEAR culturable enterococci data using the same statistical approaches employed in the 1980s studies (Cabelli, 1983; Dufour, 1984).

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 sampling days with similar indicator densities from each study location (marine beaches). The second approach, grouping by sampling 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 (seasonal and days of similar water quality) with the NEEAR culture-based enterococci data to estimate the illness associated with the recommended levels of water quality.

EPA applied the 1986 fresh water analysis described above to the NEEAR culture-based enterococci data. This analysis 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 study. Consistent with the 1986 fresh water analysis, this approach did not account for covariates. These data points generally fell within the predicted range of the published epidemiological regressions (Cabelli, 1983; Dufour, 1984) after conversion to comparable GI case definitions (U.S. EPA, 2011). However, this analysis proved to be insufficient to estimate NEEAR study illness rates, because it generated only seven data points—one for each of the NEEAR beaches.

EPA then extended the seasonal analysis of the NEEAR culture-based enterococci data using the 1986 marine water analytical approach as described above. For this analysis, EPA aggregated data by 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 then 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 3, Figures 3 and 4 - Illness rates in the 1986 criteria are presented as NGI equivalents for comparative purposes). This analysis resulted in a total of 27 data points as compared to the seven data points for the seasonal analysis. The raw data underlying these analyses are presented in Appendix B.

EPA compared the binned fresh water and marine culture-based NEEAR indicator and health data to the corresponding regressions in the 1986 criteria. Results indicated that the vast majority of these data points fall within the 95th percentile prediction intervals derived from the 1986 regression models (Figure 3[5]). It should be noted that the NEEAR marine culture-based data cluster at the lower end of the water quality and illness distribution, described by the 1986 criteria marine regression. Moreover, the NEEAR marine and fresh water culture-based data exhibited a similar correspondence between water quality and illness as observed in the freshwater studies (Figures 3 and 4).

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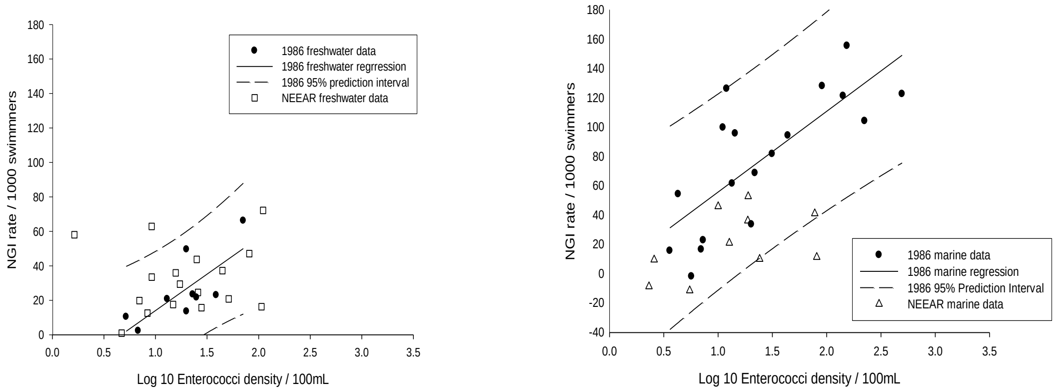
[5] The prediction intervals can be used to assess whether these NEEAR data fall within an expected range based on the 1986 criteria data.

Table 3. 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 illness (# NGI/1000 swimmers) above beach average non-swimmer illness rates
West Beach (fresh)	1.6	1122	360	556	21	60	58
	9.2	726	144	468	2	39	33.4
	25.1	463	101	299	8	28	43.7
	110.4	553	117	344	5	42	72.2
Huntington Beach (fresh)	4.7	731	426	186	43	18	1.0
	9.2	733	391	208	27	33	62.9
	15.7	526	251	167	31	22	35.9
	81.1	850	467	196	46	28	47.1
Silver Beach (fresh)	7.0	864	220	490	16	37	19.8
	14.8	2203	603	1215	36	89	17.6
	25.8	3128	900	1720	54	138	24.5
	51.3	2525	808	1281	46	98	20.8
	106.6	2152	843	945	36	68	16.3
Washington Park Beach (fresh)	8.4	722	198	398	15	30	12.6
	17.2	789	171	488	10	45	29.4
	27.9	1368	364	764	23	60	15.7
	44.6	1465	524	710	31	71	37.2
Edgewater Beach (marine)	2.3	555	135	173	10	13	-9.1
	10.0	239	66	77	7	10	45.7
	18.9	441	152	139	13	19	52.5
	77.7	108	27	40	2	5	40.8
Fairhope Beach (marine)	5.5	494	261	120	27	9	-11.8
	12.7	541	200	186	19	20	20.7
	24.1	351	126	114	5	11	9.7
	81	629	266	225	23	22	11.0
Goddard Beach (marine)	2.6	2433	1322	596	58	33	9.3
	18.8	535	262	183	15	15	35.9



a) b)

Figure 3. NEEAR study culture data aggregated by similar water quality and 1986 criteria data for (a) fresh water beaches and (b) marine water beaches.

EPA used these analyses to 1) provide a linkage to illness estimates associated with the 1986 criteria and the historically accepted level of water quality for protecting the primary contact recreation use, and to 2) estimate the potential levels of illness associated with the water quality levels recommended in the 2012 RWQC for marine and fresh waters. Based on this analysis and results illustrating the consistency between the culturable NEEAR epidemiological data to the 1986 fresh water studies, the corresponding mean estimate of illness associated with the 2012 RWQC recommendations is approximately 27 to 36 cases of NGI per 1,000 primary contact recreators for both marine and fresh water (Figures 3 and 4). See section 3.2.2 for discussion of illness rate conversion.

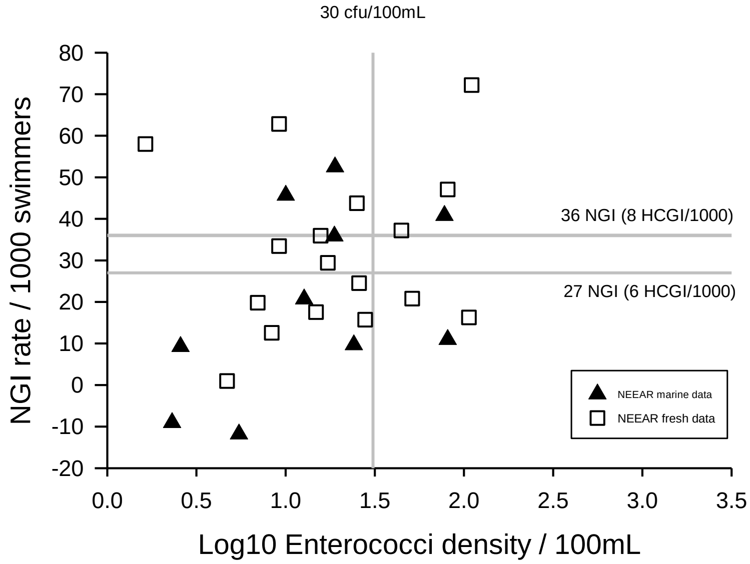


Figure 4. NEEAR marine and fresh water culture-based enterococci and illness rate data aggregated by days of similar water quality.

Approach 5

Based on public comments received on the draft RWQC document, EPA conducted an additional analysis to determine if similar results to those found in Approach 2 would occur at lower (i.e. below 35 cfu per 100 mL) enterococci densities. To achieve this, EPA extended the published approaches by developing and conducting cut-point analyses, similar to those described by Wade et al. (2003, 2008, 2010) and Colford et al. (2012), at multiple enterococci densities.

In this approach, EPA considered the daily GM culture-based enterococci data from the seven NEEAR study sites by conducting cut-point analyses at multiple enterococci densities, ranging from 5 cfu per 100 mL to 35 cfu per 100 mL, in five cfu increments and an NGI health end point. Points above 35 cfu per 100 mL are not recommended because these values would be less protective than the 1986 criteria values.

Adjusted risk estimates were developed for each of the individual cut-points, comparing swimmers in the NEEAR study exposed above and below the selected enterococci cut-points. Figure 5 presents odds ratios (and the corresponding 95% confidence intervals [CI]) for the probabilities of GI illness for swimming in water with enterococci GM levels above each of the cut-points compared to swimming in waters with enterococci GM levels below that cut-point. These odds ratios were computed as the adjusted risk of NGI among swimmers above the cut-point divided by the adjusted risk of NGI among swimmers below the cut-point. The adjusted odds ratios account for important covariates from the NEEAR epidemiological model and were calculated at the means of the covariate values (this approach is called the marginal average effects approach). The adjusted risk of NGI for non-swimmers was 56 cases per 1,000 primary contact recreators; the adjusted risk of NGI for swimmers was approximately 75-90 cases per 1,000 primary contact recreators depending on the level of water quality evaluated.

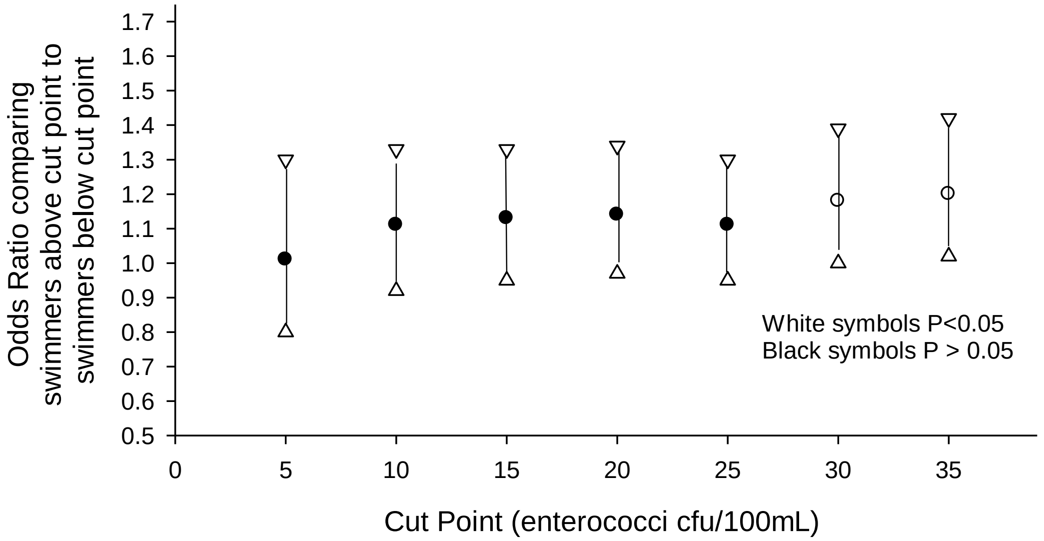


Figure 5. Adjusted odds ratios of GI illness for swimming above specific cut-points in NEEAR marine and fresh water study sites.

The odds ratios for swimming-associated GI illness are statistically significant (that is, $p \leq 0.05$) at enterococci densities of 30 cfu per 100 mL and 35 cfu per 100 mL. None of the other individual cut-points exhibited odds ratios that were statistically significant (lower 95% CI values are less than one in all other cases). These results indicate that the illness rates for swimming in waters with GMs in the narrow range of 30 to 35 cfu per 100 mL were significantly greater than the illness rates for swimming in waters with GMs below those levels. Similar illness rate changes are not seen outside this range.

Culturable *Enterococcus* conclusion

Taken together, the set of approaches described above provide lines of evidence to support the recommendation of a GM criterion value of 30 or 35 cfu per 100 mL. These approaches also provide evidence that the recommended RWQC are similarly protective of the designated use of primary contact recreation in both marine and fresh water. EPA is presenting two sets of criteria (consisting of a GM and related STV) associated with two different illness rates. EPA recommends that states make a risk management decision to choose one or the other set.

Derivation of an equivalent *E. coli* value

Using the results from the culturable enterococci analyses described above, EPA derived criteria values for culturable *E. coli* that are comparable to the two recommended enterococci GM culture-based values. First, using the preceding approaches, 35 cfu per 100 mL culturable enterococci corresponds to 36 NGI per 1,000 primary contact recreators. From the 1986 fresh water relationship between swimming-associated illness (see equation below) and water quality, 36 NGI per 1,000 primary contact recreators (8 HCGI per 1,000 primary contact recreators) corresponds to an *E. coli* density of 126 cfu per 100 mL.

$$\text{Swimming-associated HCGI illness} = -11.74 + 9.397\ (\text{mean}\ \log_{10} \textit{E. coli}\ \text{per 100 mL})$$

Similarly, EPA derived an *E. coli* density comparable to 30 cfu enterococci per 100 mL by solving the above equation at an illness rate of 7 HCGI per 1,000 primary contact recreators (translated from approximately 32 NGI per 1,000 primary contact recreators which was the estimated midpoint of the illness range derived in Approach 4) to yield an estimated *E. coli* density of 99 cfu per 100 mL. EPA rounded this estimated density to 100 *E. coli* cfu per 100 mL. EPA believes this rounding was appropriate, given the uncertainty surrounding the predicted illness range of the recommended 2012 RWQC enterococci culture-based value. This recommended criterion value (100 *E. coli* cfu per 100 mL) is consistent with the threshold suggested by Wiedenmann et al. (2006) based on an E.U. RCT epidemiological study using completely different data and statistical methods (as summarized in section 3.2.3).

Derivation of an equivalent qPCR value

EPA derived values for enterococci measured using EPA's *Enterococcus* spp. qPCR Method 1611 (U.S. EPA, 2012b) in a manner similar to the derivation for *E. coli* at 32 NGI per 1,000 primary contact recreators described above. The qPCR values were computed from the combined NEEAR epidemiological regression model (Figure 6) (see Appendix A; U.S. EPA, 2011). This model was preferred over separate models for marine 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, 2011). The statistically significant relationship between swimming-associated illness in terms of NGI per 1,000 primary contact recreators and water quality developed from the combined marine and fresh water data is defined as follows:

$$\text{Swimming-associated NGI} = -27.31 + 23.73\ (\text{mean } \log_{10} \text{ qPCR cce per 100 mL})$$

Based on the regression model, the following equation was used to derive the qPCR value:

$$\text{qPCR Value} = 10^{\frac{NGI+27.31}{23.73}}$$

where:

qPCR = qPCR value in units of cce per 100 mL
NGI = NGI rate[6] in illnesses per 1,000 primary contact recreators

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

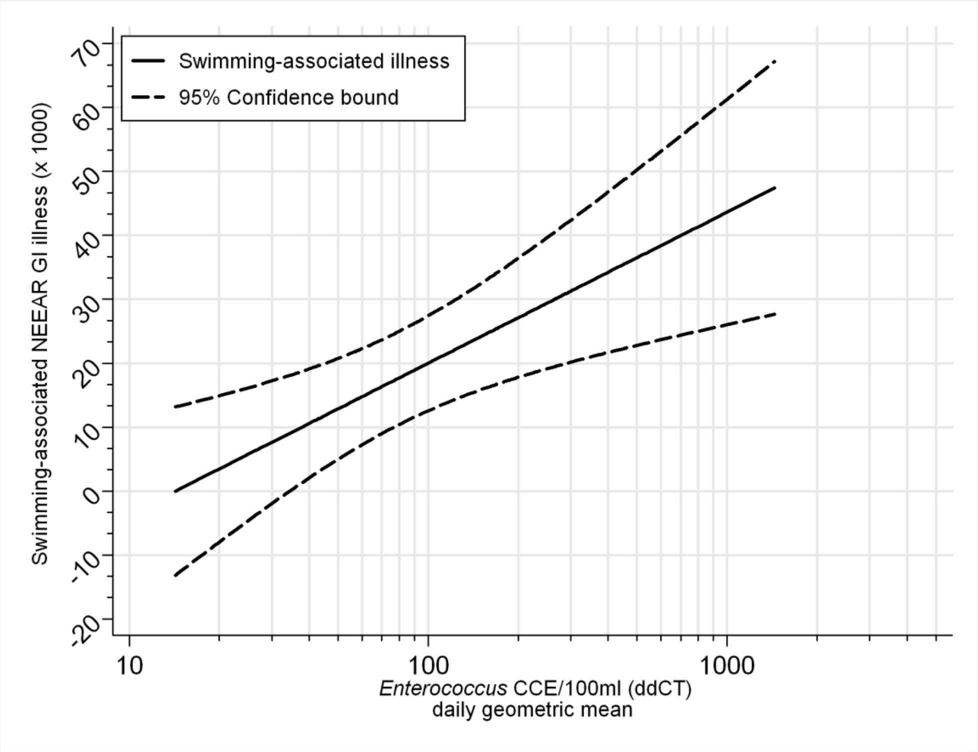

Figure 6. Swimming-associated NGI and daily average *Enterococcus* spp. measured by qPCR (cce per 100 mL). All subjects, marine and fresh water beaches combined.

Thus, qPCR-based GM values of 301 and 466 cce enterococci per 100 mL correspond to approximately 32 and 36 cases of NGI per 1,000 primary contact recreators, respectively. EPA rounded 301 to 300 cce per 100 mL, and 466 to 470 cce per 100 mL to obtain a comparable *Enterococcus* spp. measured by qPCR density to the enterococci measured by culture-based value described above.

3.3 Scope of Protected Population

EPA's 1986 criteria recommendations are supported by epidemiological studies that were conducted in the late 1970s and early 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. Thus, the illness rates corresponding to the 1986 criteria recommendations are based on the epidemiological relationship for the general population that is inclusive of children. EPA used a similar epidemiological approach for deriving illness rates for the 2012 RWQC.

As in the previous EPA epidemiological studies, children were well represented in EPA's NEEAR study population. The proportions of individuals in the under five-year and five to ten-year age categories that were enrolled in the epidemiological studies were greater than in the U.S. demographic. According to the U.S. Census data for 2009, children younger than ten years of age make up approximately 14 percent of the U.S. population (Census, 2010). At West Beach, the proportion of children aged ten years and under made up 20 percent of the study sample. A similar over-representation of children compared to the U.S. population is true for studies at 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).

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: ten 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., ten years and under) were specifically analyzed to evaluate whether they exhibit different illness rates compared to the general population.

In the NEEAR marine epidemiological studies, the association between water quality as measured by qPCR and illness in children was not different from that observed for the general population, despite a higher proportion of children age five to ten years (75 percent) immersed their bodies or head in the water compared with adults over age 55 years (26 percent) (Wade et al., 2010). Elevated GI illness rates were, however, 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). In the NEEAR fresh water epidemiological studies, the association between GI illness and water quality, as measured by EPA's *Enterococcus* spp. qPCR Method 1611 (U.S. EPA, 2012b), was stronger among children (age ten years and under) compared with the NEEAR general population, which also included children. The reason for the stronger association in children compared to the general population is not known. However, there are several possible explanations. 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 (U.S. EPA, 2010a; Wade et al., 2006, 2008) 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). Children also stay in the water longer than adults (Wade et al., 2006, 2008) and often times ingest more water (Dufour et al., 2006).

In data from the NEEAR fresh water study sites, there was considerable overlap in the CIs associated with the estimated mean illness responses between children and the general population. The CIs for the children's curve were wider than the CIs for the general population. When health effects were compared with water quality, as measured by culturable enterococci, differences between children (age ten years and under) and the general population were not observed (Wade et al., 2008). As indicated previously, swimmers exposed to water qualities above densities of 33 enterococci 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 enterococci cfu per 100 mL. Both cohorts, including children (age ten years and under) and the general population, demonstrated similar responses to water having more than 33 enterococci cfu per 100 mL.

The epidemiological studies conducted by EPA in tropical regions (Boquerón Beach, Puerto Rico) and temperate marine water that were impacted by urban runoff (Surfside Beach, South Carolina) showed no evidence of increased illness in children or the general population associated with increasing levels of FIB in the recreational waters (U.S. EPA, 2010a).

EPA considered developing criteria based specifically on the results for children. The collective results of the NEEAR study, however, provide inconclusive evidence that children (age ten years and under) exhibited a significantly different illness response given the range of water qualities measured in these studies.

Participants over the age of 55 years were studied, but in numbers that were too low to be evaluated separately. For example, in the fresh water studies, this subgroup represented seven 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 old. Additionally, EPA's NEEAR study were 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.

This RWQC document includes information regarding several additional ways to protect children at beaches through use of a lower value in beach notification programs (i.e., BAV), rapid indicator methods, and predictive modeling. The BAVs are values that correspond to the 75th percentile of a water quality distribution based on these criteria, and can be used by states to make precautionary beach management decisions before there is an excursion of the applicable WQS (see section 5.1). Rapid indicator detection methods, such as qPCR can allow beach managers to make real-time decisions to protect families and their children, in contrast to traditional culture methods, which provide estimates of water quality a day or two after the actual exposure. The qPCR method can be performed in 2–6 hours and has been shown to be successful when implementing same-day beach management decisions (Griffith and Weisberg, 2011). Predictive models can also be used for rapid notification of potential water quality problems. These models have been demonstrated to be useful tools for implementing beach notification programs in the Great Lakes (Francy, 2009; Frick et al., 2008; Ge and Frick, 2009). Because children may be more exposed and/or 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 recommendations are scientifically defensible for all surface waters of the U.S. designated by a state for primary contact recreation. Historically, the scientific evidence used to generate criteria recommendations has been based on data collected mostly from coastal, temperate and Great Lakes fresh waters. The stakeholder community asked EPA to consider whether EPA's criteria recommendations could be used to develop state WQS 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, 2010f). Additionally, EPA considered the WERF Inland Water Workshop report (WERF, 2009) and subsequent meeting report publication (Dorevitch et al., 2010). These publications 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. Specifically, these studies found 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). Further, epidemiological studies in non-coastal waters also support the inclusion of all waterbody types into the criteria. Outbreaks from recreational exposure to non-coastal waters indicate a need for public health protection in such settings. Historical use of culturable *Enterococcus* spp. and *E. coli*, paired by the recommended 1986 criteria, have been used to prevent the occurrence of outbreaks of severe illness as well as the sporadic cases of illness that occur among swimmers. The next two subsections describe the data that EPA considered in determining which waterbody types are covered by the 2012 RWQC. For additional information see the WERF Inland Water Workshop report (WERF, 2009).

<u>Waterbody type and sources of fecal contamination.</u>

EPA's literature review identified the source of fecal pollution as a factor when considering the potential differences between EPA epidemiological study sites and non-coastal waters (U.S. EPA, 2010f). 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 may potentially 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. FIB loadings in WWTP-impacted coastal and non-coastal waters are generally similar. WWTP discharges, which are known sources of human-derived pathogens and indicators from fecal pollution, are relatively steady. Differences exist in FIB loadings between waters that are WWTP-impacted and waters impacted by sources other than treated sewage effluent. Due to differences in the physical and biological characteristics, FIB survival compared to pathogen survival may differ between coastal and non-coastal waters. Some of the potential differences between coastal and non-coastal waters that may impact survival include extent of shading, hydrodynamics, potential for sedimentation, and microbial ecology.

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 determine the relationship between swimming-related morbidity and the bacteriological quality of the recreational water. Tourists (n = 5,737) 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 were best correlated to GI illness. Direct linear regression models and fecal coliforms did not predict risk as well. The concentration of fecal streptococci above which bathers exhibited higher illness rates than non-bathers was 20 fecal streptococci cfu 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 in compliance with the European standards for total coliform and fecal coliform 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. Their recommended guideline values for enterococci and *E. coli* are very similar to the 2012 RWQC recommendations.

Epibathe evaluated the health effects of swimming in E.U. fresh and Mediterranean marine waters (European Commission-Epibathe, 2009). Four riverine recreational sites were examined in Hungary in 2007, which were in compliance with the European standards specified in the E.U. bathing Water Directive (EP/CEU, 1976). For these fresh water studies, *E. coli* provided the best indicator-illness relationship between GI symptoms and water quality. These data support the use of *E. coli* as an effective fecal indicator for use in inland waters.

A PC study was recently conducted at a small inland lake in Ohio (Marion et al., 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 an increased GI illness rate among recreators. Human health data were collected during the 2009 swimming season at East Fork Lake, Ohio and adverse health outcomes were reported eight to nine days post-exposure. The authors concluded that *E. coli* was significantly associated with an elevated GI illness rate among swimmers compared to non-swimmers. The predicted illness rate increased among swimmers with increasing densities of *E. coli*.

Based on the information summarized above, EPA has determined that the 2012 RWQC recommendations are scientifically defensible and protective of the primary contact recreation use in both coastal and non-coastal waterbodies. Although some differences may exist between coastal and non-coastal waters, those differences were not significant enough to justify the development of different WQC recommendations for non-coastal waters. States wishing to address site-specific conditions or local waterbody characteristics in their WQS should refer to section 6 of this document for suggestions on approaches.

3.5 Sources of Fecal Contamination

In §on 303(i)(2)(A) of the CWA, EPA was required to promulgate criteria that are 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 WQS 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 [WQS for states based on] another approach." Thus, the federally promulgated criteria values in the 2004 BEACH Act Rule applied 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 WQS with exemptions for nonhuman 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 agricultural animals). EPA further investigated sources of fecal contamination 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 pathogens that can affect both human and other species (zoonotic). 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, the aforementioned reviews indicate that both human and animal feces in recreational waters do pose potential risks to human health, especially in immunocompromised persons and vulnerable individuals. EPA has conducted analyses to characterize the potential differences in magnitude of illness arising from different fecal sources. These analyses indicate that the human health risk associated with exposure to waters impacted by animal sources can vary substantially. In some cases these risks can be similar to exposure to human fecal contamination, and in other cases, the risk is substantially lower. 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.

3.5.1 Zoonotic Potential

Zoonotic diseases are those that are communicable from animals to humans. 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.
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 (Roy et al., 2004; U.S. EPA, 2009a; Valderrama et al., 2009). 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 et al., 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 EPA's *Review of Published Studies to Characterize Relative Risks from Difference Sources of Fecal Contamination in Recreational Water* (U.S. EPA, 2009b).

3.5.2 Differential Health Risks from Human versus Nonhuman Sources

EPA's research indicates that the source of contamination appears to be an important factor for understanding the human health risk associated with recreational waters and that the potential human health risks from human versus nonhuman fecal sources can vary (Schoen and Ashbolt, 2010; Soller et al., 2010b).

Researchers have documented human health impacts in numerous epidemiological studies in marine and fresh water 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 WWTP effluent, is thought to be viral (Soller et al., 2010a; U.S. EPA, 1986; WERF, 2011). These human viruses are generally unlikely to occur in animal feces although pigs and birds may periodically carry zoonotic viruses.

Nonhuman sources of fecal contamination and the associated potential human health risks can vary from site-to-site depending on factors such as: the nature of the nonhuman source(s), the fecal load from the nonhuman 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 (such as, differences in attachment to particulates or differences in susceptibility to environmental parameters affecting survival) (U.S. EPA, 2011l). For more information on pathogenic risks from nonhuman sources, see *Review of Zoonotic Pathogens in Ambient Waters* (U.S. EPA, 2009a).

However, only a few epidemiological studies have been conducted in waters impacted by nonhuman sources of fecal contamination. The results of these studies are less clear than those conducted in waters impacted by human sources, particularly as related to conventionally enumerated FIB in those types of waters. For example, Calderon et al. (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 may have been 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 et al., 2007). On the other hand, McBride et al. (1998) conducted an analysis of the impact on human sources versus animal sources on New Zealand beach sites and concluded that the illness risks posed by animal versus human fecal material were not substantially different. These studies collectively suggest that waterbodies with substantial animal inputs may potentially result in human health risks that vary based upon the relative proportion of the human and nonhuman fecal input and the nature of the nonhuman source of infective agent(s).

Microbial risk assessment approaches are available to assist in characterizing potential human health risks from nonhuman sources of fecal contamination (Roser et al., 2006; Soller et al., 2010b; Schoen and Ashbolt, 2010; Till and McBride, 2004). For example, New Zealand, where roughly 80 percent of the total reported 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 could be developed. The correlation between the occurrence of *Campylobacter* and *E. coli* is unlikely to hold in all waters, but this relationship was demonstrated in parts of New Zealand, particularly in waters with high levels of *Campylobacter* and *E. coli*.

The risk presented by fecal contamination from nonhuman sources has been shown in some cases, to be potentially less than the risk presented by fecal contamination from human sources (Schoen and Ashbolt, 2010; Soller et al., 2010a, b; WERF, 2011). EPA's research also indicates that some nonhuman fecal sources (cattle in particular) may pose risks comparable to those risks from human sources (Soller et al., 2010a, b; U.S. EPA, 2010g). 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 that must be accounted for in the 2012 RWQC. For waters dominated by nonhuman sources and in the absence of site-specific criteria, EPA recommends that the national criteria be used to develop WQS for all waters including those impacted by point and nonpoint sources.

Because there have been few epidemiological studies, with mixed findings, in waters impacted by nonhuman sources and QMRA shows that risks from some animals may be comparable to humans, EPA is not developing separate national criteria for nonhuman sources. However, since some studies have site-specifically shown less risk in waters impacted by 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 6.2.2 of this document for suggestions on approaches.

Naturally occurring environmental sources of traditional FIB, another nonhuman source, may exist, particularly under tropical conditions. Results of the EPA epidemiological beach study at Boquerón, Puerto Rico did not refine EPA's understanding of risk enough to justify a different criteria recommendation for tropical waters. In addition to the epidemiological study at Boquerón, Puerto Rico, EPA conducted a literature search and reported the results in the *Review of Fecal Indicator Organism Behavior in Ambient Waters and Alternative Indicators for Tropical Regions* (U.S. EPA, 2009c). The literature indicates that FIB, fecal coliforms, enterococci, and *E. coli* are endemic to tropical, subtropical, and temperate regions. Studies conducted in the tropics and subtropics show proliferation of *E. coli*, enterococci, and/or fecal coliforms (Boehm, 2007; Byappanahalli, 2012; U.S. EPA, 2009c). Changing environmental conditions in tidally-influenced sediments help support proliferation and elevated FIB in water (U.S. EPA, 2009c).

Overall, EPA believes that the state of the science is not developed sufficiently to distinguish environmental sources from other sources of FIB on a national basis. In some circumstances, the presence of FIB in water is not necessarily an indication of recent fecal contamination or potential health risk. Therefore, EPA has concluded that states adopting the 2012 RWQC would result in WQS protective of the designated use of primary contact recreation. States wishing to consider alternative indicators should refer to section 6.2 for information on how to develop alternative criteria.

3.6 Expression of Criteria

EPA identified a number of opportunities to improve clarity and to enhance implementation of the 2012 RWQC, which are discussed in the sections below.

3.6.1 EPA's 1986 Ambient Water Quality Criteria for Bacteria

In 1986, EPA recommended criteria for enterococci and *E. coli* that contain two components: a GM and an SSM. EPA derived the 1986 criteria values from beach water quality datasets that were collected as part of EPA's epidemiological studies conducted during the late 1970s and early 1980s. The GM values were computed as described in section 3.2.1. The SSM values were derived from upper percentiles of the water quality distribution around the GM criteria values. Together, the 1986 criteria GM and SSM described a water quality distribution that would be protective of primary contact recreation, based on the epidemiological studies conducted during that period. Thus, the GM and SSM values in the 1986 criteria corresponded to the same illness rate because they are both derived from the same water quality distribution.

The 1986 criteria contained four different SSM values corresponding to the 75th, 82nd, 90th, and 95th percentiles of the expected water quality sampling distribution at the GM criteria value. EPA recommended using different SSM values on the basis of the use intensity of the recreational water. However, treating the SSM as a never to be exceeded value for such an evaluation would impart a level of protection much more stringent than intended by the 1986 criteria GM value. For example, a marine beach that is in compliance with the 1986 GM criteria for enterococci (GM = 35 cfu per 100 mL) would be expected to have 25% of the sample values above 104 cfu per 100 mL (the 75th percentile of the expected water quality sample distribution) because of expected variability in individual water quality measurements. Expecting that beach to never exceed 104 cfu per 100 mL would require an actual GM much lower, associated with a lower illness rate, than the recommended GM criterion value.

3.6.2 The 2012 RWQC

In the 2012 RWQC, EPA is recommending the criteria magnitude be expressed as a GM value corresponding to the 50th percentile and a STV corresponding to the 90th percentile of the same water quality distribution, and thus associated with the same level of public health protection. EPA's criteria recommendations are both for a GM and STV (rather than just a GM or just an STV) because used together they would indicate whether the water quality is protective of the designated use of primary contact recreation.. Using the GM alone would not reflect spikes in water quality because the GM alone is not sensitive to them.

EPA is recommending that the GM of a waterbody be calculated in the same way as recommended in the 1986 criteria by taking the $\log_{10}$ of sample values,[7] averaging those values, and then raising that average to the power of 10. The STV is also derived in a manner similar to how the 1986 criteria SSM was derived by estimating the percentile of the expected water quality distribution around the GM criteria value.

EPA believes that the STV, used in conjunction with the GM, can help ensure the FIB densities in recreational waters correspond to a water quality level protective the designated use of primary contact recreation by constraining the number of high water quality values. The distribution of FIB in water is highly variable and can generally be represented as a $\log_{10}$ normal distribution (Bartram and Rees, 2000; Kay et al., 2004; Wyer et al., 1999). EPA derived the STV from the observed pooled variance of the FIB data reported in EPA's epidemiological studies. The computed pooled variances represent a wide range of weather and hydrological conditions because monitoring was conducted over the full course of the set of epidemiological studies. EPA stratified the epidemiological data by beach and water depth (14 subgroups) because FIB

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

distributions are known to differ systematically for these factors (Wade et al., 2008), and the pooled variance was then calculated. For EPA's *Enterococcus* spp. qPCR Method 1611, the pooled variance resulted in a log standard deviation (the standard deviation of the base 10 logarithms of the data) of 0.49. From the NEEAR study sites, the pooled variance estimates for culturable enterococci are 0.44 (the pooled variance for culturable *E. coli* was reported previously (U.S. EPA, 1986) as 0.40).

For the STV, EPA selected the estimated 90th percentile of the water quality distribution to take into account the expected variability in water quality measurements, while limiting the number samples allowed to exceed the STV, before deciding water quality is impaired. In addition, the approach encourages monitoring because once an exceedance is observed, at least ten more samples need to be below the STV before water quality is considered unimpaired.

Further, EPA is no longer utilizing the concept of "use intensity" as a basis for recommending multiple SSM criteria. EPA's recommends instead that states adopt both the GM and STV into their WQS for all primary contact recreation waters.

EPA now specifically recommends a duration period over which the GM of samples should be calculated and over which the STV should be compared against a recommended limit on the frequency of excursions. EPA is recommending that states use a duration for the GM and STV of 30 days. The duration and frequency of excursion should be explicitly included in the state's WQS as it is a component of the WQS.

EPA understands that a longer duration would typically allow for more samples to be collected and that including more samples in calculation of the GM and STV improves the accuracy of the characterization of water quality. However, because the designated use protected by this criterion is primary contact recreation, EPA believes that a shorter duration (i.e., 30 days), used in a static or rolling manner, coupled with limited excursions above the STV, allows for the detection of transient fluctuations in water quality in a timely manner. In the development of their monitoring program, EPA recommends that states consider the number of samples evaluated in order to minimize the possibility of incorrect use attainment decisions (see section 3.6.4).

3.6.3 Criteria Magnitude, Duration, and Frequency for CWA Purposes

EPA recommends that RWQC consist of a magnitude, duration and frequency. Magnitude is the numeric expression of the maximum amount of the pollutant that may be present in a waterbody that supports the designated use. Duration is the period of time over which the magnitude is calculated. Frequency of excursion describes the maximum number of times the pollutant may be present above the magnitude over the specified time period (duration). A criterion is set in a WQS such that the combination of magnitude, duration and frequency protect the designated use (such as primary contact recreation).

EPA’s 2012 RWQC recommendations to protect primary contact recreation consist of a magnitude, duration and frequency of exceedance.

- **Magnitude**: GM and the STV (regardless of the sample size).
- **Duration and Frequency**: The waterbody GM should not be greater than the selected GM magnitude in any 30-day interval. There should not be greater than a ten percent excursion frequency of the selected STV magnitude in the same 30-day interval.

3.6.4 Application of State WQS based on EPA’s 2012 RWQC for NPDES Permitting, 303(d) Listing, TMDL Development, and Beach Notification Programs

WQC in state WQS are used: to derive water quality-based effluent limits (WQBELs) for National Pollutant Discharge Elimination System (NPDES) permits; to identify impaired and threatened waters for waterbody assessments; to develop waste load allocations and load allocations for TMDLs; and for beach notification programs under §406 of the CWA.

NPDES permitting purposes

The NPDES regulation at 40 CFR 122.44(d) requires the development of WQBELs as necessary to attain WQS. 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”. EPA recommends that permitting authorities use an effluent limit derivation approach that considers both the GM and STV in the limit calculations, and which results in short- and long-term effluent limits that derive from and comply with all applicable criteria expressions. Once established, pathogen indicator-based limits for continuous dischargers are applied and enforced in a manner consistent with all other water quality parameters.

For non-continuous or episodic discharges, 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. Wet weather-related events influence episodic discharges such as combined sewer overflows (CSOs). The 1994 CSO Control Policy (reflected in §402(q) of the CWA) describes various approaches for addressing CSO discharges in NPDES permits and should be consulted when establishing WQBELs for intermittent dischargers. The CSO Policy also recommends WQS review and revision, as appropriate, to reflect the site-specific wet weather impacts of CSOs. In conjunction with an approved long-term CSO control plan, a WQS review could involve a use attainability analysis (40 CFR 131.10(g)) and subsequent modification of a designated use.

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

Identification of Impaired and Threatened Waters

Under §303(d) of the CWA and EPA’s implementing regulation (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 TMDLs. Impaired waters are those waters for which effluent limitations and other pollution control requirements are not stringent enough to implement any WQS applicable to the waterbody. 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 WQS 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). Both the GM and the STV would be part of the WQS and therefore both targets would be used to determine whether a 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 regulation defines “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 notification program, as well as information regarding beach closures and advisories.

Beach Notification Programs

WQC in state WQS are the applicable targets for EPA grant funded state beach notification programs under §406 of the CWA. The BAV is not a component of EPA’s recommended criteria, but a tool that states may choose to use, without adopting it into their WQS as a “do not exceed value” for beach notification purposes (i.e., advisories). While the GM and STV would be the applicable WQS, a BAV could be used at the state’s discretion as a more conservative, precautionary tool for beach management decisions. Similarly, states could also choose to use the STV as a “do not exceed value” for the purposes of their beach notification program, without adopting it as a “do not exceed value” in their WQS.

3.6.5 Practical Considerations for Implementing State WQS based on the 2012 RWQC

The number of samples, to be collected by a state in determining if WQS have been exceeded, is not an approvable element of a WQS package (Florida Public Interest Research Group vs. EPA, 2007). Therefore states should not include a minimum sample size as part of their criteria submission. When identifying sampling frequency as part of a state’s monitoring plan, a state may consider that, typically, a larger dataset will more accurately characterize the water quality in a waterbody, which may result in more meaningful attainment determinations. Therefore, EPA is recommending that states conduct at least weekly sampling to evaluate the GM and STV over a 30-day period and encourages more frequent sampling at more densely populated beaches.

4.0 Recreational Water Quality Criteria

EPA evaluated the available information and the results of the analyses presented above (section 3.2.4) and determined that the primary contact recreation designated use would be protected if one of the following criteria sets consisting of a GM and an STV were adopted into a state’s WQS and approved by EPA (see Table 4).

Table 4. Recommended 2012 RWQC.

Criteria Elements	**Estimated Illness Rate (NGI): 36 per 1,000 primary contact recreators**		OR	**Estimated Illness Rate (NGI): 32 per 1,000 primary contact recreators**	
	Magnitude			**Magnitude**	
Indicator	GM (cfu/100 mL)[a]	STV (cfu/100 mL)[a]		GM (cfu/100 mL)[a]	STV (cfu/100 mL)[a]
Enterococci – marine and fresh	35	130		30	110
OR					
E. coli – fresh	126	410		100	320
Duration and Frequency: The waterbody GM should not be greater than the selected GM magnitude in any 30-day interval. There should not be greater than a ten percent excursion frequency of the selected STV magnitude in the same 30-day interval.					

[a] EPA recommends using EPA Method 1600 (U.S. EPA, 2002a) to measure culturable enterococci, or another equivalent method that measures culturable enterococci and using EPA Method 1603 (U.S. EPA, 2002b) to measure culturable *E. coli*, or any other equivalent method that measures culturable *E. coli*.

EPA believes both criteria sets outlined above are protective of the designated use of primary contact recreation. EPA recommends that states make a risk management decision regarding illness rate to determine which set of criteria values (both a GM and related STV) to adopt into their WQS and that this risk management decision should be applied statewide. In order to ensure downstream protection of estuarine and marine swimming waters, upstream inland waters should have WQS based on the same illness rate as those downstream waters. Note that either enterococci or *E. coli* can be selected for fresh waters, as adopting one of the indicators is sufficient and only enterococci can be selected for marine waters. Adopting criteria based on one illness rate for some waters and criteria based on the other illness rate for remaining waters is not recommended. The criteria that correspond to an illness rate of 36 NGI per 1,000 primary contact recreators correlate to water quality levels associated with the 1986 criteria. Accordingly, the illness rate has a history of acceptance by the public. The criteria that correspond to an illness rate of 32 NGI per 1,000 primary contact recreators would encourage an incremental improvement in water quality.

5.0 Supplemental Elements for Enhanced Protection of Recreational Waters

In addition to the RWQC values described above, EPA is providing supplemental elements for states' consideration and possible use. These elements include the BAV and values for *Enterococcus* spp. as measured by qPCR. The BAV can be used as a precautionary tool for making beach notification decisions, and use enterococci measured using EPA's *Enterococcus* spp. qPCR Method 1611 (U.S. EPA, 2012b) qPCR is anticipated to provide increased public health protection by facilitating timely notification to swimmers from elevated levels of FIB. Details for these supplemental elements are described below.

5.1 Beach Action Value (BAV)

EPA suggests that states use a BAV as a conservative, precautionary tool for making beach notification decisions. The BAV is not a component of EPA's recommended criteria, but a tool that states may choose to use, without adopting it into their WQS as a "do not exceed" value for beach notification purposes (such as advisories). The BAV was developed from the same water quality distribution (section 3.6.2) as the criteria values in section 4.0 and corresponds to the estimated 75th percentile of the enterococci and *E. coli* water quality distributions.

For states that choose to use a BAV (see Table 5), any single sample above the BAV could trigger a beach notification until another sample below the BAV is collected. While the GM and STV would be the applicable WQS, a BAV could be used at the state's discretion as a more conservative, precautionary tool for beach management decisions. This applies to all states, including those with grants under §406 of the CWA.

EPA suggests that the state's chosen criterion illness rate be used to determine the corresponding BAV. For states that do not use a BAV, EPA suggests using the criteria STV values (provided in Table 4) as "do not exceed" values for beach notification or retaining their current beach notification values in their WQS. Additionally, if a state is not sampling during or immediately after a rain event, the state should consider advising the public of the potential additional risk of primary contact recreation when sources such as urban runoff or CSOs may be impairing water quality.

Table 5. Beach Action Values (BAVs).

	Estimated Illness Rate (NGI): 36 per 1,000 primary contact recreators	**OR**	**Estimated Illness Rate (NGI): 32 per 1,000 primary contact recreators**
Indicator	**BAV (Units per 100 mL)**		**BAV (Units per 100 mL)**
Enterococci – culturable (fresh and marine)[a]	70 cfu		60 cfu
E. coli – culturable (fresh)[b]	235 cfu		190 cfu
Enterococcus spp. – qPCR (fresh and marine)[c]	1,000 cce		640 cce

[a] Enterococci measured using EPA Method 1600 (U.S. EPA, 2002a), or another equivalent method that measures culturable enterococci.

[b] *E. coli* measured using EPA Method 1603 (U.S. EPA, 2002b), or any other equivalent method that measures culturable *E. coli*.

[c] EPA *Enterococcus* spp. Method 1611 for qPCR (U.S. EPA, 2012b). See section 5.2.

5.2 Rapid Method: *Enterococcus* spp. as measured by qPCR (EPA Method 1611)

EPA has developed a qPCR method to detect and quantify enterococci more rapidly than the culture method for ambient waters. Introduction of EPA *Enterococcus* spp. qPCR Method 1611 is anticipated to provide increased public health protection by facilitating timely notification[8] to swimmers from elevated levels of FIB. Importantly, enterococci as measured by EPA *Enterococcus* spp. qPCR Method 1611 have shown a stronger relationship to GI illness in the recent EPA NEEAR epidemiological study compared to other methods tested (Wade et al., 2008; U.S. EPA, 2010a, 2012b).

While EPA *Enterococcus* spp. qPCR Method 1611 (U.S. EPA, 2012b) offers some advantages, EPA has limited experience with its performance across a broad range of environmental conditions. States should be aware of the potential for qPCR interference (see section 3.1.1) in various waterbodies, which may vary on a site-specific basis. Thus, EPA encourages a site-specific analysis of the method's performance prior to use in a beach notification program or adoption of WQS based on the method. A "site" may be a beach, a waterbody, a particular watershed, or a larger area (such as a state) that is shown to have uniform water quality characteristics throughout. Considerations for determining how a qPCR-based WQS could be developed will be provided in additional TSM. EPA's *Enterococcus* spp. qPCR Method 1611 (U.S. EPA, 2012b) is not currently suggested for NPDES permitting or effluent-related monitoring purposes because this method may not reflect the efficacy of WWTP disinfection since it detects and enumerates both live and dead enterococci.

A state may adopt a WQS based on EPA's *Enterococcus* spp. qPCR Method 1611 (U.S. EPA, 2012b) if it would be scientifically defensible and protect the designated use. As noted above, prior to adoption EPA recommends a site-specific evaluation of the method's performance. For states interested in adopting a value for enterococci using EPA's *Enterococcus* spp. qPCR Method 1611 into their WQS, EPA is providing GM and STV values for use in marine and fresh waters based on its epidemiological study data as shown in Table 6. The state's chosen criterion illness rate would determine the suggested corresponding qPCR values to be used by the state. States may also choose a qPCR-based BAV for beach notification purposes (see Table 5).

This document includes only supplementary information about a WQS for *Enterococcus* spp. measured by EPA's *Enterococcus* spp. qPCR Method 1611 (U.S. EPA, 2012b) because of the concerns discussed in section 3.1.1 of this document.

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

Table 6. Values for qPCR in marine and fresh waters.

	Estimated Illness Rate (NGI): 36/1,000 primary contact recreators		OR	**Estimated Illness Rate (NGI): 32/1,000 primary contact recreators**	
	Magnitude			**Magnitude**	
Element	**GM (cce per 100 mL)**	**STV (cce per 100 mL)**		**GM (cce per 100 mL)**	**STV (cce per 100 mL)**
qPCR[a]	470	2,000		300	1,280
Duration and Frequency: The waterbody GM should not be greater than the selected GM magnitude in any 30-day interval. There should not be greater than a 10 percent excursion frequency of the selected STV magnitude in the same 30-day interval.					

[a] EPA *Enterococcus* spp. Method 1611 for qPCR (U.S. EPA, 2012b).

6.0 Tools to Support States and Tribes in Evaluating and Managing Recreational Waters and for Considering Alternative 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 regulation stated in 40 CFR §131.11(b)(1) provides that "In establishing criteria, states should (i) 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 waterbody and therefore they could be established for a specific site. A "site" may be a beach, a waterbody, a particular watershed, or a larger area (such as a state) that is shown to have uniform water quality characteristics throughout. When EPA reviews state WQS 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 further evaluate and manage their waterbodies (see section 6.1); and (2) tools that can be used by states in the development of WQC that differ from EPA's recommended criteria ("alternative criteria") (see section 6.2). Alternative criteria could be developed on a site-specific basis, or they could be developed using different indicators and analytical methods. State WQS including alternative criteria would need to be scientifically defensible and protective of the use. Because some alternative criteria for primary contact recreation could be based in part on assumptions regarding the current state of a watershed such as current land uses, they should be revisited no less frequently than triennially to ensure the site-specific criteria remain protective of the primary contact recreation use. This section does not provide details on how to implement these tools. Rather, detailed information on these tools will be provided in upcoming TSM.

The tools discussed below (and the corresponding subsections) include: (1) sanitary surveys (section 6.1.1); (2) predictive models (section 6.1.2); (3) epidemiological studies (section 6.2.1); (4) QMRA (section 6.2.2); and (5) approaches for developing criteria using alternative fecal indicators and/or methods (section 6.2.3).

6.1 Tools for Evaluating 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 further evaluate and manage their waterbodies, which can aid in identifying 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 the use of predictive models for timely beach notification. EPA encourages the use of sanitary surveys 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 beach notification program. Predictive modeling has the potential to identify days of poor water quality in time to inform the public of the potential risks. Together, the tools for evaluating and managing waters in this section could be used by a state or locality to assess and communicate the risks associated with fecally contaminated recreational waters. These tools would not be part of the adopted WQS and do not result in different numerical criteria values.

6.1.1 Sanitary Survey

Water quality managers often use sanitary surveys to evaluate waters for fecal contamination potential and to prioritize clean-up and remediation efforts. Sanitary surveys involve collecting information about the surrounding watershed for the purpose of cataloging physical conditions that may influence water quality in a watershed or at a beach. A sanitary survey is a detailed process that compiles information on pollution sources (such as streams or stormwater outfalls), physical features on or near a site, land use in adjacent areas and in the watershed that drains to the site, and other information that could regularly influence water quality. Additional observations may include the presence or absence of sanitary facilities or the nature of existing management activities (such as beach cleaning). Molecular source tracking tools may also be useful in verifying the results of the sanitary survey by confirming the presumed sources of fecal contamination in the watershed.

A sanitary survey collects information that relates to the specific conditions at a site at a particular time. Sanitary surveys are a snapshot of the conditions in a waterbody, which can change due to factors including those listed above. Sanitary surveys help state and local water quality managers and public health officials identify sources of fecal contamination, assess the magnitude of the contamination, and designate priority locations for water testing. Observations taken daily or at the time of water quality sampling can not only assist managers in evaluating water quality conditions (such as, turbid water conditions, rainfall, source flow), but sanitary survey data and measured FIB densities can be used to develop models to predict water quality. Other information such as molecular source tracking and watershed information may be needed to effectively delineate sources within the watershed.

Information on EPA's sanitary survey approach is available at: http://water.epa.gov/type/oceb/beaches/sanitarysurvey_index.cfm. EPA plans to include additional information on developing and using sanitary surveys in TSM.

6.1.2 Predictive Models

EPA recognizes that, at some locations and under some conditions, use of culturable or molecular enumeration methods, such as qPCR, are not feasible or are unlikely to provide timely information for making a same-day beach notification decision (i.e., in locations where water samples cannot be transported to laboratories for analysis in a timely manner). This section describes predictive modeling, an approach that may supplement water quality monitoring results to allow for timely beach notification decisions. Typically, states would use site-specific predictive models, such as statistical models, rainfall threshold levels, or notification protocols (U.S. EPA, 2010h, 2010i), to supplement monitoring using culture-based methods.

Predictive models are currently used in areas such as the Great Lakes and have proven to be an effective means of implementing beach notification programs. These models draw on existing culture-based monitoring data, are inexpensive to use, and allow for rapid water quality management decisions (U.S. EPA, 2010h, 2010i).

Predictive modeling tools fall into the following categories: statistical regression models, rainfall-based notifications, decision trees or notification protocols, deterministic models, and combinations of tools. There are various considerations for developing and selecting predictive models, and each has its own set of challenges (Boehm et al., 2007). To be effective, these models should reflect site-specific conditions (i.e., inter-seasonal variations). Development of predictive models typically requires monitoring data for establishing and maintaining statistical relevance.

EPA conducted research and published a two-volume report to advance the use of predictive models (U.S. EPA, 2010h, 2010i). Volume I summarizes the basic concepts for developing predictive tools for coastal and non-coastal waters (U.S. EPA, 2010h). Volume II provides the results of EPA's research on the development of 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, 2010i). EPA is expanding the Virtual Beach tool to include other statistical approaches. Beyond these Virtual Beach improvements, 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. More information on developing and using predictive models for water quality management purposes will be provided in upcoming TSM.

6.2 Tools for Developing Alternative Criteria

States could adopt site-specific alternative criteria to reflect local environmental conditions and human exposure patterns. An alternative WQS may involve the adoption of different numerical value(s) that are based on: (1) an alternative health relationship derived using epidemiology with or without QMRA; (2) QMRA results to determine water quality values associated with a specific illness rate; or (3) a different indicator/method combination. EPA recommends that these alternative criteria reflect the same risk management decision regarding illness rate, as discussed in section 4.0. Such alternative criteria may be adopted into a state WQS provided that the resulting site-specific WQS are scientifically defensible, protective of the use, and reviewed and approved by EPA under CWA §303(c).

6.2.1 Epidemiological Studies

Recreational water epidemiological studies describe the risks associated with exposure to fecal contamination as measured by FIB. Epidemiological studies with or without QMRA could be used to develop an alternative health relationship for a waterbody. This alternative health relationship could be used to develop site-specific alternative criteria.

EPA's NEEAR epidemiological study were conducted in water primarily impacted human fecal contamination, with the exception of one site that was impacted by urban runoff (U.S. EPA, 2010a; Wade et al., 2006, 2008, 2010). Statistically significant associations between water quality, as determined using EPA's *Enterococcus* spp. qPCR Method 1611 (U.S. EPA, 2012b), and reported GI illness were observed in the temperate marine water and fresh water WWTP-impacted beaches. Other agencies have also conducted recreational water epidemiological studies. For example, epidemiological studies of recreational water exposures have been conducted recently in Southern California (Colford et al., 2012), Southern Florida (Fleming, 2006; Sinigalliano, 2010), and Ohio (Marion et al., 2010).

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, solar radiation, water salinity, turbidity, dissolved organic matter, water temperature, and nutrient content. Additionally, numerous factors also affect the occurrence and distribution of FIB and pathogens, including but not limited to: 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 (U.S. EPA, 2010a; WERF, 2009).

States or local agencies may choose to conduct epidemiological studies in their waterbodies and use the results from those studies to derive alternative criteria, site-specifically. To derive scientifically defensible alternative WQC for adoption into state standards, ideally the epidemiological studies should be rigorous, comparable to those used to support the 2012 RWQC, and peer-reviewed. However, smaller scale epidemiological studies may also provide a scientifically defensible foundation for alternative criteria. Additionally, QMRA (see section 6.2.2) 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). 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 FIB sources.

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. Such studies may also 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). When 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 alternative criteria.

The epidemiological information underlying the recommended 2012 RWQC used a PC study design. If a state wishes to develop alternative criteria using their own epidemiological studies, EPA advises that the studies also be of the PC design to facilitate the interpretation of the alternative health relationship and potential resulting alternative criteria. EPA will provide additional information on the use of epidemiological studies in development of alternative criteria in upcoming TSM.

6.2.2 Quantitative Microbial Risk Assessment

QMRA is a formal process, analogous to chemical risk assessment, of estimating human health risks due to exposures to selected infectious pathogens (Haas et al., 1999; NRC, 1983). To the greatest possible extent, the QMRA process should include the evaluation and consideration of quantitative information; however, qualitative information is also used when appropriate (WHO, 1999). In general, 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 evaluate 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 those from food, sludge/biosolids, drinking water, recycled water, and recreational waters. Moreover, chemical 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 QMRA specifically 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 (such as, U.S. Department of Agriculture, U.S. Food and Drug Administration, and WHO) to protect public health from exposure to microbial pollutants in food and water.

Although EPA believes the 2012 RWQC are appropriate for waterbodies impacted by all sources, QMRA can be used to develop alternative site-specific criteria, where sources are characterized predominantly as nonhuman or nonfecal (U.S. EPA, 2009b). EPA’s research indicates that understanding the predominant source of fecal contamination could help characterize 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. QMRA studies have demonstrated that the potential human health risks from human and nonhuman fecal sources could 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 (Roser et al., 2006; Schoen and Ashbolt, 2010; Soller et al., 2010b; Till and McBride, 2004; WERF, 2011). Additional information and case studies of QMRA for recreational waters will be provided in upcoming TSM.

Further, research demonstrates that swimming-associated illnesses are caused by different pathogens, which depend on the source of fecal contamination. For example, in human-impacted recreational waters, human enteric viruses appear 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, bacteria and protozoa are the etiologic agents of concern (Roser et al., 2006; Schoen and Ashbolt, 2010; Soller et al., 2010b). The relative level of predicted human illness in recreational waters impacted by nonhuman sources can also vary depending on whether the contamination is direct or via runoff due to a storm event (U.S. EPA, 2010g). EPA is developing TSM for QMRA to assist states in developing site-specific criteria to account for local scale, nonhuman sources that are protective of the designated use of primary contact recreation.

To derive site-specific criteria that are considered scientifically defensible and protective of the designated use, QMRA studies should be well documented, follow accepted practices, and rely on scientifically defensible data. A sanitary characterization can provide detailed information on the source(s) of fecal contamination in a waterbody to determine whether the predominant source is human or nonhuman. EPA developed a QMRA-specific sanitary survey application, which could be included in a sanitary characterization, to capture information directly applicable to a QMRA. This sanitary characterization process will be described in upcoming QMRA TSM.

EPA's QMRA framework can also be useful for informing human health relationships with alternative FIBs (MFE, 2003; Viau et al., 2011) and may help to clarify epidemiological results in scenarios where waterbodies are impacted by nonhuman sources or the epidemiological results are inconclusive (see section 6.2.1).

6.2.3 Alternative Indicators or Methods

EPA anticipates that scientific advancements will provide new technologies for enumerating fecal pathogens or FIB. New technologies may provide alternative ways to address methodological considerations, such as rapidity, sensitivity, specificity, and method performance. As new or alternative indicator and/or enumeration method combinations are developed, states may want to consider using them to develop alternative criteria for adoption in WQS.

Previously, EPA has used the evaluation of multiple indicators and enumeration methods to describe a common level of water quality. For example, the derivation of the 1986 criteria values was fundamentally based on the comparison of multiple indicators: fecal coliform, enterococci, and *E. coli*. In those specific cases, 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. Rapid methods, such as *E. coli* enumerated by qPCR, have already been evaluated against culturable methods and demonstrated utility on a site-specific basis (Lavender and Kinzelman, 2009).

Some examples of new enumeration methods for FIB include: immunomagnetic separation/adenosine triphosphate (IMS/ATP), propidium monoazide (PMA) qPCR, reverse transcriptase (RT) qPCR, covalently linked immunomagnetic separation/adenosine triphosphate (COV-IMS-ATP), and transcription mediated amplification (TMA-RNA). New methods and additional improvements to currently available methods, platforms and chemistries may also be developed in the future.

Examples of possible alternative indicators include, but are not limited to: *Bacteroidales*, *Clostridium perfringens*, human enteric viruses, and coliphages. These possible alternative indicator organisms could be used with new methodologies or methodologies similar to those recommended by the 2012 RWQC. For example, in one case, *Bacteroidales* measured by qPCR were highly correlated with *Enterococcus* spp. and *E. coli* when either culture-based methods or qPCR methods were used (WERF, 2011). The pathogens norovirus GI and GII have also been shown to be predictors of the presence of other pathogens such as adenovirus measured by qPCR (WERF, 2011).

If a state adopts WQS using alternative indicator/method combinations, EPA will review those standards, including any technical information submitted to determine whether such standards are scientifically defensible and protective of the primary contact recreation use. To facilitate consideration of such standards, states may gather water quality data over one or more recreational seasons for the indicator/method recommended in the 2012 RWQC and the proposed alternative indicator/method combination. A robust relationship need not be established between EPA’s recommendation and alternative indicator(s) for the whole range of indicator densities (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 recommended criteria. EPA will provide information on demonstrating the relationship between two indicator/method combinations in upcoming TSM.

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