

Office of Water

Response to Comment Summary

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Acronyms & Abbreviations

BAV	beach action value
BEACH	Beaches Environmental Assessment and Coastal Health Act of 2000
cce	calibrator cell equivalents
cfu	colony forming units
CI	confidence interval
CSO	combined sewer overflow
CT	cycle threshold
CWA	Clean Water Act
DNA	deoxyribonucleic acid
<i>E. coli</i>	<i>Escherichia coli</i>
EPA	U.S. Environmental Protection Agency
EU	European Union
FIB	fecal indicator bacteria, which includes fecal coliforms, <i>E. coli</i> , enterococci, or <i>Enterococcus</i> spp.
GM	geometric mean
HCGI	highly credible GI illness
mL	milliliters
MPN	most probable number
MST	microbial source tracking
NEEAR	National Epidemiological and Environmental Assessment of Recreational Water
NGI	NEEAR-GI
NPDES	National Pollutant Discharge Elimination System
NRDC	Natural Resources Defense Council
QMRA	quantitative microbial risk assessment
qPCR	quantitative polymerase chain reaction
RWQC	recreational water quality criteria
SCCWRP	Southern California Coastal Water Research Project
SSM	single sample maximum
STV	statistical threshold value
TMDL	total maximum daily load
TSM	technical support materials
UAA	use attainability analysis
U.S.	United States
WERF	Water Environment Research Foundation
WHO	World Health Organization
WQC	water quality criteria
WQS	water quality standard(s)
WWTP	wastewater treatment plant

Introduction

This document contains the United States Environmental Protection Agency (EPA) responses to public comments on the EPA's Draft Recreational Water Quality Criteria (RWQC) published December 21, 2011 (EPA 820-D-11-002) (hereafter referred to as the draft RWQC). The public comment period on docket number EPA-HQ-OW-2011-0466 was open from December 21, 2011 to February 21, 2012. EPA received over 9,800 public comments. Over 9,600 of these comments were from a letter writing campaign organized by Natural Resources Defense Council (NRDC) and Heal the Bay. Commenter affiliations included individuals, environmental advocacy groups, industry and related trade associations, local and state governments, academia, federally elected officials, federal agencies, and scientific societies.

The comments are organized and summarized by issue category with the assigned issue number corresponding to various sections in the draft RWQC. As such, they do not reflect the exact language in the comments received. Where necessary, issue subheadings have been included to delineate subgroups of comments on a topic.

Issue 1.0 General

General Comments on Chapter 1

Comment: In chapter 1, EPA needs to explain or justify why monitoring and sampling strategies have not been included in this document.

Response: These are criteria recommendations and EPA cannot mandate monitoring or sampling within the criteria document, the purpose of which is to describe a pollutant-specific water quality threshold dividing water clean enough to support a given designated use and water quality not clean enough to support said designated use (U.S. EPA, 2006). Guidance on monitoring and sampling strategies at beaches is included in the National Performance Criteria and Grant Guidance for Beaches (U.S. EPA, 2002).

Comment: Sections 1.1 and 1.2 should “highlight that the lack of statistically significant correlations between culture methods and illness in the National Epidemiological and Environmental Assessment of Recreational (NEEAR) water studies and lack of high fecal levels during the one tropical study and the other studies.”

Response: EPA has included this information in section 3.2.4 of the final RWQC.

Comment: EPA should include history in chapter 1. The history is important for the public to understand – especially the long timeframe that EPA has had to conduct epidemiological studies and investigate and test rapid methods.

Response: This information is covered in section 3.2.1 of the RWQC.

Comment: The lag time between sampling and notification needs to be discussed in section 1.2.

Response: Lag times are discussed in sections 5.2 and 6.1.2 of the final RWQC.

Comment: In Chapter 1, EPA should provide an updated overview of how many total states have adopted water quality standards (WQS) and routinely monitor beaches and recreational waters and how many do not as of 2012.

Response: A review of how many states adopted and implemented the 1986 criteria is beyond the scope of the RWQC document.

Comment: The document is dense and not readable for the general public.

Response: EPA believes that the level of detail included in the document is appropriate. However this comment was considered as the document was revised.

Comment: The document lacks a glossary, which should be added.

Response: EPA does not believe a glossary is necessary.

Comment: The term “criteria” needs to be defined and further explained.

Response: In the RWQC, the term “criteria” refers to §304(a) criteria as described in §304(a) of the Clean Water Act (CWA) and defined in EPA’s regulations at 40 C.F.R. 131.3(c). As described in the foreword of the final RWQC document, the term "water quality criteria" (WQC) is used in two sections of the CWA, §304 (e.g., subsection 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 human health effects. The criteria recommendations presented in this document are such scientific assessments. Criteria as that term is used in §303(c)(2) refers to elements of state 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 are adopted by a state, or promulgated by EPA, as WQS under §303, they become the relevant standard for developing permit limits, assessing waters and developing total maximum daily loads 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.

Comment: Text edit for section 1.2 - EPA should not imply that indicator bacteria are not pathogens. Change “they” to “most.”

Response: The final RWQC text has been revised to incorporate this suggestion.

General Docket

Comment: Commenters noted that a request for scientific views discourages public comment and the criteria should be reissued with public input in mind.

Response: EPA specifically requested scientific views to encourage the submission of comments on the science behind the RWQC. More than 9,000 public comments were received and considered.

Comment: Commenters requested an extension of the comment period to allow for additional scientific input from laboratories, states, and other interested parties.

Response: EPA chose not to extend the comment period in order to have sufficient time to finalize the criteria by the court-ordered deadline set forth in the consent decree for publication of the final RWQC.

Beaches are Important/Big Business

Comment: Commenters noted that beaches and recreational waterbodies are vital to local, regional, and national economies through tourism, the creation of jobs, and recreational opportunities. Therefore, it is imperative for RWQC to be protective of public health and allow for rigorous assessment of beaches.

Response: EPA agrees that beaches and protecting public health are important. These criteria recommendations, if adopted in WQS, are protective of the primary contact recreation designated use and can be used by states in a rigorous assessment program. Section 6.1 of the final RWQC discusses tools for assessing beaches

Issue 2.0 Applicability And Scope of the Final RWQC

Comments Related to Designated Use

Comment: Some commenters thought that EPA should not seek to broaden the list of activities included in the primary contact standard to the extent that primary contact is considered “any contact” and that expanding the definition of primary contact recreation to other activities and waters would be inconsistent with the traditional definition of swimming and immersion related recreation. They requested that EPA strike the term “water play by children” because it is nebulous and replace with terminology such as “water play activities resulting in full body contact and/or immersion.” Other commenters listed the following activities as those that should be protected because of risk of ingestion and illness or death: swimming, snorkeling, scuba diving, wading, kayaking, rafting, canoeing, surfing, fish watching and underwater photography, angling, aquatic invertebrate collecting and any water play by children.

Other commenters supported the scope of primary contact recreation (“all surface waters of the United States designated for swimming, bathing, surfing, or similar water contact activities”), but request that EPA be more specific in its description by clarifying that the RWQC are not intended to apply to waterbodies with recreational uses that are noncontact, such as fishing or boating. Commenters were concerned that many states have already completed use attainability analyses (UAA) to remove the default assumption of primary contact use on many of their state’s waters, yet the draft RWQC do not address secondary contact uses.

Response: The final RWQC does not change the definition of primary contact recreation, does not provide criteria recommendations for secondary contact recreational uses, and does not define secondary contact.

Comment: Some commenters asked EPA clarify that the 1986 criteria recommendations were for marine and fresh water designated for primary contact recreation. Other commenters appreciated the acknowledgement by EPA in the draft RWQC that surfing is a significant and important recreational beach use.

Some commenters pointed out that many streams, rivers, lakes, and ponds of the United States do not have the designated uses of contact and non-contact aquatic recreation, although they are used as such and should support these important uses. They noted that past guidance has been limited on the application of standards to small streams, ephemeral streams, and other small waterbodies where these activities are impractical or improbable. These commenters thought that EPA should clarify not only the bacteriological threshold for primary contact on the basis of numbers per unit water, but also on water’s physical capabilities to support such uses. Commenters thought that it is not appropriate for the primary contact standard to be applied to

waters where swimming, bathing, and other immersion activity that is reflected in the epidemiological studies used by the agency to define the standard are simply not possible. Physical parameters that preclude this type of recreation should include water body overall size, depth, flow characteristics, location, and ambient temperature. Discretion should be afforded to the states to appropriately classify waters based on their capabilities. Commenters asked EPA to make it clear that primary contact recreation waters must be capable of physically supporting swimming, bathing, and other immersion activity activities.

Commenters noted that waterbodies that receive stormwater inputs are designated as having recreational uses, but in reality are not supportive of recreation year-round (e.g., seasonal, shallow, concrete-lined channels that are inaccessible due to vertical sides, fences, and locked gates) and thought that EPA should specify that the RWQC should not apply to such waterbodies that do not support actual body contact recreational use.

Commenters asked that the draft RWQC acknowledge that wet weather conditions in fresh waters should be handled differently than dry weather conditions. Commenters supported EPA adding additional clarifying language to the final RWQC that would specify that the RWQC are not intended to be applied during conditions that are not supportive of recreation due to wet weather.

Comment: Commenters asked EPA to clarify how the RWQC apply to waters classified for secondary contact. Commenters noted that risks associated with secondary contact remain undefined and that in some waterbodies, secondary contact is more important than primary contact.

Comment: Commenters noted that because EPA did not establish RWQC for any uses other than primary contact recreation at designated bathing beaches, states will be forced to develop site-specific recreational WQC for many locations, such as streams that don't support primary contact recreation. States lack resources to do this. In addition, many states have established a "secondary contact", or "non-immersion" use category, along with different bacteria criteria values based on different use intensity or probability for these type waterbodies. Since the draft RWQC document makes no mention of this methodology, states with these type provisions in their WQS are unsure of the future use of this approach. Commenters asked EPA to publish criteria that address use designations of both secondary contact recreation and non-recreation. Secondary contact recreation waters should be defined as waters where water recreation can occur but the nature of the recreation does not involve a significant risk of water ingestion. These use designations should include consideration of historic and actual uses, the flow regime, the season, and the physical characteristics of the waterbody.

Comment: Commenters thought that RWQC often are inappropriately applied to streams, which constitute the majority of monitored waters in the state. They thought that the application of primary contact criteria to streams with widely varying conditions has resulted in a large number of non-support listings where substantial costs have been incurred, but little effective action can result. They thought the draft RWQC ignores this issue. Commenters thought that EPA should provide flexibility to states that have secondary contact recreation criteria or that apply criteria year round: "For example, EPA could provide flexibility for those criteria that only apply to

primary recreation if states have a secondary use specified for a particular stream.” Commenters thought that “EPA should clarify that these criteria do not apply to secondary contact activities, and criteria development for those secondary contact uses falls under state purview.”

EPA was asked to recognize that adoption of RWQC for periods when waterbodies are unsafe can result in wasted resources in trying to protect a recreational use (i.e., swimming) that does not exist. These commenters thought it would be helpful for EPA to acknowledge that sub-categories of recreational uses based on stage (or velocity) may be appropriate because of safety concerns.

Response: EPA’s 2012 RWQC recommendations are national criteria recommendations for all waterbody types designated by a state or tribe for swimming, bathing, surfing, or similar water contact activities. The 2012 RWQC fulfill EPA’s obligation under §304(a)(9) of the CWA, as amended by the Beaches Environmental Assessment and Coastal Health (BEACH) Act, to publish new or revised WQC for “coastal recreation waters.” The phrase “designated for swimming, bathing, surfing, or similar water contact activities” is from the definition of “coastal recreation waters” in §502(21) of the CWA. EPA clarifies in section 1.1 that “swimming, bathing, surfing, or similar water contact activities” is referred to throughout the RWQC document as “primary contact recreational use.”

The RWQC document does not define “primary contact recreation.” It does include a statement that reflects EPA’s general understanding of the activities contemplated by that term: “Primary contact recreation” typically refers to 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.” Water play by children may not always involve full body contact and/or immersion but can still involve a high likelihood of incidental ingestion.

The final RWQC does not provide criteria recommendations for secondary contact recreational uses nor does it define secondary contact. Issues related to secondary contact recreational uses are outside the scope of this document. While EPA is working to better understand any difference in risk between primary and secondary contact activities, the focus of the research and studies considered for the RWQC document was for the purpose of developing criteria recommendations to protect primary contact recreation.

A state or tribal WQS is a provision of State or Tribal law which consists of a designated use or uses for the waterbody and WQC to protect that designated use and/or an anti-degradation requirement. The RWQC document provides EPA’s recommendations for the criteria component of a WQS. It does not address designated uses or anti-degradation requirements. The process by which states determine the appropriate use as well as the process to change a designated use (referred to as a “UAA”) is outside the scope of the RWQC. EPA’s regulations at 40 CFR Part 131 as well as associated guidance documents provide information on the use designation process.

Concern for Wildlife and Ecology

Comment: Commenters asked EPA to recognize that the RWQC do not evaluate fecal pollution impacts on aquatic use water designations and that aquatic use is not generally evaluated for fecal pollution impacts. A commenter was concerned that coral reefs, fish and other marine life, including endangered animals die off in polluted conditions. Commenters were concerned that domestic livestock production favors siltation, warmer waters, and reduced flows which also favor the parasites and tubificid hosts responsible for whirling disease, which places fishes, such as cutthroat trout, at risk of death or makes them susceptible to predation, resulting in impairments in water-based recreation and fishable streams.

Response: These CWA §304(a) RWQC, based on human health effects, are for the primary contact recreational designated use and not aquatic use designations. Aquatic use concerns are beyond the scope of 304(a) criteria.

Other Comments

Comment: Commenters asked what specific elements of the European Union (E.U.) or World Health Organization (WHO) approaches were considered inappropriate by EPA, making them unusable in U.S. waters.

Response: The E.U. and WHO approaches include a tiered grading system which is based on a range of public health protection levels. In contrast, §304(a) WQC recommendations, as defined in EPA's implementing regulations, are "based on the latest scientific information on the relationship that the effect of a constituent concentration has on a particular aquatic species and/or human health."

Comment: Commenters asked EPA to consider adding consequences for non-compliance with federal criteria.

Response: Compliance issues are beyond the scope of the RWQC.

Comment: Commenters noted that weekly testing and notification of results are being focused exclusively at designated bathing beaches, and adequate testing and notification are not being done at non-designated bathing areas that are designated for primary water contact purposes. And that EPA should provide guidance for those cases.

Response: Monitoring and sampling strategies are not included in the final RWQC. However, in section 3.6.5 EPA recommends at least weekly sampling. Since the final RWQC are intended to apply to all primary contact recreation waters, this recommendation would apply to all such waters, not just designated bathing beaches.

Comment: A commenter listed the bottom 10 states, for least clean public spaces and was concerned about "problem" beaches including litter problems.

Response: CWA §304 criteria, such as the RWQC, address the relationship that the effect of a constituent concentration in water has on particular aquatic species and/or human health. The

constituent concentration of concern in the final RWQC recommendations is fecal contamination. Other problems with beach quality are beyond the scope of these criteria.

Issue 2.1 Citation of CWA or Other Laws

RWQC and the CWA

Comment: Commenters thought that the proposed changes are inconsistent with the CWA. They commented that the RWQC ignores the mandates of the CWA to promote drinkable, swimmable and fishable waters and may be subject to legal challenges because the new standards are weaker than the 1986 criteria. These commenters thought that the criteria must be revised in order to comply with both the spirit and the letter of the CWA.

Response: The RWQC are not standards. They are criteria recommendations. States may adopt WQC in their WQS that are more stringent than EPA's criteria recommendations and more stringent than required by EPA's implementing regulations (See §510 of the CWA and 40 CFR 131.4.) In any event, EPA does not agree that the draft or final RWQC are "weaker" than the 1986 criteria. See page 1 of the final RWQC for a description of what is new or different in the 2012 RWQC as compared to the 1986 criteria. EPA believes these revisions are improvements.

Comment: Commenters stated that the CWA BEACH Act require EPA to conduct studies associated with pathogens and human health under §104(v), and to publish new or revised criteria for pathogens and pathogen indicators based on those studies. These commenters thought that the only reason that these criteria are even being proposed is because EPA was sued over its failure to update the criteria and was directed by a court to release new criteria by October, 2012.

Response: EPA is required under §304(a)(9) of the CWA, as amended by the BEACH Act to "publish new or revised water quality 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), for the purpose of protecting human health in coastal recreation waters." EPA embarked on this effort long before EPA's was sued for missing the deadlines in §104(v) and 304(a)(9).

Comment: Commenters agreed with EPA's choice not to lower criteria values due to studies not showing an increase in public health protection (as explained in EPA's January 25, 2012 webinar).

Response: Based on EPA's review of public comments and further scientific analyses, EPA has amended and expanded the recommended criteria values as explained in Sections 3.0 and 4.0 of the RWQC document.

Consideration of Economic Impacts

Comment: Commenters thought that EPA should address the potential economic impacts of the recommended criteria and provide guidance for states in addressing the costs of criteria implementation. EPA should also demonstrate an improved public health benefit when applying the recommended criteria to all primary contact recreation designated waterbodies, regardless of

use intensity. Other commenters did not think that EPA complied with CWA §304(a) to develop water quality “based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects.” These commenters believed that EPA took economic considerations into account in developing the criteria and should not have according to the CWA.

Response: WQC developed under CWA §304(a) are based solely on data and scientific judgments about the relationship between pollutant concentrations and environmental and human health effects. States will apply their standards to specific waterbodies. CWA §304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting the criteria in ambient water.

RWQC Impacts on UAA

Comment: Commenters were concerned about the potential interpretation of when UAA may be used in the draft RWQC: whether it is limited to “partial” or “time limited” recreational uses, or includes the complete removal of a recreational use. These commenters thought that EPA should clarify that 40 CFR 131.10(g) allows the complete removal of a recreational use if it is neither existing nor attainable. In addition it would be costly for each wastewater treatment plant (WWTP) or Municipal Separate Stormwater Sewer Systems (MS4) to demonstrate “partial” or “time limited” use on an individual basis and they suggested adding sub-categories for recreational use to increase flexibility regarding implementation of UAA. These commenters suggested adding sub-categories for recreational use to increase flexibility regarding implementation of UAA and noted that the inclusion of tiered designated uses would allow stakeholders to undertake (or to continue) use UAAs.

Response: The final RWQC are scientifically defensible and if adopted into state WQS, would protect all waterbodies designated for primary contact recreational use. The RWQC document does not address designated uses or UAAs. States may remove a designated use that is not an existing use (as defined in EPA regulations at 40 CFR 131.3) or establish sub-categories of uses if the state can demonstrate that attaining the designated use is not feasible through UAA. EPA’s regulations also state that the standards must be sufficient to protect the use and must be scientifically defensible. Therefore any state standard must include documentation that shows that it is protective of the use and based on sound science. 40 CFR 131.10(g) may allow complete removal of a recreation use if it is neither existing nor attainable; however, in most circumstances, a state can identify some level of recreational use that is existing or attainable, even if it is “less” than full primary contact recreation. EPA expects, when removing a designated use, states would adopt the highest attainable use and associated criteria.

Use BEACH Rule language for SSM

Comment: Commenters disagreed with EPA’s statement that the statistical threshold value (STV) is equivalent to the single sample maximum (SSM). Commenters thought that the proposed changes to the RWQC pose a significant burden to states in regards to the ability to both implement and regulate in a manner consistent with the CWA. They “strongly suggested” a return to the language of the WQS for Coastal and Great Lakes Recreation Waters (or BEACH Act) rule (69 FR 67217), “EPA intends that states and territories should retain discretion to use

SSM values as they deem appropriate in the context of CWA implementation programs other than beach notification and closure, consistent with the CWA and its implementing regulations (U.S. EPA, 2004)."

Response: EPA's promulgation of WQS for certain states in the rule cited by commenters was pursuant to §303(i)(2) of the CWA. CWA §303(i)(2) directed EPA to promulgate WQS based on EPA's 1986 criteria for states that did not already have criteria as protective of human health as EPA's 1986 criteria recommendations. This action (i.e., EPA's publication of water quality recommendations under CWA§304(a)) is a different type of action. This document includes recommendations based on the latest available science (e.g., the studies EPA conducted under §104(v) and other available studies).

In the 2012 RWQC, EPA is recommending the criteria magnitude be expressed as a geometric mean (GM) value and a STV corresponding to the 50th and the 90th percentiles 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 believes that the STV, used in conjunction with the GM, can help ensure the fecal indicator bacteria (FIB) densities in recreational waters correspond to a water quality level protective of public health 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 log₁₀ normal distribution (Bartram and Rees, 2000; Kay et al., 2004; Wyer et al., 1999).

Other Comments

Comment: Commenters thought that for the most part, the draft RWQC are a re-adoption of the 1986 criteria and there appears to be still many unanswered questions that need to be addressed.

Response: The final RWQC are different from the 1986 criteria. Refer to Text Box 1 in section 1.0 for a summary of these differences.

Issue 2.2 Hazardous Algal Blooms, Other Pathogens, and Other Hazards

Comment: Commenters requested that the criteria provide instructions for evaluating impairment due to algae on a beach in near shore waters, including risks from secondary exposure. These commenters also requested new research to understand algal impairment and manage risks appropriately.

Response: The RWQC recommendations are designed to consider the occurrence of fecal contamination and the pathogens that accompany fecal contamination in recreational waters as per the BEACH Act Of 2000. See section 3.1 for an explanation of EPA's decision to focus on fecal contamination. Hazardous algal blooms are being considered separately.

Comment: Commenters thought that the limitations of EPA’s existing studies themselves highlight that much remains to be learned about pathogens and other pollution-related health risks. For example, antibiotic-resistant bacteria have been identified in the coastal environment, yet the public health implications of these findings are not well known but could be great.

Response: EPA agrees that much remains to be learned about waterborne pathogens. EPA believes that the RWQC reflect the current state of the science. As new information becomes available, EPA will consider that information when RWQC are updated.

Comment: Commenters thought that EPA should also consider narrative standards relating to: nuisance algal blooms; discoloration of the water; odors (e.g., odors associated with livestock waste); taste diminishment; visual degradation (e.g., seeing foam associated with livestock waste runoff, fecal matter in and near surface waters; and muddying of water from wading domestic livestock that are carrying fecal matter, viruses, other pathogens, noxious weed seeds, and parasites). They were also concerned with return flow irrigation water that is often contaminated with fecal coliform bacteria and suffer from warmer temperatures, increased biochemical oxygen demand, pollution from ammonia, nitrates, and phosphates associated with livestock wastes, depressed dissolved oxygen concentrations, altered pH, increased salinity and conductivity, and anthropomorphic-derived elevated sediment loads (e.g., turbidity, percent fines, siltation). Other concerns were about other water-borne diseases, pathogens, viruses, parasites, and also aquatic invasive species, like zebra and quagga mussels, New Zealand mudsnails, rock-snot, and non-native aquatic plants that threaten aquatic ecosystems and the contact and non-contact recreation that are dependent on them.

Response: The issues listed above are beyond the scope of concern for this 304(a) RWQC.

Issue 3.0 Science and Policy Underlying the Final RWQC

Supportive of Science and Policy Used to Develop Criteria

Comment: Commenters noted the aggressive schedule with which EPA was required to meet when conducting epidemiological studies and developing criteria. They thought that this schedule limited EPA’s ability to assess non-EPA studies, conduct analyses where weather and other factors compromised results, and adequately evaluate other indicators. Overall however, these commenters understood EPA’s rationale for maintaining water quality levels and generally supported EPA’s draft RWQC.

Response: Thank you for your comment.

Comment: Commenters also indicated that results from several of the epidemiological studies suggest that higher levels of indicator bacteria could be allowed and still provide the intended level of protection.

Response: EPA agrees that for some fecal contamination sources at specific locations, higher levels of indicators could provide the intended level of protection. However, the national RWQC

are broadly applicable, scientifically defensible, and protective of public health at the recommended levels specified.

Concerned with Science and Policy Used to Develop RWQC

Comment: Commenters found that EPA failed to propose scientifically defensible recreational water criteria. They requested that EPA use the best and latest available science in the development of the RWQC and thought that the agency ignored a significant amount of the latest science (e.g., microbial source tracking (MST), rapid methods, and risk assessment) and that the criteria were not scientifically defensible. Commenters thought that the draft RWQC was inadequate and overlooked critical data. A commenter thought that the draft RWQC was written with a narrow perspective to justify EPA’s recommendations for the continued use of the current RWQC. Commenters thought that the information presented in the RWQC is not sufficient enough to justify a “one size fits all standard.”

Response: EPA has explained the scientific basis of the RWQC in section 3.2 of the final RWQC document, which has been revised since the draft RWQC. The RWQC are based on the latest available science, including a comprehensive set of studies EPA conducted over the course of several years as well as relevant studies conducted by others.

Comment: Commenters expressed concern that the proposed RWQC might result in inadequate control of exposures to microorganisms that pose significant threats to human health through contamination of recreational waters. These commenters urged EPA to revise the draft RWQC to establish a clear, enforceable baseline that will result in better sampling, better public notification, and regulatory compliance measures leading to investments in infrastructure that will actually improve water quality, not maintain the status quo.

Response: The RWQC are not enforceable. They are recommendations for consideration by states in adopting new or revised WQS. Nevertheless, based on EPA’s review of public comments and further scientific analyses, EPA has decided to modify the RWQC as explained in sections 3.6.2 and 4.0 of the RWQC document. Monitoring, sampling, and public notification will be discussed in upcoming technical support materials (TSM). Refer to Text Box 1 in section 1.0 for a summary of differences.

Need for Additional Research

EPA continues to support additional research that provides a greater understanding of pathogens, pathogen indicators, and human health. EPA also intends to review the criteria every five years as required by the BEACH Act.

Issue 3.1 Indicators of Fecal Contamination

General Comments on the Recommended Indicators

Comment: Commenters expressed support for continued use of *Escherichia coli* (*E. coli*) and enterococci as FIB for WQC recommendations as well as the stringency of their respective GM values.

Response: Thank you for your comment.

Comment: A commenter provided information on the differences in advisories based on *E. coli* versus enterococci (either culture or quantitative polymerase chain reaction (qPCR)). The intent of their comment was not to preclude the use of enterococci or qPCR at fresh water beaches but to encourage comparative analyses prior to considering implementation of either alternative indicators or methods.

Response: EPA determined the criteria levels for both *E. coli* and enterococci based on available epidemiological data. States can conduct comparative analyses prior to considering implementation of alternative indicators or methods.

Comment: Commenters noted that EPA did not develop a qPCR method for *E. coli*. Lacking a rapid method for *E. coli* creates a double standard in fresh water beaches versus marine beaches using the rapid qPCR method for *Enterococcus* spp. They requested that EPA include *E. coli* criteria for rapid methods or adequately substantiate why *E. coli* is insufficient for a rapid method indicator. They pointed out that programs in the Great Lakes are utilizing an *E. coli* qPCR approach that appears to be working quite well (>95% agreement) (Kinzelman, personal communication; Lavender and Kinzelman, 2009; Noble et al. 2010).

Response: A reliable qPCR method for *E. coli* was not available to EPA for use in the fresh water NEEAR study sites. Therefore, EPA was not able to observe statistical correlation between water quality and illness needed for criteria development. States can evaluate *E. coli* qPCR using the TSM for alternative indicators and methods as described in section 6.2.3.

Comment: Commenters pointed out that it is possible for one indicator to exceed the criteria while the other does not, depending on the source contributions to the receiving streams and the method employed and the laboratory performing the test.

Response: EPA is aware that there is variability in indicator levels from different sources, and methods and laboratories also introduce variability. EPA believes that the RWQC are protective considering the variability. States can adopt whichever RWQC indicator they feel is most appropriate for their waters.

Other Comments

Comment: Commenters stated that a more thorough discussion is needed regarding sources of error associated with using fecal indicators for the protection of public health and their impacts on properly implementing the revised criteria (e.g., bacteria have a strong tendency to adhere to organic matter rather than remaining uniformly distributed within a water sample).

Response: EPA agrees that these factors do influence indicator dynamics; however EPA believes that the NEEAR epidemiology studies looked at real world situations and therefore adequately include consideration of these types of factors.

Suitability of the Use of FIB in Non-Point Source Influenced Waters

Comment: Commenters asked that EPA provide a defense for the use of FIB WQC in non-point source-influenced waters that is similar to the defense provided for determining the suitability of FIB for coastal, inland, and flowing water.

Response: EPA agrees that non-point source influenced waters receive microbial loads, including FIBs, during precipitation and other weather influenced events. Additional discussion of the use of FIB in non-point source influenced waters is in section 3.1 of the final RWQC.

Comment: Commenters thought that enterococci is an appropriate indicator of fecal pollution in WWTP-impacted waters, but asked EPA to provide more guidance on options for the use of alternative indicators in non-WWTP impacted waters.

Response: Section 6.2 of the final RWQC discusses the tools EPA is providing for states to develop alternative indicators and methods.

Health Risk Associated with FIB

Comment: Commenters argued that little or no basis is provided in the draft RWQC to conclude that the human health risk posed by indicator bacteria in fresh water is the same as that posed by indicator bacteria in marine waters. A commenter requested that EPA design a study to measure and compare health risks in both fresh water and marine waters and to account for the health risks posed by various sources of bacterial contamination.

Response: Section 3.2.4 of the RWQC document summarizes the analyses that were conducted and the rationale for concluding that the illnesses levels in marine and fresh water are similar at the suggested RWQC levels. EPA's approach for analyzing the NEEAR data as one data set was peer reviewed.

Comment: Commenters questioned the validity of the conclusion that *Enterococcus* spp. is a better indicator of risk in fresh water compared to marine because epidemiological studies have found *Enterococcus* spp. to be a better predictor of risk in marine waters compared to fresh.

Response: EPA recommends the use of either enterococci or *E. coli* as FIB in fresh water and enterococci in marine water. Please see section 3.2.3 of the final RWQC for additional justification of the continued use of enterococci in both marine and fresh waters and for information on the relationship between water quality (as measured by levels of FIB) and illness.

Comment: Commenters stated that more research is needed to identify appropriate indicators and criteria that truly assess human health risks.

Response: Though EPA supports and encourages research to better understand fecal indicators and their relationship to human health.

Continued Support for the Use of Other Indicators (Not Adopt *E. coli* or enterococci)

Comment: Commenters disagreed with EPA's recommendation to formally adopt *E. coli* and enterococci into state WQS because they believe that other indicators provide similar or better levels of human health protection.

Response: EPA continues to support the use of *E. coli* and enterococci as FIB to identify potential for illness resulting from exposure to recreational surface waters contaminated by fecal pollution. Please see section 3.1 for additional justification of the use of *E. coli* and enterococci as FIB. In the final RWQC, EPA provides states the flexibility to use alternative fecal indicators and methods, as long as the criteria are scientifically defensible and protective of the designated use.

Comment: Commenters believed that states would no longer have the latitude to develop programs most relevant to existing environmental, anthropogenic, and regulatory conditions.

Response: Section 6 of the final RWQC provides states with tools to derive scientifically defensible site-specific criteria based on understanding of their surrounding watersheds.

Comment: Commenters noted that, in their state, testing for *E. coli* and enterococci may demonstrate an exceedance of one standard but not the other, causing confusion regarding regulatory and enforcement response. Because of this confusion, their state has chosen to utilize fecal coliform rather than *E. coli* or enterococci.

Comment: Commenters indicated that EPA should allow for a fecal coliform bacteriological standard and not require a supplemental *E. coli* test in addition to fecal coliform for fresh, inland waters. They stated that programs that have been developed to address a single indicator organism should not be required to change the indicator organism.

Response: EPA determined the criteria levels for both *E. coli* and enterococci based on available epidemiological data. While EPA is aware that different indicator-method combinations may not correlate at every site, under every condition, that does not change EPA's conclusion that the criteria recommendations are scientifically defensible and protective of the use. EPA no longer recommends fecal coliform as an indicator because the vast majority of epidemiological studies conducted worldwide indicate that enterococci and *E. coli* are better indicators of fecal contamination. Specifically, in the EPA studies that supported the development of the 1986 bacteria criteria, EPA found that fecal coliforms had only a weak correlation to gastroenteritis in marine waters and no correlation to gastroenteritis in fresh waters (Cabelli, 1983; Dufour, 1984; U.S. EPA, 1986). Additionally, in a review article conducted for the WHO evaluating the health risks associated with recreational waters, Prüss (1998) indicated that the indicator organisms which correlate best with health outcome were enterococci/FS for both marine and fresh water, and *E. coli* for fresh water. Similarly, Wade et al. (2003) conducted a systematic review that supports the recommended shift from the use of fecal coliform (U.S. EPA, 2002) as an fecal

indicator because there was no evidence that risk of gastrointestinal (GI) illness increased at levels above the previously proposed guideline value. EPA determined the criteria levels for both *E. coli* and enterococci based on available epidemiological data. EPA is aware that different indicator-method combinations may not correlate at every site, under every condition. States can conduct comparative analyses prior to considering implementation of alternative indicators or methods.

Comment: Commenters asked if states will need to resubmit their justification for use of alternative fecal indicators and also noted that the use of alternative fecal indicators is complicated in interstate waters.

Response: States will not have to resubmit their justification for use of alternative fecal indicators. However, states are required under CWA §131.20 to review at least once every three years their WQS and as appropriate modify and adopt standards.

CWA Programs (NPDES and TMDLs) and Indicators

Comment: A number of commenters raised issues regarding the implementation of the RWQC on CWA programs, including total maximum daily loads (TMDL) and National Pollutant Discharge Elimination System (NPDES) permits.

Response: Implementation of the RWQC in CWA programs is beyond the scope of the current document.

Concerns with *E. coli* Indicator for Fresh Water

Comment: Commenters were concerned with the applicability of *E. coli* as an indicator for all fresh waterbodies because non-beach waters were not part of the NEEAR study from which the *E. coli* criteria were derived. These commenters asked what studies were used to develop criteria for *E. coli* in fresh water and were concerned that EPA proposed modifying the criteria for *E. coli* from the 1986 criteria even though there were no new epidemiological studies undertaken on fresh waters that evaluated *E. coli*.

Response: Please see section 3.2.3 of the final RWQC for more information on the epidemiological studies used to evaluate the relationship between water quality and illness. For a description of how EPA derived the criteria for culturable *E. coli* see section 3.2.4 in the final RWQC document.

Indicators can be Pathogenic

Comment: Commenters stated that some indicator organisms can be pathogenic and EPA should not imply that most strains and species of *E. coli* and enterococci are not pathogens; EPA should recognize the latest science that some FIB are important causes of hospital-acquired infections. Commenters specifically noted that in lines 519-520 the statement, “although generally not inherently pathogenic” seems misleading as some of these indicators are pathogenic.

Response: The RWQC has been edited to address this comment.

Issue 3.1.1 Methods

Comments on qPCR Method

Comment: Commenters thought EPA did not sufficiently highlight that qPCR methods are faster and have been consistently shown to have a stronger correlation to health effects than culture methods, thus making them more accurate.

Response: EPA agrees that the NEEAR data showed a good correlation between GI illness and qPCR. We believe that the strengths and limitations of qPCR are adequately described in the RWQC document.

Comment: Commenters indicated support for the use of a rapid, qPCR-based criterion for *E. coli*.

Response: A reliable qPCR method for *E. coli* was not available to EPA for use in the fresh water NEEAR study sites. Therefore, EPA was not able to observe statistical correlation between water quality and illness needed for criteria development. States can evaluate *E. coli* qPCR using the TSM for alternative indicators and methods as described in section 6.2.3.

Comment: Commenters indicated that culture methods are obsolete, and rapid methods need to be implemented nationally.

Response: EPA continues to support the use of culture methods for quantifying the indicator organisms, *E. coli* and enterococci. As mentioned in the RWQC document, EPA is providing STV and GM values. Please see section 3.1.1 of the final RWQC for a discussion of why EPA is not recommending that qPCR be implemented nationally. EPA continues to support the use of rapid methods such as qPCR where they are effective and where states have developed the capacity to use those methods.

Comment: Commenters requested flexibility in choosing the qPCR chemistry and calculation method and approval of the use of a mix of qPCR and culture-based methods in site-specific performance characterization. They requested clarification on which reporting unit should be used for the qPCR data: calibrator cell equivalents (cce) or target sequence copy numbers. It was recommended that EPA use a single reporting unit to avoid confusion and allow qPCR criteria to be standardized. Commenters asked for additional justification of the qPCR cce values presented in the RWQC (i.e., 475 cce [GM] and 1,000 cce [STV] per 100 milliliters (mL)). Commenters expressed concern that different qPCR methodologies were utilized during the epidemiological study at Doheny State Beach and during EPA's epidemiological studies.

Response: EPA acknowledges that multiple qPCR chemistries and calculation methods exist. If a state wishes to utilize EPA's qPCR Method 1611 for *Enterococcus* spp., then all quantities should be reported in cce. EPA is providing a spreadsheet tool for converting machine results (cycle thresholds (CT)) to reporting unit results (cce per 100 mL). Additionally, states have flexibility to develop alternative fecal indicator/method combinations to support the development

of site-specific criteria. Such criteria must be scientifically defensible and protective of the designated recreational use.

Comment: Commenters asked if there is a difference in qPCR criteria for waters with sewage discharges versus waters without known sewage discharges because waters downstream of disinfected sewage discharges would have higher densities than waters with only runoff or nonpoint source discharges because disinfection kills bacteria but does not destroy its DNA. They emphasized that qPCR may not be appropriate for all water quality assessments because both nonviable and living cells are counted when determining concentration.

Response: EPA is providing an *Enterococcus* spp. qPCR value that is applicable to all waters. However, EPA does not currently suggest qPCR Method 1611 for NPDES permitting or effluent-related monitoring purposes because this method may not reflect the efficacy of WWTP disinfection.

Comment: Commenters also recommended more discussion about the potential confounding variables associated with qPCR.

Response: EPA intends to issue a troubleshooting guide for the qPCR assay in 2013. The guide will include potential confounding variables (and possible ways to address them). EPA also provides a more detailed discussion on potential confounders associated with qPCR in the report “A Study of the Various Parameters that Affect the Performance of the New Rapid U.S. Environmental Protection Agency Quantitative Polymerase Chain Reaction (qPCR) Method for *Enterococcus* spp. Detection and Comparison with Other Methods and Pathogens in Treated Wastewater Mixed with Ambient Water” (U.S. EPA, 2010a).

Other Methods Are More Promising Than EPA’s Methods

Comment: Commenters stated that the proposed EPA Method for rapid enumeration of *Enterococcus* spp. in recreational water does not incorporate the latest qPCR technology and uses a method of calculation that has the potential to introduce significant variability to results.

Response: EPA’s *Enterococcus* spp. qPCR Method 1611 (U.S. EPA, 2012) was used to collect the epidemiological data that was used for criteria development. EPA is currently validating an updated version of the method that includes more recent technology and hopes to make this new method available in 2013.

Comment: A commenter argued that EPA did not use the most promising methods to monitor recreational waters for Bacteroidales and for *Bacteroides* because the qPCR methods EPA used to evaluate Bacteroidales and *Bacteroides thetaiotamicro* did not measure for human-specific sources of sewage and lacked human-specific markers. EPA was asked to be clear in the RWQC document that they did not use the potentially more reliable human-specific assays for Bacteroidales and for *Bacteroides*. The commenter pointed out that EPA didn’t inform readers that the EPA methods used to assay for *Clostridium perfringens* and male-specific coliphages were not the same culturable methods used in previously published reports that provided promising data. The commenter said that EPA has made conclusions based on using their

selected methods and experimental approaches, which were not the best reported available methods and experimental approaches and that EPA has an obligation to inform the readers of the limitations of the conclusions they reached with regard to alternative fecal indicators. The commenter questioned the adequacy of EPA's evaluation of alternative fecal indicators (e.g. *Clostridium perfringens*, male specific coliphages, and Bacteroides/Bacteroidales).

Response: A detailed discussion of alternative methods is beyond the scope of the RWQC. EPA evaluated the most recent science when developing the final RWQC. EPA did not think that it was appropriate to propose national criteria using the mentioned fecal indicators at this time because of the limited experience with their performance in a wide range of environments; however alternative fecal indicator/method combinations may be used to support the development of site-specific criteria.

Problems with Current Methods

Comment: Commenters asked that EPA highlight problems associated with current culture methods (e.g., colony size issues, inhibition and interference, visual counting errors, confluent growth) and the lack of correlation when the time lag in notification is considered.

Response: EPA is aware that problems may occur when culture methods are used, including the factors provided by the commenter. However, these problems are inherent in most culture methods. EPA has included a quality control section in all of the culture methods that should be used to address such issues. Regarding the time lag issue, EPA is aware that the application of data from samples collected 24 hours or more prior is less than optimal.

Comment: Commenters indicated that EPA should address indicator test method performance issues for wastewaters other than sanitary sources.

Response: EPA-recommended culture-based methods for the indicator organisms discussed in the final RWQC have been approved for use in wastewater. Please see 40 CFR Part 136, Table 1A.

Comment: Commenters expressed reservations over the practicality of using the qPCR method and adopting new fresh water criteria if there is no significant public health benefit.

Response: EPA is not recommending qPCR-based criteria for adoption in state WQS. Rather, EPA is simply providing states information on qPCR. EPA encourages states to explore the use of rapid methods such as qPCR where they are effective and where states have developed the capacity and capability to use those methods.

Comment: Commenters asked EPA to discuss how differences in colony counting and reporting between earlier and later studies have influenced relationships between observed health outcomes and FIB measurements made in recreational waters they also asked that EPA address the discrepancies in enumeration densities determined using different culturable methods and recommended that EPA include method-specific units and numeric values based on most

probable number (MPN) methodologies, which often produce different results than membrane filtration testing.

Response: These issues and other issues of method performance are beyond the scope of the current document.

Comment: Commenters requested that EPA clearly indicate what tests are considered “equivalent.” A clear link for approved other methods like IDEXX should be stated.

Comment: Commenters requested more discussion of qPCR validation studies and that EPA state the option to use EPA methods for culturable *E. coli* and enterococci or “...any other equivalent method...” They recommend changing the occurrences of the wording to this: “or any other culturable methods approved by EPA for ambient water testing”, in the following sections of both the notice and supporting materials: the Federal Register, page 79177, bottom of column 1 and top of middle column, Page 4 line 271 through line 280 (a) fresh waters and (b) marine waters, and Page 45 line 1914-1954 (a) Fresh water criteria and (b) Marine water criteria.

Response: Tests that may be considered "equivalent" to the culture methods include those that are approved in 40 CFR Part 136, Table 1H. Please see the appropriate lines by bacterium. The RWQC has been revised to indicate “equivalent” methods are acceptable.

Revisions to RWQC Text

Comment: Commenters suggested eliminating the reference to test tubes associated with IDEXX and replacing this term with ‘quanti-trays.’

Response: The reference to test tubes in the final RWQC is associated with the 1978 EPA report titled “Microbiological Methods for Monitoring the Environment: Water and Wastes” (U.S. EPA, 1978).

Comment: Commenters asked that the recently published inter-laboratory comparison study that showed low variability regardless of qPCR protocol be included in the appendices.

Response: Results of the inter-laboratory validation study are available in the docket. The purpose of the study was to develop performance acceptability criteria for the method, which was added to the final version of the method (U.S. EPA, 2012).

MST Methods Are Useful

Comment: Commenters recommended the use of MST techniques and noted that qPCR quantification of source-specific genetic markers appear useful.

Response: EPA acknowledges that newer technologies may provide alternative ways to address methodological considerations, such as rapidity, sensitivity and specificity, and method performance in site-specific situations, but may not be appropriate for all CWA purposes. While MST methods for the application of beach monitoring are not included in the final RWQC, states have the discretion to develop the use of MST for beach monitoring. For more information on

EPA's efforts to explore the utility of MST, please see the EPA report titled "Evaluation of the Suitability of Individual Combinations of Indicators and Methods for Different CWA Programs" (U.S. EPA, 2010b).

Issue 3.2 Linking Water Quality and Health

No comments were associated with this issue.

Issue 3.2.1 History of Ambient Water Quality Criteria

No comments were associated with this issue.

Issue 3.2.2 Human Health Endpoint (HCGI vs. NGI)

Comment: Commenters were concerned that the use of a different human health endpoint in EPA's most recent studies will create the appearance that the new criteria lower public health protection.

Response: EPA appreciates that the commenters understand that the NEEAR-GI (NGI) health endpoint does not result in lower public health protection, but could create that misunderstanding.

More Illness Endpoints Should Be Considered

Comment: Commenters asked that EPA consider non-GI illnesses including: earaches and ear ailments; skin rash; conjunctivitis and eye ailments; upper respiratory tract or lung infections (including symptoms such as coughing and running nose); meningitis; hepatitis; sinus information; infected cuts and skin infections; encephalitis; Lemierre's syndrome; kidney damage; and neurological damage. These commenters are concerned that the RWQC fails to address the rarer cases of life-threatening illness from waterborne pathogens.

Response: EPA's NEEAR study looked at many types of endpoints, such as respiratory, dermal, or eye, ear, nose and throat symptoms or infections, and urinary tract infections, as well as GI illness. GI illness was most consistently associated with fecal contamination indicators and was the most sensitive health endpoint. The other endpoints may have occurred too infrequently to discern a correlation. Earaches were related to swimming, but not to fecal indicator levels. Relationships between the more severe health endpoints that the commenters mentioned and swimming have not been well established by epidemiology studies. Overall, the RWQC protect against all general illnesses associated with fecal contamination. This general approach is the same as is used by many other countries around the world, and is similar to the approach taken by the WHO.

Comment: Commenters were concerned with mosquito-borne diseases like West Nile Fever and West Nile Encephalitis that threaten imperiled species like sage-grouse, but also place contact and non-contact recreators at risk of illness and even death. They also suggested consideration of drug-resistance arising from the use of antibiotics in livestock.

Response: These issues are beyond the scope of the current RWQC.

Comment: Commenters noted that in the CWA as amended by the BEACH Act §104(v), “the Administrator shall initiate (1) an assessment of potential human health risks resulting from exposure to pathogens in coastal recreation waters, including non-GI effects.” They interpreted this to mean non-GI effects should be addressed in the RWQC. They also pointed out that EPA should not be selective in prioritizing illness types when public health is on the line and should not develop public health-based criteria on a single type of illness (i.e., GI illness). Commenters noted that EPA states that numerous epidemiological studies were reviewed and considered during the development of the draft RWQC and wondered why illness types other than GI illness were not considered when determining health risk association.

Comment: Commenters stated that EPA’s proposed GM does not target GI illness, as required in the BEACH Act; it only targets highly credible gastrointestinal (HCGI) illness. They asked how EPA justifies prioritizing one adverse health effect over another, especially given BEACH Act requirements. They thought that EPA should prioritize illness types and should not develop public health-based criteria on a single type of illness (i.e., GI illness). Commenters also stated that EPA presents no evidence that other illnesses mentioned in the RWQC document are always associated with GI or HCGI illness.

Response: EPA conducted the “assessment” by including other health endpoints in the NEEAR epidemiology studies and therefore met any requirement in §104(v). EPA does not interpret §104(v) to require EPA to publish new or revised criteria for pathogens and pathogen indicators that address non-GI illness. EPA believes that GI is the most common fecal associated illness and serves as the most sensitive surrogate for fecal contamination. By protecting against GI illness, other less common fecal contamination associated endpoints are also protected against. The RWQC are protective against NGI as well as HCGI. NGI, respiratory, rash, earache and eye infections were treated as separate illnesses and evaluated. This approach was approved by the peer reviews and also is consistent with the literature.

Comment: Commenters asked if EPA intended to conclude that swimmers don’t have an elevated health risk of these other health outcomes regardless of FIB densities. Commenters thought that if this conclusion is inconsistent with numerous other epidemiological studies, not to mention frequent swimmer and surfer complaints, about ear and sinus infections and skin rash. All illness types, including upper respiratory, skin rash, eye ailments, earaches, and infected cuts should be considered an equivalent public health threat, regardless of their occurrence rate. This more inclusive approach is supported by science.

Response: The non-GI illness endpoints do often show an association with swimming, but not usually with FIB levels. There are no indicators specific to non-GI illnesses. Other illnesses were

considered, but EPA found that GI illness was the most sensitive health endpoint and most strongly associated with the fecal indicators of concern.

Comment: Commenters asked why EPA ignored the significant association between elevated enterococci levels and skin rash. Commenters asked how EPA concluded that there were no significant increases in health risks for skin rash from all of the NEEAR study sites and asked if these conclusions included results from studies conducted at Great Lakes beaches and regardless of age groups.

Response: The NEEAR study found elevated skin rash at some beaches, but did not find an association with indicators. GI illness was the most sensitive endpoint. Fleisher et al., 2010 found a relationship between skin illnesses and increasing enterococci exposure among bathers [1.46 times (95% confidence interval (CI) 0.97–2.21; P=0.07) per increasing log₁₀ unit of enterococci exposure].

Comment: Commenters stated that recreational users need to be made aware of the additional health risks from non-GI endpoints. They also thought it is important that these illnesses be looked at in different geographical areas and water conditions, such as tropical areas and high energy coasts, to determine if risks vary by location, sources and dynamics including wave action.

Response: EPA's NEEAR study covered a wide range of locations/study sites. Although differences occur among locations, EPA is unaware of any consistent differences in illness-indicator relationships between temperate versus tropical waters. EPA understands that sites are different based on many parameters, but different fecal associated illnesses is not a parameter for which consistent trends have been observed. It is beyond the scope of the RWQC document to suggest guidance on how public awareness can be increased.

Comment: Commenters noted that the Dufour 1984 report included data for both GI and HCGI and asked: They asked why EPA did not utilize GI data from the Dufour report as a direct comparison to the NGI data. Commenters asked if it would have been more appropriate to make a direct comparison of GI data from each study rather than estimating GI illness rates from HCGI rates.

Response: Prior to the draft RWQC, HCGI was the health endpoint that EPA used to estimate the criteria's associated illness rate. EPA believes it is important to provide a historical linkage between the 1986 associated illness rates and the 2012 associated illness rate in order to permit use of both the NEEAR data and 1986 associated illness rates in developing the current criteria. The 1986 illness rates were not based on the Dufour 1984 GI data, they were based on HCGI. Therefore, EPA chose to compare the 2012 illness rate to the HCGI data that were used to estimate an associated illness rate in 1986.

Comment: Commenters noted that Dufour indicated one of the reasons HCGI was used in the original criteria was the regression and correlation analyses indicate that the strength of the relationship between the indicators and highly credible symptom rates is much greater than that

with total GI symptom rates. These commenters asked if there are there similar concerns with the GI data in the NEEAR study.

Response: The NGI definition was developed in consultation with CDC and other experts before the NEEAR study began. The NGI definition reflects potential infections from a variety of waterborne pathogens that cause gastroenteritis. This definition of GI illness is the currently accepted definition and is used worldwide in recreational water epidemiology studies. It is also consistent with the most common adverse health effects associated with the anticipated etiologic agents in WWTP effluent impacted waters.

Issue 3.2.3 Epidemiological Relationship

Comment: Commenters agreed that epidemiological studies completed in the U.S. and abroad have consistently found an increase in health risk associated with swimming in waters containing elevated levels of fecal bacteria indicators. They thought that the data and epidemiological studies presented in the RWQC adequately support the validity of the proposed criteria.

Response: Thank you for your comment.

Comment: Commenters requested that EPA continue supporting research to develop more appropriate indicators and criteria to offer the best possible outcome in terms of truly protecting human health, reducing inaccuracies in monitoring data, and minimizing financial impacts. They asked EPA to support ongoing research in this area including encouraging EPA to continue supporting epidemiological studies to grow this important dataset, particularly for urban runoff-impacted waterbodies and flowing streams.

Response: EPA plans to continue to take an active role in furthering the science that will support future RWQC.

Comment: Commenters stated that there should be a separate section in the RWQC that looks at the correlation between the water quality at the time of notification and health effects. They indicated that the public should understand that when the culture results become available what the actual risk is and whether there even is a correlation at the time of notification based on the method used.

Response: The data from the NEEAR study is public information and was made available to the public previously (December, 2011).

Comment: Commenters asked if the NEEAR study data were analyzed for the appropriate GM and SSM to protect public health at an equivalent level to the 1986 criteria.

Response: Since the draft RWQC, EPA has updated the approach for determining the recommended criteria values (see section 3.2.4). The final RWQC provide improved water quality and public health protection compared to the previous criteria.

Consider Other Epidemiological Studies

Comment: Commenters did not think that EPA followed the CWA and BEACH Act requirements to incorporate new studies regarding pathogens and human health, relying instead on older studies and the 1986 criteria.

Response: The 2012 RWQC recommendations are based on the latest available science, including the comprehensive set of studies EPA conducted over the course of several years pursuant to CWA §104(v). EPA considered all of those studies in the development of the RWQC, the underlying summary data for 1986 criteria as well as other studies (e.g., epidemiological studies) conducted by others. The final RWQC recommendations are based on EPA's consideration of all of these studies and data. The studies and data EPA considered are in the docket for the criteria.

Comment: Commenters asked if other non-EPA epidemiological studies were used, and they encouraged EPA to use these studies to determine the proposed criteria. They encouraged EPA to reanalyze all current epidemiological data (both EPA and non-EPA), including Southern California Coastal Water Research Project (SCCWRP) studies to determine new criteria; the requested analysis is to determine what concentration of FIB is associated with the lowest significant health risk.

Response: The revised RWQC criteria are based on a multi cut-point analysis as described in section 3.2.4. Several non-EPA studies were evaluated and considered for inclusion via qualitative methods during the development of the final RWQC. As of the date of the draft RWQC, EPA received data from SCCWRP, which were generally consistent with the data supporting the final RWQC.

Comment: Commenters suggested that if all the epidemiological study data were used to derive new numeric endpoints for the indicators with the best correlations to health effects, those standards would be higher than the standards carried out using the 1986 criteria.

Response: Based on EPA's review of public comments and further scientific analyses, EPA has decided to modify the criteria as explained in section 3.6.2 of the RWQC document. The new criteria provide improved water quality and public health protection.

Limitations of Epidemiological Studies and Request for More Studies

Comment: Commenters suggested EPA complete a more thorough analysis of existing epidemiological data to determine the SSM *Enterococcus* spp. density associated with the health risk based on EPA's determined acceptable risk.

Response: Based on EPA's review of public comments and further scientific analyses, EPA has decided to modify the criteria as explained in section 3.6.2 and 4.0 of the final RWQC document. In addition to the STVs for determining criteria exceedances, EPA is providing precautionary beach action values (BAVs) for beach notification purposes (such as advisories and closings) (see section 5.1).

Comment: Commenters stated that EPA's studies focused only on beaches and risks to swimmers and EPA's approach does not sufficiently address non beach waters.

Response: The recommended RWQC are for waters designated for primary contact recreation, not just waters adjacent to beaches.

Comment: Commenters expressed concern that they would find it difficult to defend what may be a costly modification to their fresh water recreational bacteriological criterion because the RWQC rely heavily on epidemiological studies at marine beaches, with little to no new health effects data from inland fresh water recreational beaches. For example, some states regulations require that the state Agencies produce a fiscal analysis of any proposed regulation. Commenters noted that lake data may not be appropriate to use for inland flowing waters. Commenters also indicated that more marine beach areas should have been examined to examine different energy levels, contamination sources, and geographic differences.

Response: EPA's goal at the outset of criteria development was to provide consistent protection to all water body types with the primary contact recreation designated use. See section 3.4 for justification of inclusion of inland waters.

Comment: Commenters stated that there should theoretically be no WWTP-impacted beaches based on NPDES permit conditions unless there are emergency conditions that occur that result in inadequately treated wastewater discharge.

Response: Wastewater treatment in the U.S. has improved dramatically and expanded substantially over the last century. In fact, it is reasonable to conclude that many of the water quality improvements that have been realized are due to these infrastructure gains. However, while conventional wastewater treatment is effective in reducing pathogen levels, it does not eliminate all pathogenic microorganisms that are potentially present. Because the NEEAR study evaluated real world situations, the RWQC takes into consideration the efficacy of wastewater treatment to set forth and recommend water quality levels that are protective of the recreational use.

Comment: Commenters requested that EPA highlight the lack of statistical significance between culture methods and illness in the NEEAR study. They noted that none of the NEEAR study sites showed a significant correlation between the proposed indicator bacteria levels and illness rates, and another commenter thought that this lack of definitive correlation between GI distress and bacteriological counts would make capturing the benefit to citizens difficult and extremely challenging.

Response: Based on EPA's review of public comments and further scientific analyses, EPA has decided to modify the criteria recommendations as explained in section 3.6.2 of the final RWQC document. A statistically significant multi cut-point analysis based on the NEEAR study was used to derive criteria values for culturable enterococci. The illness rate associated with this level of culturable enterococci was used to compute criteria for the other indicators. See section 3.2.4.

Comment: Commenters said that EPA needs to highlight the lack of high fecal levels during the one tropical study and other studies.

Response: EPA discusses NEEAR study findings from Boquerón, Puerto Rico, in the RWQC document. The health effects study conducted at the beach in Boquerón, Puerto Rico, suggest consistency with previous EPA studies that were conducted using culture-based methods to measure water quality. These results indicate that there were low enterococci (colony forming unit [cfu]) levels measured by membrane filtration (only one day exceeded a GM of 35 cfu per 100 mL) and that the frequency of observing evidence of GI illness in swimmers was also low to non-detectable.

Comment: Commenters thought that potential for Type I error (false positives) plays an exaggerated role in determining the illness rate in small studies such as the one conducted in Ohio.

Response: EPA agrees that small scale epidemiology studies have limitations. EPA will consider this comment during development of future TSM.

Comment: Commenters pointed out that it seems highly unlikely that the new STVs, which are based on different epidemiological data, share the exact same 75th percentile number as the 1986 data for both marine and fresh water beaches.

Response: The draft RWQC carried forward water quality associated standard deviations from the 1986 criteria, which is why the 75th percentile was the same value. Based on EPA's review of public comments and further scientific analyses, EPA has decided to modify the criteria as explained in section 3.6.2 of the RWQC document. The new STV criteria are based on 90th percentile of the water quality distribution from the NEEAR study.

Comment: Commenters asked if bacterial groups other than enterococci, such as heterotrophic plate count bacteria were monitored in the NEEAR study as other microbe groups could be correlated with illness rates.

Response: Table 2 (*Fecal indicator organisms and enumeration methods tested in the NEEAR epidemiological studies*) from the final RWQC document lists the methods that were included in the NEEAR study.

Comment: Commenters expressed concern because EPA has noted the data from their earlier studies have been lost. The only data for comparison are summary statistics that exist only in the published documents, making it very difficult to compare historical data to more contemporary data.

Response: As discussed in section 3.2.4 of the 2012 RWQC, EPA could not reanalyze the 1980s data using the NEEAR statistical approaches because the raw data from those earlier studies are no longer available. However, EPA analyzed the NEEAR culturable enterococci data using the same statistical approaches employed in the 1980s studies (Cabelli, 1983; Dufour, 1984), allowing for several important comparisons between the two datasets.

Combining Fresh and Marine Water Epidemiology

Comment: Commenters agreed with EPA's interpretation about the similarity of risks in marine and fresh waters at the proposed RWQC levels.

Response: Thank you for your comment.

Comment: Commenters disagreed with EPA's position that the more recent *Enterococcus* spp. data are a better estimate of health risk than that reported in the 1986 criteria. They were skeptical about EPA's finding there is no health risk difference between marine and fresh waters at the proposed RWQC levels. They expressed confusion about how marine and fresh waters pose similar risks now (as opposed to 1986) when the bacteria density values have not changed.

Response: EPA believes that the NEEAR study adequately support the associated illness rates that correspond to the final RWQC. EPA's approach for combining the data from the marine and fresh water study sites was peer reviewed. Please see section 3.2.4 of the final RWQC for additional discussion.

Issue 3.2.4 Compare Culture to qPCR

Comment: Commenters thought that it is inappropriate for EPA to develop qPCR criteria based on culture methods or the 1986 criteria and disagreed with EPA's claims that qPCR criteria correspond to the same level of water quality associated with the previous 1986 criteria recommendations. They asked that rapid method criteria for qPCR be based on current epidemiological data, including the Doheny Beach SCCWRP study, and independent from criteria derived using culture methods.

Response: Based on EPA's review of public comments and further scientific analyses, EPA has decided to modify the criteria values as explained in section 3.6.2 of the RWQC document. The qPCR values EPA suggests correspond to the same level of health protection and water quality as the criteria for the culture methods.

Comment: Commenters pointed out that the NEEAR culture-based *E. coli* and illness rate for each of the seven beaches as described in Table 2 of the draft RWQC is missing from the document. They thought that this comparison will be helpful when comparing the fresh water and marine swimming-associated illness for culture-based *E. coli*.

Response: EPA did not include *E. coli* as an indicator in the NEEAR study, so that is why it is not included in the table.

Comment: Commenters indicated that greater discussion is needed within this section regarding the potential for site-specific water quality variables to influence the relationship between qPCR and culture-based indicator results.

Response: This type of methodology comparison discussion is beyond the scope of the RWQC document.

Comment: A commenter noted that in approach 2 (starting at line 1059), the differences in fecal contamination and sources need to be explained as these differences are likely related to the different number of illnesses observed between the 1986 and NEEAR study. Comparing the illness rates without the actual FIB levels is illogical. The determination of the six to eight health risk level for marine waters is also inadequately supported based on the lack of statistical correlations with the culture methods and is highly questionable. The commenter felt there is insufficient evidence to reduce the illness rate from 19 to eight for marine waters.

Response: Based on EPA's review of public comments and further scientific analyses, EPA has decided to modify the criteria as explained in section 3.6.2 of the RWQC document. A statistically significant multi cut-point analysis based on the NEEAR study was used to derive criteria for culturable enterococci. The illness rate associated with this level of culturable enterococci was used to compute criteria for the other indicators. See section 3.2.4.

Comment: A commenter thought that illness rates above and below the SSM based on individual sample results should have been included.

Response: Illness rates are associated with the criteria's recommended GMs. EPA is also providing a BAV associated with the 75th percentile of the water quality distribution and including an STV associated with the 90th percentile of the water quality distribution. The purpose of these values is discussed in detail in sections 3.6.2 and 5.1 in the RWQC document.

Comment: A commenter found the analysis of the NEEAR data using the seasonal GM and illness rates was insufficient. The commenter thought that EPA should not allow the use of the seasonal GM for water quality assessments.

Response: Based on EPA's review of public comments and further scientific analyses, EPA has decided to modify the criteria as explained in section 3.6.2 of the final RWQC. EPA now recommends a duration of 30 days for computing GMs.

Comment: A commenter suggested that qPCR data be provided on the graph and noted that currently only a regression line is shown.

Response: Figure 6 in the final RWQC shows swimming-associated NGI illness and daily average *Enterococcus* spp. qPCR cce.

Comment: A commenter thought that although the GM determination is explained and based on the NEEAR data, questions remain as to whether these studies capture the health risks of raw sewage given the ethical limitations of these studies that apparently do not allow EPA to subject participants to high levels of contamination or known raw sewage sources.

Response: The final RWQC were based on data collected from waters likely impacted by a mixture of WWTP effluent and other human sources. If raw sewage is compared to effluent, raw

sewage has a higher ratio of indicators to pathogens than effluent. So at the same indicator level, raw sewage would be predicted to have lower levels of pathogens than effluent. Therefore EPA believes that basing RWQC on WWTP effluent provides the most conservative level of protection and adequately accounts for situations where raw sewage is the source.

Issue 3.3 Scope of Protected Population (Children, Sensitive)

General Population is the Correct Target

Comment: Commenters supported EPA's decision to base the revised RWQC on the larger general population datasets rather than the more limited susceptible population datasets (e.g., children, elderly, immune-compromised). They agreed with the approach where EPA used data from the NEEAR study for the final RWQC 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.

Response: Thank you for your comment.

Target Population Should be Children and Other Subgroups

Comment: Commenters expressed concern that EPA's assessment of health risks to children and other vulnerable populations was inadequate, with some commenters arguing that children are the most appropriate target population for the criteria. They noted that children are especially vulnerable, because they tend to submerge their heads more often and are more likely to swallow water in large volumes when swimming; they are also more vulnerable to pathogens in recreational waters because they have never been exposed to these pathogens previously.

Response: Both the studies from the 1980s and the NEEAR study employed strategies to ensure that children were highly represented in those epidemiology studies. Compared to national demographics, the NEEAR epidemiological studies included an over-representation of children. Thus, the illness rates corresponding to the criteria are based on an epidemiology relationship that included children. EPA conducted statistical analyses of the data from each of EPA's epidemiological studies at fresh water, marine, and tropical beaches to evaluate whether children at these sites were at an increased risk of illness following exposure to recreational waters. The collective results of the NEEAR epidemiological studies, 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 than from the general population (which included children). See section 3.3 of the RWQC for more information.

Comment: Commenters noted that other studies demonstrate that children, the elderly, and the immune-compromised have an increased health risk when swimming in fecal contaminated waters. These studies should be taken into consideration in the final RWQC. They said that EPA indicated that the NEEAR study found no increased risk for children was measurable. However, this finding is inconsistent with numerous epidemiological studies and the NEEAR sand study reported children at higher risk.

Response: EPA considered many studies qualitatively, but thought that quantitative adjustments for determining the criteria values in the RWQC were not supported scientifically.

Comment: A commenter thought that EPA should consider other susceptible populations such as triathlon runners and tourists.

Response: EPA believes that the scope of exposures that were included in the epidemiology studies is adequate for protection of public health. In the NEEAR study exposures ranged from 15 minutes to several hours.

Comment: Commenters thought that society includes children, pregnant women, persons over the age of 55, persons with human immunodeficiency virus, and other sensitive populations who must be included in statistically significant numbers for relevant studies and criteria calculations. Commenters noted that one societal need is for WQC to further environmental justice, which is not even addressed in the draft RWQC.

Response: There are ethical issues associated with conducting a study that specifically enrolled known vulnerable populations. These vulnerable populations do occur in the general beach going population and are included in small numbers in the NEEAR study. The NEEAR study enrolled over 53,000 participants.

General Population is Not Weighted to Include Children

Comment: Commenters disagreed with the statement that “[...] the NEEAR epidemiological studies included an over-representation of children.” While the NEEAR study may have had more children sampled, compared to other epidemiology studies, this should not be considered an “over-representation” unless the studies included a higher percentage of children than there were represented as swimmers at those beaches.

Response: Unlike some studies that only enrolled adults, this study enrolled children in proportion to the beach going population which is greater than the general population. Because of the NEEAR study design EPA was able to enroll children. EPA chose one of the epidemiology study designs that allow children to participate. See section 3.3 of the final RWQC for the percentage of children enrolled in the NEEAR study compared to the percentage of children in the general population.

Comment: Commenters noted that the risks associated with beach and recreational water pollution are very difficult topics to explain to the public. EPA should consider simplifying the presentation of the criteria for public notification in a way that makes it more protective than the current criteria and work to better communicate the health risks to the public.

Response: EPA has revised the RWQC to make it easier to understand. To the extent this comment raises concerns regarding the implementation of criteria in beach monitoring and notification programs, it is beyond the scope of this document.

Comment: In section 3.3 it is unclear if the beach populations used represents the general population in terms of ethnicity, and if ethnicity even affects risk level. The EPA should have also evaluated whether tourists from other geographic areas are more at risk than local populations in areas where there are high levels of use by non-local tourists. It is unfortunate that EPA was not able to determine specific health risks for children or other vulnerable subpopulations.

Response: The NEEAR study design used the actual beach going population. In some epidemiology studies participants are enrolled, then are instructed to arrive at the beach for the study. For the NEEAR study, people were enrolled that were already visiting the beach, so the demographic distribution is representative of actual beach attendees. In the NEEAR study, EPA collected information on ethnicity and tourists, but those parameters did not provide useful differentiations in risk. EPA did evaluate the epidemiological relationship for children, but the dataset was small enough that the uncertainty was considerably larger than the uncertainty for the participants as a whole. The dataset for other vulnerable populations was too small to draw conclusions.

Comment: In section 3.3, it is ironic that EPA has highlighted the need for rapid testing to better protect children and yet is delegating rapid methods to the states instead of working to ensure the national implementation of rapid methods and thus better health protection for all beach goers, including children.

Response: Please see section 3.1.1 in the RWQC document for an explanation of why qPCR was not recommended nationally.

Issue 3.4 Waterbody Type

Consider Saline versus Freshwater

Comment: Commenters requested clarification on the distinctions between fresh and salt waters in addition to coastal and non-coastal areas. Commenters thought that coastal fresh waters would be more comparable to inland waters than coastal marine waters, yet the reverse is implied in the RWQC.

Response: Discussion of waterbody types is in section 3.4 of the final RWQC. The grouping of coastal waters with the Great Lakes is due to the scope and definitions described in the BEACH Act. Therefore, it should not be interpreted or implied that these waterbodies have been grouped together for other reasons, or that they are a scientific grouping.

Comment: Commenters asked that the influence of salinity levels on culture and qPCR methods be considered.

Response: Method performance is beyond the scope of the RWQC.

Limit Criteria to Waterbody Types that Have Epidemiological Data

Comment: Commenters requested that studies on the Great Lakes, on tropical beaches, on recreational activities in warm climates, and on areas where WWTP impacts are prevalent not be used to establish standards applicable to all CWA waterbodies.

Response: EPA agrees that there are different types of waterbodies that may be impacted by different sources of contamination. However, EPA supports the use of criteria that are universally protective of public health regardless of waterbody type. In the final RWQC, EPA has provided the flexibility and tools for the development of site-specific criteria. It is possible to develop site-specific criteria in cases where a waterbody may be uniquely impacted.

Limit RWQC to Coastal Recreational Waters (as Defined by BEACH Act)

Comment: Commenters pointed out that the Consent Decree and Settlement Agreement only applied to coastal recreational waters, which are defined as the Great Lakes and marine coastal waters (including coastal estuaries) that states, territories, and tribes designate in their WQS for use for swimming, bathing, surfing, or similar water contact activities. Commenters noted that, as defined by the BEACH Act, coastal waters do not include inland fresh waters outside of the Great Lakes and believe that criteria should not be proposed for inland flowing waters. They asked that EPA recognize that these criteria were developed, and most accurately apply, to beach advisory programs that focus on waters that are the most highly used recreational waters and drop the statement that these recommendations are for all waters in the U.S. They indicated that the paragraph at lines 1401-1408 also does not make much sense. Because different conditions between coastal and non-coastal waters that result in different FIB concentrations are the same sort of differences that exist between two coastal areas that would also result in different FIB concentrations.

Response: EPA acknowledges that §304(a)(9) of the CWA directs EPA to publish criteria recommendations for coastal recreation waters (i.e., marine and Great Lakes waters designated by a State for swimming, bathing, surfing, or similar water contact activities). However, §304(a) of the CWA also directs EPA to publish and, from time to time, to revise the WQC to accurately reflect the latest scientific knowledge for all waters. Today's RWQC are 304(a) criteria for all waters designated for primary contact recreation; as such, they also fulfill the requirement at 304(a)(9) for coastal recreation waters. EPA will continue to review any new data or information related to the RWQC. However, based on EPA's review of the currently available scientific information, EPA recommends that the RWQC be used in both coastal and non-coastal waterbodies.

More Studies are Needed on Inland Waters

Comment: Commenters requested that EPA conduct epidemiological studies on inland and inland flowing waters in order to derive scientifically defensible criteria for inland waters.

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 final RWQC for all waterbody types (U.S. EPA, 2010c). Additionally, EPA considered the Water Environment Research Foundation (WERF) Inland Water Workshop report (WERF, 2009) and subsequent meeting report publication (Dorevitch et al., 2010), which concluded that the inclusion of non-coastal waters in the final RWQC will result in public health protection by preventing illnesses associated with exposure to non-coastal waters if states adopt WQS based on EPA's final RWQC recommendations. See section 3.4 for explanation of the inclusion of inland waters in the national RWQC.

Comment: Commenters asked that EPA include language in the RWQC that directly addresses the development of site-specific criteria for inland flowing fresh waters.

Response: EPA intends to provide TSM on tools for developing alternative RWQC on a site-specific basis. These tools can be applied to inland flowing fresh water. The tools include epidemiological studies in both marine and fresh waters, quantitative microbial risk assessment (QMRA), and alternative indicators or methods (see section 6). However, EPA believes that the distinction of whether a water is flowing or not 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.

Comment: Commenters pointed out that no discussion of springs, ponds, or wetlands was included in the RWQC nor was there discussion of recreational swimming from watercraft away from the shoreline.

Response: The final RWQC does not provide recommendations or definitions based on physical water quality parameters (i.e., depth and source). The final RWQC are recommended for any waterbody designated by the state, tribe or territory for primary contact recreation regardless of the proximity of primary contact activity to the shore.

Comment: Commenters questioned the change in criteria for inland and flowing waters without new epidemiological data.

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 final RWQC for all waterbody types (U.S. EPA, 2010c). Additionally, EPA considered the WERF Inland Water Workshop report (WERF, 2009) and subsequent meeting report publication (Dorevitch et al., 2010), which concluded that the inclusion of non-coastal waters in the final criteria will result in public health protection, by preventing illnesses associated with exposure to non-coastal waters if states adopt WQS based on the final RWQC recommendations. Additionally, outbreaks from exposure to non-coastal waters indicate a need for public health protection in such settings. FIB monitoring can be used as a way to reduce the occurrence of outbreaks of severe illness, as well as the sporadic cases of illness that occur among swimmers. Overall, the distinction of non-coastal waters versus coastal waters is of less importance than more fundamental variables such as the source of fecal contamination,

scale of the body of water, and the effects of sediment, which translate into differences in the densities, transport, and fate of indicators and pathogens.

Support for RWQC for All Waters

Comment: Commenters supported EPA’s efforts to develop criteria for all waterways designated for recreational use, including all surface waters.

Response: Thank you for your comment.

Requests for Clarification

Comment: Commenters indicated that the sentence at lines 1391-1392 “loadings and hydrodynamics of FIB in WWTP-impacted coastal and non-coastal waters are generally similar” is not correct and inconsistent with the rest of the paragraph which is not clearly written. The hydrodynamics of FIB in a small lake, a river, and ocean waters vary considerably. There are large differences within any natural waters due to differences in physical dynamics, turbidity, salinity, and biology.

Response: The paragraph has been edited for clarity.

Comment: Commenters requested that in the epidemiological non-coastal water section, it should be explained that enterococci is a more human-specific subgroup of fecal streptococci.

Response: EPA agrees that enterococci are a subgroup within the fecal streptococci group and are typically more human-specific than the larger fecal streptococci group. The RWQC document has been edited to clarify this point.

Tropical versus Temperate

Comment: Commenters argued that results from epidemiological studies in subtropical and tropical waters do not fully support the standard proposed in the RWQC.

Response: Even though the NEEAR study was conducted in temperate waters, EPA believes that the recommended criteria are scientifically defensible and protective of the use if adopted into state standards for tropical waters. Criteria were developed using waters impacted by WWTPs and are thus protective in other water body types. States or territories can develop site-specific data if they believe that another approach is more applicable for their location.

EPA has discussed NEEAR study findings from Boquerón, Puerto Rico, in the RWQC document. The health effects study conducted at the beach in Boquerón, Puerto Rico, suggest consistency with previous EPA studies that were conducted using culture-based methods to measure water quality. These results show that low fecal indicator levels measured by *Enterococcus* spp. cfu (only one day exceeded a GM of 35 cfu per 100 mL) and the frequency of observing evidence of GI illness in swimmers was also low to non-detectable.

Comment: Commenters recommended that EPA conduct additional research on the distribution of enterococci in tropical and sub-tropical waters, and relationships with GI and upper respiratory diseases.

Response: EPA appreciates the recommendation to conduct additional research. EPA continues to encourage ongoing research efforts; however the epidemiological studies presented in the final RWQC support the use of the recommending criteria in tropical and sub-tropical waters.

Issue 3.5 Sources of Fecal Contamination

Comment: Commenters suggested that EPA change "All surface waters receive FIB from point sources, diffuse sources (which may consist of point source and nonpoint source pollution), direct deposition, and resuspension of FIB contained in sediments" to " All surface waters receive FIB from one or more of the following sources: point sources, diffuse sources (which may consist of point source and nonpoint source pollution), direct deposition, and resuspension of FIB contained in sediments" because not all surface waters receive FIB from point sources.

Response: EPA agrees that point sources may not be a contributing FIB source to all surface waters. The RWQC document has been edited to clarify.

Not All WWTP Sources Pose Same Risk

Comment: Commenters noted that not all WWTPs should be characterized with the same risk and that this may require further study. A commenter suggested that the level of treatment (such as, enhanced nutrient removal, use of sand filters, and ultraviolet disinfection) may reduce the risk of illness. The commenter noted that not all WWTPs should be characterized with the same risk and supported further study of this issue.

Response: EPA agrees that it is possible that WWTP treatment can vary in its effectiveness to remove pathogenic microorganisms depending on the treatment processes employed including the type and strength of disinfection. The NEEAR study encompassed the most common forms of WWTP treatment (including conventional secondary treatment) and a relatively wide range of disinfection types. EPA believes that the NEEAR study sites are broadly representative of conventional wastewater treatment that occurs nationally. The final RWQC recommendations are scientifically defensible and protective of the use in all waters, regardless of the source of fecal contamination.

Comment: Commenters indicated that WWTPs chlorinate effluent which is effective at killing enterococci, but not viruses, thus masking the truer health risk.

Response: EPA is aware that viruses are present in significant numbers in the feces shed by infected individuals and that sewage serves as a potentially important source for viruses which can contaminate public water supplies, shellfish, and recreational water. EPA recognizes that many wastewater treatment processes can remove microorganisms, but no process removes all microorganisms from wastewater and sampling specifically for viruses in wastewater is not

required at this time. In the final RWQC, EPA acknowledges that viruses cause of many of the illnesses, particularly those resulting from exposure to WWTP effluent. The NEEAR study was conducted at beaches which were impacted by WWTP effluent including facilities that used chlorination for their disinfection.

Comment: Commenters asked if the point sources impacting NEEAR study beaches employed disinfection methods sufficient to kill or inactivate enterococci, thus making the enterococci enumerated using culture techniques most likely derived from nonhuman sources. If so, any culturable enterococci concentration/human illness relationship must reflect either 1) human illness from animal-derived or indigenous pathogens or 2) a fortuitous relationship between animal or indigenous enterococci concentrations and human source-derived pathogens (this need not be true for qPCR enterococci concentrations as non-viable enterococci are also measured in this test).

Response: The point sources impacting the NEEAR beaches did employ disinfection. The disinfection employed was sufficient to substantially reduce the levels of enterococci in the effluent. However, EPA disagrees with the conclusion that human illness must be from animal-derived or indigenous pathogens, or due to a fortuitous relationship between animal or indigenous enterococci concentrations. Numerous recreational water epidemiology studies have been conducted in waters impacted by disinfected effluent and have found correspondences between enterococci and human illness. These results highlight the fact that attenuation but not complete removal of indicators and pathogens occurs during wastewater treatment. The extent to which animal derived or ‘indigenous’ pathogens contributed to the observed illnesses was not quantified. However, EPA’s QMRA research indicates that in many cases, those contributions would be predicted to be relatively low provided that the culturable enterococci levels were at or below the proposed criteria levels.

Comment: Commenters stated that exposure to pathogens from nonhuman fecal contamination remains a risk factor and risk may increase over time with due to changes in climate and land use. They recommended that EPA support research that improves the state of the science sufficiently to fully evaluate risks from nonhuman fecal contamination, to identify suitable indicators for such contamination, and to develop approaches to manage risks.

Response: EPA agrees that research that improves the state of the science surrounding pathogens from nonhuman fecal contamination is important.

Not All Human Sources Pose the Same Risk

Comment: Commenters cited lines 1569-1570 of the RWQC, which state that “While human sources of fecal contamination are fairly consistent in the potential human health risks posed during recreational exposure” and asked that EPA provide evidence that human sources of fecal contamination are fairly consistent in the potential human health risks posed during recreational exposure. They advised that a section on the difference in risks from different human sources be added to the document because raw sewage sources would be expected to have greater risks than disinfected human sources from functional wastewater treatment facilities.

Response: EPA agrees that wastewater effluent and raw sewage are not the same. The RWQC text has been edited to clarify this.

RWQC Should Not Apply to Nonhuman Sources

Comment: Commenters noted that the risks for swimming related waterborne transmission of GI diseases as predicted by the RWQC are applicable when the recreational waters are known to be contaminated with human sewage, but argues that the same predictable risks are not applicable when the sources of FIB to contaminate recreational waters are not from sewage.

Response: EPA agrees that different sources may have different associated risks. However, EPA believes that applying the recommended final RWQC to waters impacted by scenarios other than known sources of human sewage is still scientifically defensible and protective of primary contact recreation. Few epidemiological studies have been conducted in waters impacted by nonhuman sources of fecal contamination and sufficiently robust data were not available to develop national recommendations for non-WWTP effluent impacted waters. States have flexibility to develop alternative site-specific criteria for waters impacted by other sources. See section 6 of the final RWQC document. EPA intends to provide TSM for the development of site specific criteria.

Comment: Commenters asked that EPA more transparently address the issue of applying criteria, which were based on epidemiological studies at point source influenced beaches, to nonpoint source influenced waters.

Response: EPA has identified only a limited number of epidemiological studies conducted at nonpoint source impacted beaches. These studies are described in more detail in section 3.5 of the final RWQC document. The available epidemiological data do not support the development of separate national criteria for nonpoint source impacted beaches. EPA intends to provide flexibility and TSM for states to develop site-specific alternative criteria. Alternative site-specific criteria may be appropriate for waterbodies with nonpoint sources.

Comment: Commenters requested that EPA point out that *E. coli* and enterococci also occur naturally in the environment as free-living organisms and are not always associated with fecal pollution.

Response: EPA reviewed the available scientific literature on environmental populations of fecal indicators. The literature supports, and EPA agrees with, the conclusion that FIB (i.e., fecal coliforms, *E. coli*, enterococci) can multiply and persist in tropical, subtropical, and temperate climate zones; in all water types (marine, estuarine, and fresh); and in soils and the water column. Thus, their presence in water is not necessarily an indication of recent fecal contamination. The final RWQC document has been edited to reflect this conclusion and ‘Review of fecal indicator organism behavior in ambient waters and alternative indicators for tropical regions’ has been referenced in the document.

Comment: Commenters suggested that the RWQC recommend separate criterion values for the following scenarios: 1) fresh cattle feces; 2) storm runoff from land applied cattle, chicken or pig

manure; and 3) wildlife sources; gulls, ducks, geese, or mammals. They noted that the sources of contaminating FIB will determine the relative risks (highest to lowest) to swimmers in the following manner: human sewage > some animal feces known to harbor human pathogens > many animal feces, which are less likely to harbor human pathogens > environmental sources (e.g., soil, sediments, plants, water, and sand) of FIB. Other commenters asked EPA to provide a scientific basis for implementing RWQC for the purpose of health protection in situations where *E. coli* or enterococci assay outcomes are positive in pulp and paper mill effluents but where these outcomes do not appear to be linked with human fecal contamination or with the presence of pathogens.

Response: EPA agrees with the ranking of these relative risks. EPA believes sufficiently robust data are not available to support national criteria for the scenarios listed. A variety of scenarios are covered in the alternative site-specific criteria approaches. In section 6 of the final RWQC document, EPA has provided information for states to develop site-specific alternative criteria.

Comment: A commenter pointed out that methods used to assay for concentrations of FIB cannot distinguish between sewage sources or non-sewage sources of FIB, and therefore water monitoring data cannot be used to establish defined risks without assuming that the source of FIB is primarily from sewage.

Response: EPA agrees that conventional methods (i.e., culture) used for the detection and enumeration of FIB do not include an element of source tracking. EPA recommends that states understand the potential sources of fecal contamination impacting their surface waters. Understanding the susceptibility of a water body to fecal contamination is important for informing effective risk management approaches. Assuming that the FIB source is human is the conservative health protective assumption. For cases where the predominant source is nonhuman, site-specific alternative criteria can be developed. See section 6 of the final RWQC document.

Comment: Commenters asked EPA to emphasize demonstration that *E. coli* and enterococci are valid fecal indicators in nonpoint source-influenced waters.

Response: EPA's epidemiological studies and other epidemiological studies conducted worldwide have demonstrated that *E. coli* and enterococci are associated with human GI illness in waters impacted by WWTP effluent. For all other sources these same levels of indicators would provide at least the same level of human health protection. If a state believes these indicators relate to illness differently, or are not associated with illness for specific waterbodies, then the state has the flexibility to develop site-specific alternative criteria.

Comment: A commenter suggested that the concentrations of environmental FIB will not be related to the degree of sewage contamination and predictable concentrations of human pathogens.

Response: EPA agrees that environmental FIB are not necessarily related to the degree of human sewage contamination. As with other sources of FIB that are not associated with human

pathogens. EPA is providing TSM to support flexibility for states to develop site-specific alternative criteria. See section 6 of the final RWQC document.

Comment: Commenters noted that the ecological behaviors of *E. coli* and enterococci are not fully known, which can confound predictions of illness risk. They asked EPA to point out that FIB, *E. coli*, and *Enterococcus* spp. occur naturally in the environment as free-living organisms and are not always associated with fecal pollution. They noted that enterococci may persist longer than *E. coli* in sand and algae, and that bacteria are living organisms that can reproduce and multiply in the environment, even in the absence of additional discharges. In addition, they pointed out that the RWQC does not specify that enterococci and other FIB may persist and multiply in the environment long after the initial fecal contamination, resulting in bacteria concentrations that have no correlation with the initial fecal contamination source or health risk.

Response: In the final RWQC, EPA acknowledges that sand may serve as a source of FIB in recreational waters and FIB may persist and multiply in the environment. The final RWQC document has been revised to discuss environmental *E. coli* and enterococci. EPA agrees that *E. coli* and enterococci behave differently with respect to their fate in the environment due to the physiological differences between these genera (e.g., cell wall structure, mechanisms of mobility, response to standard disinfection practices, etc.). Additionally, the relative fate and transport behavior of FIB and microbial pathogens can differ as pointed out by the commenter. EPA believes that understanding the potential sources of fecal contamination contributing to a water body and the susceptibility of that water body to fecal contamination is an important aspect of state risk management programs. Understanding the watershed will place the water quality monitoring results in context. Site-specific criteria may be developed in conditions where environmental sources of FIB are predominant in a waterbody.

Develop Criteria for Stormwater/Wet Weather Events

Comment: Commenters asked why the document did not specifically address stormwater and recommended that EPA develop storm specific criteria that assume recreational use during storms, even though recreation during storm events would be unlikely and unsafe. They asked for clarification on the phrase “sampling of waterbodies should be representative of meteorological condition.” Commenters noted that many waterbodies that receive storm water inputs are designated as having recreational uses, but in reality are not supportive of recreation year-round, yet would be held to standards that are unreasonable during wet weather events.

Response: The final RWQC recommendations are for waterbodies designated for primary contact recreation by the state, tribe or territory rather than for specific sources or physical conditions (e.g., stormwater, shallow streams).

Comment: Commenters indicated that the criteria should also contain implementation strategies that allow for more flexibility when applied in the context of TMDL and stormwater requirements.

Response: This is beyond the scope of the RWQC.

Comment: Commenters asked if wet weather samples should be included in water quality assessments and recommended that EPA require additional wet weather sampling.

Response: This comment is beyond the scope of the RWQC.

Comment: Commenters asked that MST be explicitly added to the RWQC.

Response: EPA does not plan to issue further guidance on MST at this time. Please refer to EPA's document "Using Microbial Source Tracking for TMDL Development and Implementation" (U.S. EPA, 2011).

Epidemiological Studies do not Support Risks from Nonhuman Sources

Comment: Commenters stated that supporting documentation (draft RWQC Appendix C1, section 3.2.2) showed ambiguous results or a lack of correlation when epidemiological studies were conducted in waters impacted by nonhuman sources. They were concerned about this ambiguity and lack of information available to develop RWQC for receiving waters with nonhuman or mixed sources of FIB (draft RWQC section 3.5, line 1625-1631). And that when a predominant source of a FIB is demonstrated to be nonhuman or plant-derived it is not clear what specific steps are required in order to develop alternative, site-specific RWQC

Response: TSM will discuss development of site-specific criteria in more detail.

Comment: Commenters thought the Cheung et al. (1990) Hong Kong beach study, which is described as non-WWTP impacted, to be misleading because it is likely that the area is densely populated and impacted by human sources. They thought other studies (e.g., Wiedenmann et al., 2006) to be equally misleading because they provide the reader false impressions, as if nonhuman only sources were in fact studied and found to be equal to human source impacts.

Response: EPA acknowledges in the final RWQC that little epidemiological data are available to evaluate the relationship between illness and FIBs in waters predominantly impacted by nonhuman sources of fecal contamination. For example, Cheung et al. (1990) reports that some of the Hong Kong beaches evaluated in that epidemiological study were impacted by livestock sources of fecal contamination while other beaches were reported as directly impacted by human fecal sources. Similarly, some of the sites studied by Wiedenmann et al. (2006) were predominantly by human sources and others by nonhuman sources. The final RWQC text has been edited to clarify the sources for these studies.

Comment: Commenters thought that EPA gave the impression that nonhuman sources and human sources are equal in their human health risk, when that claim is not shown in any of the cited studies and likely overestimates the risk for human health at many waterbodies impacted mostly by runoff, where human sources are unlikely.

Response: EPA does not take the position that nonhuman and human sources are equal in health risk. Section 3.5 indicates that waters impacted by nonhuman sources may carry risks. Because these risks are possible under some situations, national criteria for nonhuman sources are not

appropriate. The site-specific nature of nonhuman sources is one reason EPA is developing tools to assist states that want to adopt site-specific alternative WQC to take into account the variation in risk from nonhuman sources. The final RWQC text has been edited accordingly.

Agree with EPA Approach to Apply Criteria to All Sources

Comment: Commenters agreed with EPA that the risk presented by fecal contamination from nonhuman sources varies and has been shown in some cases to be potentially less significant than the risk presented by fecal contamination from human sources; they also agreed that not all animal fecal material presents the same level of risk.

Response: Thank you for your comment.

Comment: Commenters agreed with EPA's efforts in developing criteria that consider all fecal sources as a potential human health risk rather than advocating for the development of separate national criteria for nonhuman sources of fecal contamination of recreational waters.

Response: EPA thanks the commenters for their support and agrees that it is appropriate for national criteria recommendations to consider all fecal sources at this time. In addition, EPA believes that site-specific alternative WQC might be appropriate for some waterbodies.

Comment: Commenters thought that Soller et al. (2010) indicates that only bird guano has the potential to generate false positives. Feces from cow, pig, etc. are high in pathogens and people should not be exposed to them.

Response: EPA acknowledges that animal wastes from many different animal sources may contain zoonotic pathogens. The research the commenter mentions has been continued and expanded to other animals. Soller et al (2010) indicates that cattle under certain scenarios (e.g., accounting for fecal loading, diet, and shedding status) can result in risks similar to human fecal material.

Comment: Commenters asked that EPA consider requiring proof of the nonhuman source (i.e., birds) as the primary cause of high *Enterococcus* spp. concentrations.

Response: EPA expects that its TSM for site-specific alternative WQC will include details on demonstrating the predominance of a nonhuman source. Case studies may also be included to show users how the support for site-specific criteria may be built and documented.

Comment: Commenters thought that there is insufficient data to allow development of criteria for situations where fecal contamination is primarily from nonhuman sources.

Response: EPA believes that there is insufficient data available at this time to develop national criteria for situations where fecal contamination is primarily from nonhuman sources. However, EPA believes that site-specific alternative criteria might be appropriate for some waterbodies.

Issue 3.6 Expression of Criteria

Support for Continuing with 1986 Values

Comment: Commenters expressed support for the use of the GM for expression of WQC, and for this draft RWQC carrying the same level of protection forward and adopted criteria values for the culture methods as the 1986 criteria values. They supported the rationale and science that this recommendation is based upon and urged EPA to expand the explanation and rationale for keeping the 1986 values.

Response: Based on EPA's review of public comments and further scientific analyses, EPA has decided to modify the criteria as explained in section 3.6.2 of the RWQC document.

Issue 3.6.1 Use of the STV for Beach Notification

Support for STV Approach for Beach Notification

Comment: Commenters expressed support for the concept of a STV (formerly SSM) as part of the recommended criteria for marine and fresh waters. They agreed that the use of the 25% excursion allowance of the STV makes sense when one considered the statistical distribution of bacteria water quality. They also expressed anticipation that the additional clarity provided by EPA in using the STV (as a replacement for SSM) will reduce inconsistencies in interpretation of SSM values and implementation of the bacteria criteria. Commenters supported EPA's clarification in the draft RWQC that the interpretation of SSM values as not-to-be exceeded values effectively creates a WQS that is more stringent than is needed to be protective of primary contact recreation. They agreed that 25% excursion allowance of the STV is more scientifically correct than a "never to exceed" value.

Response: Based on EPA's review of public comments and further scientific analyses, EPA has decided to modify the criteria as explained in section 3.6.2 of the final RWQC document. The STV is based upon the 90th percentile of the water quality distribution. EPA has determined that a maximum 10% frequency of excursions (ambient conditions worse than those described by the combination of the criterion magnitude and criterion frequency) is consistent with full support of primary contact recreation.

When to Apply STV

Comment: Commenters thought that the GM and STV concepts are inconsistent and urged EPA to apply the GM whenever more than one sample is available and the STV when only one sample is available.

Response: EPA disagrees that the GM and STV concepts are inconsistent. These concepts are consistent with water quality observations, and accurately describe, in a statistical sense, conditions which will be protective of the designated use of primary contact recreation. EPA guidance regarding monitoring and assessment of waterbodies for 303(d) listing and 305(b)

reporting purposes appears in the Agency's Integrated Reporting Guidance (IRG) (U.S. EPA, 2006). Commenters may find the sections on data set size and the degree to which certain sampling data is likely representative of WQC-relevant waterbody conditions to be of particular interest.

Comment: Commenters requested explicit recognition of "uncontrollable sources" and site-specific STV calculations to account for "uncontrollable sources."

Response: Section 6 of the RWQC document describes tools for managing and assessing waters on a site-specific basis. The term "uncontrollable sources" is not well defined enough to be sure what sources the commenters are including. EPA is not providing national criteria for different sources.

Comment: Commenters suggested that EPA explicitly recommend the use of the STV (75th percentile) in waters of all states, including waterbodies receiving predominantly urban runoff.

Response: Based on EPA's review of public comments and further scientific analyses, EPA has decided to modify the RWQC as explained in section 3.6.2 of the final RWQC document. The STV is based upon the 90th percentile of the water quality distribution. EPA has determined that a maximum excursion rate of 10% (frequency = 10%) is consistent with full support of primary contact recreation. The recommended RWQC (including the GM and STV) are recommended for all U.S. waters regardless of source.

Comment: Commenters asked EPA to clarify that the STV is generally applicable to (and protective of) both wet and dry weather, flowing streams and beaches, marine and fresh water, urban runoff, and WWTP-impacted waters.

Response: The final RWQC are protective of the designated use of primary contact recreation for U.S. waters. This statement applies to flowing streams and beaches, marine and fresh water, and WWTP-impacted waters.

Comment: Commenters asked that EPA clarify that the STV is protective of urban runoff beaches (if that is the case) based on epidemiological data that were considered.

Response: The final RWQC are protective of the designated use of primary contact recreation in all waters regardless of source. EPA's perspective is consistent with the available epidemiological data which were considered in the development of the final RWQC.

Comment: Commenters indicated that the FR notice should indicate that the excursion rate of 25 percent applies for CWA purposes other than beach notifications.

Response: Based on EPA's review of public comments and further scientific analyses, EPA has decided to modify the RWQC as explained in section 3.6.2 of the final RWQC document. The STV is based on the 90th percentile of the water quality distribution with 10% frequency of excursions allowed.

Suggested Changes to STV

Comment: Commenters suggested that EPA retain and/or expand the use of a SSM criteria and offered options that included daily excursions, weather-adjusted excursions, and changing the maximum excursion rate from 25 to 10 percent, or in other comments, to 0 percent. Commenters noted that the STV as defined as the 75th percentile concentration seems to be grandfathered in from the original 1986 document that defined a SSM as the 75th percentile concentration. However, the 75th percentile concentration seems to be arbitrary. These commenters thought that there was a lack of scientific evidence from epidemiological studies that the 75th percentile concentration was based on any cause-effect relationships between *Enterococcus* spp. distributions and illness rates. They asked what the justification was for using this percentile.

Response: Based on EPA's review of public comments and further scientific analyses, EPA has decided to modify the criteria as explained in section 3.6.2 of the final RWQC. The STV is based upon the 90th percentile of the water quality distribution. EPA has determined that a maximum 10% frequency of excursions (ambient conditions worse than those described by the combination of the criterion-magnitude and criterion frequency) is consistent with full support of primary contact recreation. Please see section 3.6.2 of the final RWQC for additional discussion.

Comment: Commenters suggested EPA maintain the SSM approach and/or strengthen the STV or even withdraw it. They argued that the STV has little statistical value, and that the SSM approach is an invaluable tool for public health protection and risk management (beach closures and postings), as well as a regulatory tool to ensure that beneficial uses are protected.

Response: EPA is not recommending an SSM value, as explained previously. 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 percent of the samples used to calculate the GM. For the STV, EPA selected the estimated 90th percentile to take into account the expected variability in water quality measurements, while limiting the number of excursions above the STV, and to encourage additional monitoring. In addition, EPA is providing BAVs as an option for states to use for beach notification purposes (such as advisories and closings), see section 5.1 of the final RWQC document.

Comment: Commenters suggested that an STV that allows up to a 25 percent excursion rate for beaches has the potential to permanently mask chronically polluted beaches, and is therefore inappropriate. They suggested that the GM and STV together should be used to make beach management decisions. These commenters urged EPA to provide additional analyses to substantiate the 104 cfu per 100 mL SSM criteria regarding the association between an FIB SSM and adverse health effects. They suggested that EPA complete a more thorough analysis of existing epidemiological data to determine the SSM enterococci density associated with the health risk based on EPA's determined acceptable risk.

Response: Based on EPA's review of public comments and further scientific analyses, EPA has decided to modify the criteria as explained in section 3.6.2 of the final RWQC document. The STV is based upon the 90th percentile of the water quality distribution. EPA has determined that a maximum 10 percent frequency of excursions (ambient conditions worse than those described

by the combination of the criterion-magnitude and criterion frequency) is consistent with full support of primary contact recreation. Both the GM and STV apply independently and would need to be evaluated to determine whether or not water quality in a given waterbody meets the WQS for primary contact recreation. EPA believes that a shorter duration (30 days), coupled with limited excursions above the STV, allows for the detection of transient fluctuations in water quality in a timelier manner than over a greater period of time (e.g., a recreational season). EPA is also providing BAVs as an option for states to use for beach notification purposes (such as advisories and closings).

Document is Not Clear on Applications to Different CWA Programs

Comment: Commenters indicated that the document does not distinguish between criteria for recreational water monitoring programs and other programs (use attainment, 303(d), etc.)

Response: The final RWQC specifically specify levels of water quality that are protective of the designated use of primary contact recreation. Please see section 5.1 of the final RWQC for discussion of BAVs for beach notification and section 3.6 for discussion of other CWA programs.

Support for Retaining the SSM

Comment: Commenters thought that the SSM was intended to be applied as a value not to be exceeded and applied in that way is neither restrictive nor overprotective. They supported the use of a SSM rather than the STV for identifying, tracking, and posting chronically polluted beaches to EPA's 303(d) list.

Response: EPA is providing an STV as one component of the recommended criteria. If adopted in a State standard, the GM and the STV together would be the applicable WQS for CWA programs such as listing and NPDES permits. Additionally, EPA is providing BAVs as a precautionary tool for states to use for beach notification purposes (such as advisories and closings).

Comment: Commenters argued that the proposed STV runs contrary to the November 2004 WQS for Coastal and Great Lakes Recreation Waters where EPA indicated that single samples were only necessary for beach closure/notification purposes.

Response: EPA has clarified the use of STV criteria value and the BAVs in the final RWQC document. Please see sections 3.6 and 4.0.

Comment: Commenters argued that the STV is simply the upper bound confidence level around the GM; hence, it has no scientific meaning and is a policy statement.

Response: The STV represents an upper percentile of the water quality distribution that, when used in conjunction with the GM, is protective of the designated use of primary contact recreation.

Comment: Commenters suggested EPA maintain the reliance on the GM as providing the intended level of health protection and leave any use of the STV to the discretion of the states.

Response: The GM and the STV serve two different purposes. The GM protects the long-term health of the waterbody, while the STV catches short-term excursions. The STV ensures that the variance of the water quality distribution in a waterbody is consistent with the water quality that is protective of the designated use of primary contact recreation. States do have the flexibility to adopt WQS that are more stringent than the recommended final RWQC.

Site-specific Standard Deviations to Determine STV

Comment: Commenters asked EPA to clarify whether states could use their own site-specific data distributions (standard deviations) to determine their own STVs, particularly for inland waters. They requested the criteria incorporate site-specific standard deviation (variability) for calculation of the STV because the costs may be difficult for states to justify without new data for inland waters.

Response: As discussed previously, states may adopt WQC into their WQS that differ from EPA's recommended WQC. EPA would evaluate any such criteria to determine whether they are scientifically defensible and protective of the primary contact recreation use.

Other Comments

Comment: Commenters indicated that a 90-day period is necessary to correctly evaluate compliance with the STV.

Response: Based on EPA's review of public comments and further scientific analyses, EPA has decided to modify the criteria as explained in section 3.6.2 of the RWQC document. An averaging duration of 30 days is recommended for computing GMs and STVs for decisions relating to use attainment.

Comment: Commenters urged EPA to clarify the appropriate application and intent of the revised recommendations, because the use of the averaging period and STV differ for beach notifications versus CWA §303(d) listing purposes.

Response: Beach notification decisions can be made using the same data that are collected for §303(d) listing purposes. See section 3.6 in the final RWQC document for information on GM and STV for CWA purposes and section 5.1 for BAVs for beach notification.

Comment: Commenters urged EPA to define "single sample". Some states take multiple (3) samples at a beach on a given day to gain more confidence in determining the indicator density for that beach at the time of sampling. They calculate an average or mean of the results and compare that number with the 75th percentile SSM (STV) to make a beach management decision. Within this context, commenters asked how EPA would interpret 'single sample.' A commenter asked for clarification about how to handle duplicate or triplicate samples.

Response: FIB can be highly variable even over short time periods. The GM and STV are used to describe a water quality distribution that would be protective of primary contact recreation use. For computation of the 30-day GM and comparison to the STV, each of the samples should be treated independently so that each sample can be used to most accurately estimate the water quality distribution at that location. For daily beach notification decisions, if multiple samples are available for a particular site, the best estimate of the water quality is the GM. Therefore, if multiple daily samples are available for a particular site, the daily GM for those samples can be compared to the BAV.

Comment: Commenters suggested that the title of the section include ‘and GM,’ unless the STV concentration is identical to the GM concentration. Commenters recommended that EPA set the SSM or STV at the GM level and guide states to close or issue advisories for recreational waters when single samples exceed the STV for acute contamination. Based on program experience, a commenter argued for use of short-term GM (as opposed to STV values) in making beach postings or closure decisions when using culturable methods. Commenters asked for clarification regarding EPA’s allowance of short-term GM use for beach advisories (for manager use or for Healthy Beaches program).

Response: EPA is offering BAVs that can be used as a threshold for beach notification decisions based on individual samples.

Comment: Commenters disagreed with EPA’s suggested use of the actual detection limits for the GM calculation for observations reported below the detection limit, and recommended that instead the non-detects be replaced with the median value of the observed samples.

Response: EPA guidance regarding monitoring and assessment of waterbodies for CWA §303(d) listing and §305(b) reporting purposes appears in the Agency’s IRG (U.S. EPA, 2006). Commenters may find the sections on data screening to be of particular interest.

Comment: Commenters thought that the use of the STV may result in more beach closures than are necessary based on the epidemiological data.

Response: Beach notifications will occur only when there are excursions of the STV. EPA believes that the STV is protective of the recreational use.

Comment: Commenters suggested that EPA not rely on states to implement more conservative standards than what is recommended.

Response: The CWA allows states to adopt standards that are more stringent than the EPA’s recommendations, should they deem that appropriate.

Comment: Commenters asked why both the GM and STV must be included if they are equivalently stringent.

Response: Based on EPA’s review of public comments and further scientific analyses, EPA has decided to modify the draft RWQC as explained in sections 3.6.2, 4.0, and 4.1 of the final

RWQC document. The GM and STV serve two different purposes. The GM protects the longer-term health of the waterbody, while the STV with ten percent allowable excursion frequency catches short-term fluctuations. Either measure alone is not sufficient to protect the primary contact recreation designated use. Statistically the GM indicates where the water quality distribution lies on the X-axis and the STV indicates the width of the WQ distribution (i.e., how spread out the data are around the GM).

Lognormal Distribution and Standard Deviation of Water Quality Data

Comment: Commenters argued with numerical and visual examples that beach water data quality results do not generally fit a lognormal distribution.

Response: Actual water quality at a beach tends to be log-normally distributed, based on the fact that water quality data typically span many orders of magnitude and that the distributions are right skewed since they are bound by zero on the left. General environmental sampling data tend to follow log-normal distributions, a phenomenon discussed by Esmen and Hammad (1977). The use of the GM for recreational WQC is discussed in detail and further justified by Wymer and Wade (2007). Additionally, the GM has been used by numerous researchers to discuss the central tendency of water quality at beaches (for examples, see Boehm et al., 2009 and Whitman et al., 2004). Importantly, the GM was used for the draft RWQC because the GM at the NEEAR beaches is linked to health effects.

The commenters present a valid point – that data sets from some beaches may not fit a log-normal distribution. However, based on data from the NEEAR beaches, and studies from the literature, if enough data are collected and the samples below the detection limit are treated in statistically rigorous manner, the log-normal distribution tends to be a good fit for most data sets. For example, WHO based their recreational water Guidelines (WHO, 2003) on a lognormally distributed dataset from the E.U. from over 11,000 bathing locations and over 121,000 enterococci observations (Kay, et al. 2004). In addition, even in cases where beach water quality is not log-normally distributed, application of the recommended RWQC, if attained, should provide protection consistent with full support of primary contact recreation. Martinez et al. (2010) examined data sets from beaches in the European Union and found beach classification for beaches with data that were not log-normally distributed was generally unchanged when using parametric methods versus non-parametric methods to estimate percentiles.

Comment: Commenters also argued that beach water data quality results do not generally have the same log₁₀ standard deviation as those assumed by the proposed criteria and pointed out that yearly variations exist. In view of site-specific variations, the commenters urged EPA to permit each jurisdiction to establish its own site-specific standard deviation values, and thus allow site-specific STV value for a universal GM limit.

Response: The commenters are correct that there is variation in the log₁₀ standard deviation. The recommended final RWQC is based on a standard deviation of 0.44. Higher variances than this may give rise to more illnesses than deemed tolerable, even if the beach meets the GM. Together, the recommended GM and the STV describe waterbodies that would protect the designated use of primary contact recreation. The STV value ensures that even when a

waterbody meets the GM criteria, its variability is constrained, such that high values would be captured.

Comment: Commenters pointed out that if the bacteria sample results follow a lognormal distribution, the sample median can be used as an estimate of the sample GM.

Response: The commenters point out the fact that for a true lognormal distribution, the median is indeed equal with the GM. EPA has historically used the GM and the log10 standard deviation to describe the water quality distribution associated with the recommended RWQC protective of the designated use of primary contact recreation. At this time, EPA does not see a marked advantage to using the median in the expression of the criteria.

Issue 3.6.2 Criteria Magnitude, Duration, and Frequency

Issue 3.6.2.1 Criteria Magnitude

Agree with Criteria Magnitude for Beach Notification

Comment: Commenters agreed that numeric endpoints for FIB that are expressed in the draft RWQC are likely very conservative and sufficient for making beach management decisions while maintaining at least the same level of protection as the previous criteria. Commenters supported the use of a GM of 35 cfu per 100 mL for enterococci for beach management as being protective of public health and pointed out a lack of evidence that more stringent values are significantly more protective.

Response: Based on EPA's review of public comments and further scientific analyses, EPA has decided to modify its recommendations as explained in sections 3.6.2 and 4.0 of the RWQC document. In addition, the BAVs provided for beach notification purposes (section 5.1). The final RWQC are based on the latest science and provide improved public health protection and flexibility to states.

Want Lower Illness Rate

Comment: Commenters thought that the illness rate of 1 in 28 is too high.

Response: Based on EPA's review of public comments and further scientific analyses, EPA has decided to modify its recommendations as explained in sections 3.2.4, 3.6.2 and 4.0 of the final RWQC document. The illness rates associated with the final RWQC recommendations are approximately 32 cases of NGI per 1,000 primary contact recreators for a culturable enterococci GM criteria of 30 cfu per 100 mL (corresponds to 1 in 31 NGI) and 36 cases of NGI per 1,000 primary contact recreators for a culturable enterococci GM criteria of 35 cfu per 100 mL (corresponds to 1 in 28 NGI), in both marine and fresh water.

Want Flexibility to Lower Magnitude

Comment: Commenters urged EPA to amend the draft RWQC to permit each jurisdiction to easily determine its own WQC at a given risk level.

Response: The 304(a) RWQC are national recommendations; they are not regulations. As described in 40 C.F.R. 131.11, states may adopt and submit to EPA for approval WQC that is not based on EPA's criteria recommendations. EPA would evaluate the WQC to determine whether they are scientifically defensible and protective of primary contact recreation. Also, as recognized by §510 of the CWA, states may develop more stringent WQS than those recommended in EPA's 304(a) criteria.

Comment: Commenters asked EPA to lower the SSM/STV as justified by a smaller confidence interval, and the acknowledged larger health risk to the public.

Response: Based on EPA's review of public comments and further scientific analyses, EPA has decided to modify its recommendations as explained in sections 3.6.2 and 4.0 of the RWQC document. EPA is recommending an STV criterion associated with the 90th percentile of the water quality distribution.

Comment on how GM is Calculated

Comment: Commenters indicated that there are apparent inconsistencies in the recommendations for the use of STV of 235 cfu per 100 mL in fresh waters. If used as a "never to be exceeded" value, the GM of that waterbody would need to meet 28 cfu per 100 mL GM (not the 126 cfu per 100 mL GM proposed based on data that did not include inland waters).

Response: EPA disagrees that there are inconsistencies in the RWQC document. The commenter is referring to the statement in the draft RWQC document that indicates that "if 235 cfu per 100 mL value is interpreted to be 'never to be exceeded' values for assessing a waterbody, the resulting water-quality standard is much more stringent than needed to protect the designated use of primary contact recreation if the GM were used. For example, in fresh water, if the STV of 235 cfu per 100 mL is used as a 'never to be exceeded' value, the GM of that waterbody would need to meet 28 cfu per 100 mL." The final RWQC document explains that EPA believes that concentrations of FIBs can go above STV concentrations ten percent of the time in a waterbody, and said waterbody will be able to fully support primary contact recreation. In the past, many states treated the SSM values in the 1986 criteria as "never to exceed values," which did result in inconsistencies in terms of public health protection between the GM and SSM components of the criteria. The current approach with the STV resolves these issues. EPA has decided to modify the STV as explained in sections 3.6.2 and 4.0 of the final RWQC document.

Comment: Commenters noted that when determining compliance with the GM, background levels of indicator bacteria are not considered.

Response: Compliance issues are beyond the scope of the RWQC.

Comment: Commenters urged EPA to update the magnitude of the GM and SSM to reflect new scientific information about GI illness rates.

Response: Based on EPA's review of public comments and further scientific analyses of the NEEAR study, EPA has decided to modify the criteria as explained in sections 3.2.4, 3.6.2, and 4.0 of the RWQC document. EPA believes the criteria are based on the latest scientific information.

Comment: Commenters asked that the RWQC document include guidance and methodology to determine the GM, including for *Enterococcus* spp. using qPCR.

Response: Section 3.6 discusses how to calculate a GM. Further guidance on the *Enterococcus* spp. qPCR Method 1611 (U.S. EPA, 2012) will be provided in upcoming TSM.

Issue 3.6.2.2 Criteria Duration

Support for 90-Day Average

Comment: Commenters supported the flexibility of the recommended duration of 30 to 90 days because as the sample size increases, the chance of misclassification errors with respect to attainments status decreases.

Response: EPA is recommending a 30-day averaging period. See section 3.6.2 in the final RWQC document for additional discussion. EPA guidance regarding monitoring and assessment of waterbodies for 303(d) listing and 305(b) reporting purposes appears in the Agency's IRG (U.S. EPA, 2006). Commenters may find the sections on data set size/quantity to be of particular interest.

Want 30-Day Average

Comment: Commenters supported the GM being calculated over a shorter (30-day) time period. They thought that a 30-day or rolling 30-day GM is more protective and argued that EPA should mandate the use of a 30-day GM, coupled with the continued use of a SSM 'never to be exceeded' standard that, if exceeded, results in a regulatory response and compliance measures that will improve water quality. Commenters argued that extending the GM period beyond a 30-day mean will only add more uncertainty and decrease public health protection. Commenters suggested that increasing the allowed duration/averaging period for the GM WQC from 30 days to 90 days with no corresponding decrease in the concentration significantly weakens beach warning/closing policy and increases the risk of illness to swimmers, surfers, kayakers, and boaters. Commenters argued that EPA did not provide data to demonstrate that 90-day evaluation time frame is indeed safe.

Response: EPA is recommending a 30-day averaging period. See section 3.6.2 in the final RWQC document for additional discussion.

Comment: Commenters indicated that seasonal GMs allow combined sewer overflows (CSO) to continue.

Response: Based on EPA’s review of public comments and further scientific analyses of the NEEAR study data, EPA has decided to modify the final RWQC as explained in sections 3.2.4, 3.6.2, and 4.0 of the final RWQC document. EPA is also now recommending a 30-day averaging period, which EPA believes will be more effective in dealing with wet weather events.

Comment: Commenters asked EPA to define ‘short-term GM’ and how it can be useful in beach advisory context.

Response: EPA is providing BAVs for beach notification purposes (such as advisories and closings). See section 5.1 of the final RWQC. The term “short-term GM” has been removed from the final RWQC document.

Want Seasonal Average

Comment: Commenters disagreed with EPA that the averaging period be limited to 90 days. They asked for justification as to why the averaging period was reduced from seasonal average to 90 day average, and asked EPA to allow states to select an averaging period that coincides with their recreational season and beyond to protect public health. Commenters thought that rolling GMs should not be used and rather seasonal GMs should be used. They asked EPA to provide guidance as to the appropriate seasonal duration (which could be more than 90 days in certain regions) and the number of samples and spacing of samples during the sampling interval (of 30 to 90 days) so that it is clearly understood whether the samples should be evenly distributed.

Response: The final RWQC recommend an averaging duration of 30 days for determining GMs and STVs to support impairment decisions. EPA believes that a 30-day averaging duration is effective at identifying short-term fluctuations in water quality. More frequent evaluations can allow some pollution problems to be identified sooner so that they may be addressed in a timely manner.

Other Comments

Comment: Commenters thought that the draft RWQC allow states far too much flexibility.

Response: CWA §304(a) criteria are recommendations, not binding requirements. The CWA and EPA’s implementing regulations provide states with the flexibility to adopt WQC that are different from EPA’s criteria recommendations.

Comment: Commenters pointed out that GM and STV determinations based on data over a duration of 30 to 90 days would be meaningless for streams that are monitored at a much lower frequency.

Response: EPA is recommending a 30-day averaging period. See section 3.6.2 of the final RWQC document. Regardless of the number of samples, the GM and STV are recommended for primary contact designated waters.

Comment Commenters had reservations regarding adopting criteria studied and developed for one purpose (beach management) for other, completely different purposes, without further scientific study.

Response: EPA disagrees that the criteria were developed for only beach management. The applications of the final RWQC for various CWA purposes are discussed in section 3.6.3. In addition, the BAVs are provided for beach notification purposes.

Comment: Commenters noted that there is inadequate assessment, notification, and protection for offseason recreational water use and a lack of guidance during this time period.

Response: States establish WQS to protect designated uses. EPA is recommending the RWQC specifically to be protective of the designated use of primary contact recreation. The RWQC apply to all waters that are designated for primary contact recreation. If states have different uses for specific waterbodies during specific time periods, then the applicable WQS would apply during those time periods. It is beyond the scope of the RWQC to discuss how states determine which designated use applies.

Comment: Commenters asked EPA to revise the RWQC so that the GM can be utilized only for long-term permit limits, and for short-term permit limits, only the STV should be used.

Response: Application of the RWQC to establishing permit limits is beyond the scope of the RWQC.

Comment: Commenters stated that using all of the data in the recreation season would provide the best representation of the GM and the STV and recommended use of the STV on a daily basis for appropriate notification of the public of potentially unsafe conditions.

Response: States determine the appropriate monitoring frequency for their beaches. The BAVs are provided for beach monitoring purposes.

Comment: Commenters commented that for infrequently monitored waters, the GM could become the defacto single sample limit, and that this should be corrected.

Response: Monitoring strategies and the implications of them are beyond the scope of the RWQC.

Issue 3.6.2.3 Frequency (see Issue 3.6.1 for ‘Other STV Frequency Comments’)

Support for 25 percent Allowable Excursion Frequency

Comment: Commenters supported EPA’s shift to the STV with an allowable excursion frequency of 25 percent.

Response: Based on EPA’s review of public comments and further scientific analyses, EPA has decided to modify the criteria as explained in section 3.6.2 of the final RWQC document.

A 25 percent Allowable Excursion is Too High

Comment: Commenters suggested that converting the 75th percentile SSM value into an allowable excursion frequency would be difficult to justify statistically or from a public health protection perspective. They believed that the criterion of an excursion rate of up to 25 percent of the STV is too high. Commenters supported the use of a ten percent allowable SSM excursion frequency as a more protective value with respect to public health than the 25 percent frequency.

Response: Based on EPA’s review of public comments and further scientific analyses, EPA has decided to modify the criteria as explained in section 3.6.2 of the final RWQC document. The STV is based upon the 90th percentile of the water quality distribution. An excursion frequency of ten percent is allowable for decisions relating to use attainment.

Allow Site-Specific Frequencies

Comment: Commenters asked EPA to allow calculation of site-specific excursion frequencies.

Response: The final RWQC document explains that only a specific portion of samples should be higher than the STV values to prevent inconsistencies between the GM and STV. EPA believes that the STV set at the 90th percentile with a ten percent allowable excursion frequency is protective of the primary contact designated use.

Comment: Commenters recommend that GM exceedances be allowed based on local reference systems where naturally generated bacterial sources are known to cause or contribute to exceedances. Commenters asked that EPA acknowledge that the use of the reference watershed approach would be a valid application of the criteria. The reference watershed approach uses the water quality objective exceedance probabilities in a reference/background system to calculate a number of allowable excursion days for impaired watersheds.

Response: The final RWQC provide a series of tools and flexibilities for waterbodies whose predominant source of contamination is different than those upon which the RWQC are based. EPA is familiar with the reference watershed approach that is used in various locations throughout California. Use of the reference watershed approach should become unnecessary because the RWQC clearly indicate that waterbodies protect the recreational use (provided that the GM is at or below the recommended value) as long as no more than ten percent of all samples are higher than the STV. California and a number of other states interpreted the (previously recommended) SSM as a value which was not to be exceeded. This interpretation led to the need for the “reference watershed approach,” referred to by the commenter. EPA anticipates that the final RWQC could help to resolve the need for use of the reference system watershed approach. If a waterbody is found to be impacted by nonhuman sources, EPA has

provided a series of tools and flexibilities to derive scientifically defensible site-specific criteria values.

Other Comments

Comment: Commenters noted that only where primary contact occurs (i.e., designated bathing beaches) should the STV be employed as it is more restrictive than the GM when no STV excursions are allowed.

Response: The GM and the STV are set such that they are equivalently protective. EPA determined that both are necessary to control the central tendency and the variance of FIB in waters designated for primary contact recreation. Note that the STV is allowed an excursion frequency of ten percent

Comment: Commenters requested guidance on sample size for evaluation of waterbodies relative to the STV.

Response: EPA is not recommending a specific sampling size.

Issue 3.6.2.4 Using Criteria Derived For Beaches for NPDES

Comment: A number of comments were received regarding implementation of the RWQC in NPDES permits.

Response: These comments are beyond the scope of the RWQC.

Issue 3.6.2.5 CWA §303(d) Impaired List

Comment: Several comments were received regarding implementation of the RWQC for 303(d) listings.

Response: Implementation of the RWQC for 303(d) listings is beyond the scope of the criteria.

Issue 3.6.3 Practical Considerations for Applying the Criteria

Concerns with Sampling Frequency and Magnitude

Comment: Commenters expressed concern regarding why sampling frequency is not considered by EPA to be an approvable element of a WQS. Commenters asked EPA to give states more intense monitoring requirements at high-use beaches and weekly sampling when recreational use is high. Commenters also requested clarification on allowing states to use less than weekly sampling, even over 90 days, and asked that EPA recognize the benefit in better temporal

distribution of the same sample size. Commenters asked for justification to support the conclusion that only 4 samples in 30-day or 12 in a 90-day consecutive period is acceptable.

Response: Design of monitoring programs is beyond the scope of the RWQC. See section 3.6.5 for discussion of impact of number of samples.

Issue 4.0 Recreational Water Quality Criteria

Comments on the RWQC are included in Issue 3 and sub-issues below.

Issue 4.1 qPCR As Part of Recreational Water Quality Criteria

qPCR Should Not Be Included In The RWQC

Comment: Commenters supported EPA's decision not to include qPCR values as a part of the RWQC. They argued that rapid testing does little to increase protection of public health because of issues including low variability at most beaches, site-specific inhibition, low correlations between culture and qPCR methods when *Enterococcus* spp. concentrations are below the SSM/STV of 104 cfu, and usefulness in calculating a GM (i.e., data collected below 104 cfu). Commenters expressed a lack of support for qPCR because of its associated costs.

Response: While EPA's overall testing of qPCR in ambient waters has been limited, EPA continues to support the use of rapid methods such as qPCR where they are effective and where states have developed the capacity to use those methods. See section 5.2 of the final RWQC for a discussion of qPCR.

Comment: Commenters pointed out specific limitations that a state like Alaska may encounter in using qPCR, such as difficult environmental conditions that would impact qPCR performance, in addition to limited and difficult access to facilities, laboratories, and the high-level skilled staff.

Response: EPA appreciates the issues raised by the commenter and acknowledges that qPCR is not appropriate for all waters.

Comment: Commenters agreed with EPA that qPCR results should not be incorporated into the NPDES and TMDL programs under the CWA.

Response: Thank you for your comment.

Comment: Commenters suggested that EPA wait until a standardized method has been shown to work in most of all types of U.S. waters before recommending the methodology.

Response: EPA acknowledges that there is limited information on the performance of the *Enterococcus* spp. qPCR method in all types of waters. However, there is evidence from the

NEEAR study that the *Enterococcus* spp. qPCR method may offer advantages compared to the culture method including rapidity and stronger and more sensitive health relationships. EPA therefore continues to support the use of rapid methods such as qPCR where they are effective and where states have developed the capacity to use those methods.

Comment: Commenters requested that EPA evaluate the role of interference in analytical results before recommending the method. The commenters also suggested that EPA would place an unrealistic and undue burden on states to refine and evaluate a new method.

Response: As stated in the RWQC document, EPA will provide guidance on how to evaluate performance with respect to sample interference at a particular site at a later date. Despite the potential for sample interference and the lack of complete data on the performance of the method in all types of waters, EPA believes there is sufficient evidence that the *Enterococcus* spp. qPCR Method 1611 (U.S. EPA, 2012) may offer potential benefits compared to the culture method including rapidity and stronger and more sensitive health relationships. EPA therefore continues to support the use of rapid methods such as qPCR where they are effective and where states have developed the capacity to use those methods.

Rapid Methods, Including qPCR, Should be Required for Beach Monitoring Purposes

Comment: Commenters pointed out that one major goal for EPA during the development of the draft RWQC was to create WQC based on rapid methods in order to provide timely water quality results and increase public health protection for those recreating in and around coastal waters. They supported the required use of rapid based methods, including qPCR, nationally at high-use beaches and areas with known pollution problems by a specific date (i.e., no later than 2015). Commenters expressed disappointment with EPA for not requiring the use of qPCR or other rapid methods for analyzing recreational water samples and thought that the criteria did not properly emphasize that qPCR methods are faster and have been consistently shown to have a stronger correlation to health effects and thus are more accurate than the culture methods.

Response: While EPA's overall testing of qPCR in ambient waters has been limited, EPA continues to support the use of rapid methods such as qPCR where they are effective and where states have developed the capacity to use those methods. See section 5.2 of the final RWQC for a discussion of qPCR.

Comment: Commenters supported use of *Enterococcus* spp. qPCR and suggested that the qPCR method act as a replacement for cultural methods, where appropriate to detect and quantify enterococci for beach monitoring.

Response: The text in the RWQC has been edited to clarify that qPCR can replace culture methods.

Base qPCR Criteria on Epidemiology

Comment: Commenters asked that EPA base rapid method criteria on the best and most current epidemiological data. They thought that EPA should develop rapid method criteria for qPCR

based on current epidemiological data and a criterion that is independent from culture-methods. They asked EPA to analyze all current qPCR epidemiological data, including the Doheny SCCWRP study, to determine the lowest value associated with health risk, in order to scientifically determine a SSM and GM.

Response: See Issue 3.2.3 for response regarding the use of non-EPA epidemiological data.

Other Comments

Comment: Commenters expressed concern that EPA has included a potential disincentive for deploying qPCR in their monitoring programs: an as yet undefined, but potentially multi-year period during which both qPCR and current cultural methods must both be utilized.

Response: The RWQC provides states information for using rapid methods such as qPCR in the development of criteria based on such methods. The potential disincentive described is not in the RWQC.

Comment: Commenters requested that EPA analyze waters, apart from epidemiological studies, to see if the qPCR methodology was applicable to all or most areas.

Response: EPA does not have the resources to further analyze the qPCR method in most or all types of waters. In addition, qPCR provides the most benefit in waters that have high daily usage. Therefore it's best for states to determine which waterbodies would benefit most from qPCR.

Comment: Commenters asked for clarity on why qPCR was included in the RWQC when EPA stated earlier in the criteria document that culture methods are adequate for measuring FIB for beach monitoring purposes.

Response: Despite the potential for sample interference and the lack of complete data on the performance of the *Enterococcus* spp. qPCR method in all types of waters, EPA believes there is sufficient evidence that the *Enterococcus* spp. qPCR method may offer potential benefits compared to the culture method including rapidity and stronger and more sensitive health relationships. EPA therefore continues to support the use of rapid methods such as qPCR where they are effective and where states have the capacity to use those methods. EPA reiterates that states may choose not to adopt WQS based on a qPCR method.

Issue 4.2 Use Intensity

Support of the Elimination of Use Intensity

Comment: Commenters supported the elimination of use intensity values and a tiered approach to criteria based on use intensity. They acknowledged that this was likely a policy decision to create uniformity and consistency between regions of the country.

Response: Thank you for the comment.

Comment: Regarding the removal of the tiered approach, commenters requested EPA proactively give states more intense monitoring requirements (such as higher sampling frequency) where warranted.

Response: EPA is not recommending specific monitoring requirements. Regardless of sample size, EPA is recommending that states calculate a GM over a 30-day period. See section 3.6.3.

Against The Elimination of Use Intensity

Comment: Commenters disagreed with the elimination of multiple use intensity values (with different STVs for different levels of recreational contact) and found their elimination to be scientifically unjustified. They argued that this policy decision is best addressed by the appropriate state agency, at the local level and that use intensity allows states the flexibility in assessing and prioritizing beach monitoring programs for high-use beaches as well as when developing WQS that are most protective of public health. Commenters suggested that elimination of use intensity values might divert limited monitoring resources to areas that are not frequently used by human bathers. Commenters thought that the elimination of use intensity values would impact recreational use UAA efforts for developing realistic recreational use expectations. Commenters expressed concern with the effect of eliminating use intensity on the perceived illness rate for a waterbody. Commenters were concerned that the modifications to the *E. coli* criteria take away some of the methodological flexibilities present in the 1986 criteria (e.g., the application of multiple illness rates for GM data, and multiple confidence levels for SSM data [now STV]). Commenters noted that intensity values “had some merit; a waterbody could conceivably meet the requirements of the CWA but at the same time not have the same strict discharge restrictions on waterbodies that are infrequently used for primary contact.” Commenters requested EPA strengthen its justification for elimination of use intensity, especially in the context of the failure of some studies to show associated high risk with indicator occurrences.

Response: EPA’s previously recommended multiple use intensity values, as laid out in the 1986 criteria, should not be interpreted as recommending differing risk levels for different intensities of use. Instead, the multiple use intensity values represented alternative levels of statistical confidence at the *same* level of risk, with the highest level of statistical confidence reserved for the greatest intensity of use. In no longer recommending multiple use intensity values, EPA is recommending the use of the same level of statistical confidence for all intensities of use. EPA expects this recommendation to increase national consistency across bodies of water and ensure equivalent public health protection in all waters. EPA reiterates that intensity of use in this context refers to the frequency at which a body of water is used for full body primary contact recreation; it does not refer to secondary contact uses. EPA believes that discharges should be managed regardless of likelihood of exposure.

These RWQC are for the primary contact designated use. States determine the designated use if applicable. State standards must be sufficient to protect the use and must be scientifically

defensible. Therefore any submitted state standards must include documentation that shows that the WQS is protective of the use and based on sound science.

The draft and final RWQC state that EPA is no longer recommending multiple “use intensity” values, in an effort to increase national consistency across bodies of water and ensure equivalent public health protection in all waters.

Issue 5.0 Tools – Managing and Alternate Criteria

Site-Specific Standards Add Flexibility and Better Quantify the Level of Health Risk

Comment: Commenters expressed support for the increased discretion and flexibility in developing site and state-specific standards where the data and information defend such action (such as for waterbodies which are believed to be predominantly impacted by nonhuman sources). Another commenter supported the use of STV (75th percentile) and site-specific criteria, pointing out that this will allow better allocation of resources to waterbodies posing the highest risks for human health. One commenter stated that site-specific tools do not “relax” WQS, but instead serve to quantify the actual level of health risk for watersheds based on unique, site-specific conditions, and thereby improve water quality and public health protection programs. Another commenter pointed out that the site-specific tools highlighted by EPA will be valuable for many municipalities that would like to improve their ability to predict recreational health risks and develop health-effective strategies for implementing best management practices.

Response: Thank you for your comments.

Concerns with the Use of Site-Specific Criteria

Comment: A commenter expressed concern that site-specific criteria requirements are too stringent and fail to complement existing infrastructure. A commenter expressed concern regarding EPA’s lack of research and studies in areas and on waters where a new standard might be applicable. This questions EPA’s ability to provide accurate, science-based guidance for states.

Response: EPA’s primary concern is the protection of public health. Although the RWQC include a wide range of tools for states and tribes to develop site-specific criteria, EPA expects that sufficient information and technical documentation would be needed to support the appropriateness of site-specific criteria at any given location. Moreover, EPA will issue a series of TSM that will help to explain how site-specific criteria may be developed.

Issue 5.1 Tools for Assessing and Managing Recreational Waters

Combined Use of Sanitary Surveys and QMRA

Comment: A commenter supported the use of sanitary surveys and QMRA to fully assess exposure risk, particularly if the concern is over exposure to human sewage versus other sources of FIB. A commenter suggested that additional development to merge sanitary surveys with pathogen monitoring is necessary to fully exploit the power of QMRA.

Response: The forthcoming TSM will describe in detail the synergy EPA anticipates with respect to compilation of information from sanitary surveys as input to QMRA for recreational waters.

Recommendations for Other Efforts and Additional Data Collection

Comment: A commenter suggested that EPA support a microbial transport and fate program, including an improved understanding of molecular marker transport and degradation.

Response: EPA will consider this suggestion as one component of future work.

Comment: A commenter recommended that EPA accept sanitary surveys, regional and watershed scale assessments, existing permitting information, and local knowledge as guidance as to the appropriate level of contact and risk to the general populace. Previously collected data should also be applicable to determine a scientifically supported confidence level (i.e., 90% confidence level). Another commenter suggested that pollution reduction efforts need to be emphasized more and that the sentence at lines 2036-2037 in the draft RWQC should be expanded to: “This section discusses tools that states can use to reduce sources of pollution and enhance public health protection.” Another commenter requested that TMDLs, enforcement of stormwater regulations, or other mechanisms to reduce sources be described in this section.

Response: These comments are beyond the scope of the RWQC.

Issue 5.1.1 Sanitary Survey

Support for the Use of Sanitary Survey

Comment: A commenter expressed support for the inclusion of information on tools such as sanitary surveys to support states and tribes manage recreational waters. Sanitary surveys help identify pollution sources and provide data to develop predictive models, while also providing data to assess beach health and identify problem spots.

Response: Thank you for your comment.

Widen the Scope of Sanitary Survey

Comment: A commenter expressed disappointment that sanitary surveys were relegated to section 5 of the draft RWQC (“Tools to Consider Alternate Indicators...”) and not an integral

part of the criteria themselves (section 4) for BEACH Act purposes (designated bathing beaches).

Response: EPA agrees that sanitary surveys are an important component of beach water quality protection. However, EPA does not consider sanitary surveys part of the numerical WQC.

Comment: A commenter pointed out that the document has a narrow focus on bathing beach applications, and suggested that this section 5.1.1 in the draft RWQC be expanded to discuss the use of sanitary surveys in the context of watersheds.

Response: The nationally recommended criteria apply to all waters of the United States with a primary contact recreation designated use. Sanitary surveys are usually conducted at the beach, but can be extended into nearby watersheds. States may consider using sanitary surveys in conjunction with other watershed assessment tools.

Guidance Is Needed

Comment: A commenter urged EPA to expedite the development of tools for conducting sanitary surveys and if possible, publish them simultaneously with the final RWQC.

Response: The sanitary survey tool for the Great Lakes is online (U.S. EPA, 2008). The marine sanitary survey tool will be issued in early 2013.

Comment: A commenter suggested that EPA provide updated guidance on source tracking methods to identify fecal pollution sources, such as EPA's April 2011 document "Using Microbial Source Tracking for TMDL Development and Implementation" (U.S. EPA, 2011) as part of this section or as a new section.

Response: Fecal source tracking is a rapidly evolving field. As indicated previously, guidance on specific aspects of implementation of these criteria will be provided separately as TSM documents. EPA will provide in one of the TSM documents a summary of a case study for site-specific criteria that includes use of fecal source tracking as one component of the site-specific criteria development considerations.

Comment: A commenter asked for clarification regarding whether sanitary surveys could be used instead of routine water quality monitoring for a recreational beach, or if they are to only be used to direct the sampling to the best locations as implied on line 2065 of the draft RWQC.

Response: EPA considers sanitary surveys to be a tool to be used in addition to monitoring of water quality since the surveys do not provide numerical values for indicator organisms. Sanitary surveys help to provide the context for the monitoring results. Sanitary surveys can help refine the risk characterization and priorities for beach monitoring programs.

Issue 5.1.2 Predictive Models

Utility of Predictive Models

Comment: Commenters expressed support for the inclusion of information on real time predictive modeling for recreational waters to supplement culture-based sampling methods, until such a time when sampling rates and testing ability allows real time decisions on actual data. Another commenter encouraged EPA to support the use of predictive modeling especially in those areas where it will allow the agency to better define the proper and improper implementation of the primary contact recreation standard to waters where it is inappropriately applied today. Another commenter noted the usefulness of this tool for known contamination events and areas with reoccurring problems, such as for provisional rainfall closures. Finally, a commenter suggested that predictive models should only be used for supplemental purposes as indicated and should not replace sampling and monitoring programs that actually detect the presence of fecal contamination.

Response: Thank you for your comments.

Guidance is Needed

Comment: A commenter urged EPA to expedite the development of tools for performing predictive modeling, and if possible, publish them simultaneously with the final RWQC.

Response: EPA has released *Predictive Modeling at Beaches Volume I: Review and Technical Protocol* (U.S. EPA, 2010d) and *Predictive Modeling at Beaches Volume II: Predictive Tools for Beach Notification* (U.S. EPA, 2010e).

Issue 5.2 Tools for Use in Developing Alternative RWQC

Utility of Tools for Use in Developing Alternative RWQC

Comment: A commenter expressed agreement that it is important to be able to use tools such as QMRA or epidemiological studies to assess the relative significance of regularly elevated FIB concentrations at locations known to have natural sources of bacteria reservoirs and for areas with existing best management practices in place.

Response: Thank you for your comment.

Suggested Requirements for Alternative RWQC

Comment: Commenters asked that any alternative RWQC be demonstrated to be at least as protective as EPA's RWQC.

Response: Alternative site-specific criteria must be scientifically defensible and protective of the primary contact designated use.

Support for the Development of Site-Specific Criteria

Comment: A commenter expressed support for EPA providing additional flexibilities including tools for developing site-specific criteria.

Response: Thank you for your comment.

Concerns Associated With the Development of Site-Specific Criteria

Comment: A commenter argued that application of site-specific criteria is dangerous for public health. It was suggested that this theory is not supported by epidemiological research conducted over decades (lack of studies showing enterococci is from nonhuman sources and causes beaches to appear noncompliant when there is no health risk (false-positive), and a plethora of positive-positive studies). The commenter noted that the most appropriate levels (bacterial and risk) for the criteria are those reported in the study where no significant associated risk was measureable.

Response: The revised RWQC values are based on water quality from the epidemiological studies and are the lowest values which exhibit a statistically significant difference between swimmers (above and below specific water quality values). Those FIB levels represent conditions in wastewater impacted areas. Current research indicates that the levels of indicators and pathogens vary widely depending on the source of contamination. EPA disagrees that application of site-specific criteria is dangerous for public health because alternative criteria must be scientifically defensible and protective of the primary contact recreation designated use.

Comment: Commenters suggested EPA make the requirements for site-specific criteria very tight, considering issues such as: no exemption if an outfall is within a generous distance (based on volume and level of treatment), or if a beach has a certain level of attendance; an exemption if treated sewage discharge volume is large; the requirement for states to perform epidemiological studies if they plan to use QMRA at beach with visitors; and the requirement of proof of nonhuman source as the primary cause for enterococci concentration.

Response: EPA does not intend to establish additional requirements for site specific criteria beyond those in 40 C.F.R. Part 131. EPA plans to issue TSM to help states that want to perform either QMRAs or epidemiological studies to support site-specific criteria.

Guidance/Clarification is Needed

Comment: Commenters asked EPA to provide eligibility guidance for when and how (specific steps) site-specific criteria can or should be developed, and what scientific evidence or testing is required to justify development of alternative criteria.

Response: Refer to RTC Issue 6.0 for response regarding timing of TSM.

Comment: A commenter suggested that the draft RWQC, TSM, and guidance state whether the reference watershed approach is a viable tool for implementing RWQC and suggested that this approach could be a viable alternative to expensive QMRA studies for hundreds of watersheds to account for bacteria sources and transport characteristics.

Response: EPA is familiar with the reference watershed approach that is used in various locations throughout California. Use of the reference watershed approach should become unnecessary because the RWQC clearly indicate that waterbodies protect the recreational use (provided that the GM is at or below the recommended value) as long as no more than 10% of all samples are higher than the STV. California and a number of other states interpreted the (previously recommended) SSM as a value which was not to be exceeded. This interpretation led to the need for the “reference watershed approach,” referred to by the commenter. EPA anticipates that the final RWQC could help to resolve the need for use of the reference system watershed approach. If a waterbody is found to be impacted by nonhuman sources, EPA has provided a series of tools and flexibilities to derive scientifically defensible site-specific criteria values.

Comment: Commenters suggested that based on previous discussions, EPA gave the impression that site-specific criteria could only be developed under narrow conditions, such as at remote beaches with no known FIB sources, or very simple land uses such as open space or agricultural drainages.

Response: The forthcoming TSM will provide detailed information about the recommended approach for considering whether site-specific criteria are appropriate for a particular location or not.

Comment: Commenters urged EPA to provide clarification regarding the development of site-specific criteria, particularly when background bacteria indicator levels are high, for areas where the risk from exposure to pathogens and illness incidence is low, or for waters impacted by nonhuman fecal contamination.

Response: The forthcoming TSM will provide information about the recommended approach for considering whether site-specific criteria are appropriate for a particular location. EPA does not intend to limit site-specific criteria development to areas such as remote beaches with no known FIB sources, or very simple land uses such as open space or agricultural drainages.

Other Comments

Comment: A commenter applauded EPA on its skepticism of the science behind "natural sources" of *Enterococcus* spp.

Response: Thank you for your comment.

Comment: A commenter suggested EPA should provide considerably more discretion to the states on the development of watershed level recreation standards, and it should accept standards

developed using other scientifically defensible methods including geographic information system modeling.

Response: States have substantial flexibility to adopt criteria in their WQS that differs from EPA's recommendations, including, but not limited to site-specific criteria. EPA would review them to determine whether they are scientifically defensible and protective of the use.

Issue 5.2.1 Epidemiological studies

Support for the Use Of Site-Specific Epidemiological Studies

Comment: A commenter strongly supported EPA's allowance of site-specific criteria using epidemiological studies because these studies are particularly needed in areas where most waterbodies are impacted by urban runoff but without influence from wastewater treatment plant effluent. The commenter asked EPA to consider local, site-specific epidemiological studies when allowing states to develop site-specific criteria.

Response: As indicated in the RWQC document, local, site-specific epidemiological studies can be used as a basis of site-specific criteria that are scientifically defensible and protective of the use.

Feasibility and Practicality of States' Ability to Conduct Epidemiological Studies

Comment: Commenters expressed concern that EPA's expectation that states to carry out epidemiological studies is unrealistic, since these studies are costly and have uncertain outcomes (especially with small population sizes), leading states to default to EPA criteria.

Response: States interested in developing site-specific alternative criteria may choose to conduct epidemiological studies. However, EPA is also providing other tools and flexibilities to support site-specific alternative criteria. No additional studies are needed for states to adopt and implement WQC in their WQS based on the final RWQC.

Comment: A commenter suggested that removal of differential percentile STVs for different use intensities interferes with state's flexibility in assessing and prioritizing beach monitoring programs based on high use intensity and makes epidemiological studies impractical.

Response: EPA believes that the final RWQC, with a GM and an STV at the 90th percentile of water quality, provides a health protective approach to protecting the designate use of primary contact recreation. BAVs reflecting a 75th percentile value have been provided for beach notification purposes (such as advisories and closings).

Need for Guidance

Comment: A commenter suggested EPA provide specific implementation guidance for urban runoff-impacted beaches, and urgently support epidemiological and QMRA studies at such

beaches so that protective yet scientifically-defensible and achievable criteria are developed for these particular streams and beaches given their unique FIB sources and levels of recreational illness risk.

Response: EPA conducted an epidemiological study at an urban runoff-impacted site in South Carolina in 2009 as part of the critical path science plan underlying the final RWQC. Although the results of that epidemiological study were ambiguous compared to the studies conducted at human impacted beaches, EPA is currently collaborating with SCCWRP to evaluate the use of sanitary surveys, fecal source tracking and QMRA to develop site-specific criteria at an urban runoff impacted beach in Southern California. The results of this work will be provided in TSM upon completion of the study and could serve as the basis for similar consideration in other locations.

Comment: A commenter suggested EPA provide clarification on the source of EPA's uncertainty regarding the use of epidemiological study designs other than the prospective cohort study design, and whether this uncertainty extended to any alternative criteria, not just site-specific criteria.

Response: Review of the epidemiological literature indicates that both designs have been implemented successfully. However, guidelines and criteria values based on these two different study designs are derived differently. There are substantial differences in the experimental designs of both types of studies which preclude a direct comparison of the results. The RWQC are based on prospective cohort study results, and thus, uncertainty would exist in deriving any alternative criteria based on study designs other than the prospective cohort study design, site-specific or otherwise. A WQS submission derived from a site-specific epidemiological study should demonstrate the scientific defensibility and protection of the designated use. The uncertainty in how to compare non- prospective cohort study results to those underlying the RWQC may preclude both of these requirements until the state of the science allows for a better comparison among different types of epidemiological studies.

Other Comments

Comment: A commenter urged EPA to acknowledge in section 5.2.1 the lack of significant correlations with culture methods in the nine study sites in the U.S. EPA's NEEAR Water Study, although the number of participants was quite large.

Response: This information is covered in section 3.2.4 of the final RWQC.

Comment: Commenters thought that EPA needs to specify the level or risk deemed acceptable, and that site-specific criteria must be at least as protective as EPA's national criteria.

Response: Site-specific criteria could be based on one of the illness rates associated with the final national recommended RWQC, regardless of the source of contamination. In addition, states may choose another illness rate if it would protect the designated use of primary contact recreation. EPA would evaluate it as part of the state's submission in such a situation.

Issue 5.2.2 QMRA and Sanitary Survey

Support for QMRA

Comment: Commenters expressed support for the development of site-specific criteria using QMRA for waterbodies believed to be predominantly impacted by nonhuman sources. A commenter suggested EPA continue to perform studies such as QMRA, and collect information regarding the risk for human health at waterbodies predominantly impacted by nonhuman sources.

Response: Thank you for your comment.

Limitations of QMRA

Comment: A commenter emphasized that QMRA's potential for site-specific criteria would only be applicable at beaches impacted by birds.

Response: EPA agrees that beaches impacted predominantly by birds may be good candidates for site-specific criteria development, but disagrees that the scope of the candidate waters would be limited to beaches predominantly impacted by birds. There is additional information that may support relative risk differences with other nonhuman sources of fecal contamination.

Comment: A commenter thought that site-specific QMRA studies might require extensive species-level testing to properly characterize the composition of bacteria in a waterbody, and many states lack resources for these kinds of analyses.

Response: EPA emphasizes that states always have the option of adopting the nationally recommended criteria. EPA believes that the final RWQC are appropriate for most sites in the country. Where states opt to pursue alternative or site-specific criteria for specific waters, additional information (e.g., other studies) would be submitted with a state's WQS package. EPA agrees that site-specific QMRA studies might call for collecting additional evidence to demonstrate the sources of fecal contamination at a specific site (e.g., using MST markers). EPA is currently collaborating with SCCWRP to evaluate the use of sanitary surveys, fecal source tracking and QMRA to develop site-specific criteria at an urban runoff impacted beach in Southern California. EPA plans to provide the results of this work in TSM.

Comment: A commenter expressed that QMRA should not be used for site-specific criteria development at frequently visited beaches and beaches in urbanized or mixed land-use areas, unless the resulting WQS are more strict and protective than the national criteria. The commenter's concern is that urban runoff is complex and variable, making QMRA difficult. Commenters urged EPA to wait for the science of QMRA to become more developed before recommending QMRA implementation at locations with limited historical monitoring data.

Response: EPA and other federal agencies use risk assessment to make a wide range of decisions to protect public health. The science that underpins QMRA is sound and extensively

documented in the scientific literature. QMRA supplements the currently available epidemiological data and allows for prediction of risks in locations where existing epidemiological studies may not accurately predict precise illness rates for recreators. EPA is currently developing 1) case-studies to show how QMRAs relate to available epidemiologic data and 2) TSM for states wanting to implement QMRA on a site-specific basis. QMRA will be especially useful for waterbodies not predominantly impacted by human fecal contamination. The forthcoming TSM will provide detailed information about the recommended approach for considering whether site-specific criteria are appropriate for a particular location or not.

Broaden the Scope of Applicability

Comment: Commenters suggested EPA broaden its discussion of the applicability of QMRA to include locations and sources different than those observed during the NEEAR study, such as flowing fresh water (river and creeks) and/or sites with human fecal sources, since in certain states the criteria developed based on the frequency of use are applied to inland surface waters where the frequency of use is significantly below bathing beaches.

Response: QMRA may be useful for consideration of site-specific criteria in waters that are predominantly impacted by sources other than human fecal contamination. In waters that are predominantly impacted by human fecal contamination, EPA believes that the nationally recommended criteria are protective and appropriate. EPA has recommended these criteria in all U.S. waters that have the primary contact recreation designated use, regardless of the source and of how intensely waters are used – thus, all recreators are provided with the same level of protection.

Comment: Commenters proposed that EPA encourage and/or support additional QMRA studies at urban runoff-impacted waterbodies to strengthen the pathogen monitoring and site-specific criteria datasets and to allow evaluation of different water body types (e.g., open marine beaches and flowing fresh water creeks/streams).

Response: EPA is collaborating with SCCWRP to evaluate the use of sanitary surveys, fecal source tracking and QMRA to develop protective yet scientifically-defensible and achievable site-specific criteria at an urban runoff impacted beach in Southern California. The results of this work will be provided in TSM upon completion of the study and could serve as the basis for similar consideration in other locations.

Comment: Commenters suggested EPA incorporate flexibility that provides for regional, statewide, or multistate QMRA analyses as this could allow states to prioritize site-specific efforts on waters which are more likely to pose pathogen-associated human health risks.

Response: Pursuant to EPA's implementing regulations at 40 C.F.R. Part 131.11(b), states have the flexibility to adopt alternative WQC state wide, or on a site specific basis.

Comment: A commenter suggested EPA clarify whether states may consider use intensity when characterizing site-specific waters using a QMRA approach. The concern here was that

elimination of designated uses will result in implementation of permit limitations in areas where there is little potential for human health risk.

Response: EPA is recommending the final RWQC criteria in all U.S. waters that have been designated as primary contact recreation, regardless of how intensely those waters are used – thus, all recreators are provided with the same level of protection. Site-specific criteria, whether derived via QMRA or other means must be scientifically defensible and protective of the use.

Need for Guidance and Models

Comment: Commenters suggested that EPA provide clear implementation guidelines and eligibility requirements for QMRA. Commenters expressed concern regarding the TSM release timeframe that includes additional guidance on conducting QMRA.

Response: EPA is currently developing 1) case-studies to show how QMRAs relate to available epidemiologic data and 2) TSM for states wanting to implement QMRA on a site-specific basis. EPA anticipates that QMRA will be especially useful waterbodies that are impacted predominantly by nonhuman sources.

Comment: A commenter asked that EPA provide additional QMRA models for the states to use that characterize additional fecal sources (e.g., sources other than agricultural animals and gulls, such as wildlife and nonfecal sources) and additional exposure scenarios (e.g., exposure scenarios other than agricultural runoff).

Response: EPA will consider this recommendation as one potential area of future research.

Comment: A commenter suggested that EPA provide clarification on what standards will be used for QMRA, and that these analyses be allowed only where enhanced sanitary surveys and comprehensive MST studies have been conducted and have concluded that there is no possibility of human sources other than individual recreational users. Thus, eligibility must be specific and allowed only in limited circumstances.

Response: EPA does not agree with the comment because recent research indicates that small amounts of human contamination are not associated with illness rates that are above the illness rates associated with the nationally recommended RWQC. And the nationally recommended RWQC are protective of the primary contact designated use.

Comment: A commenter remarked that EPA also needs to specify whether the QMRA tool will be developed sufficiently to address issues with natural sources of fecal indicators such as wildlife and endemic non fecal derived FIB.

Response: The TSM for QMRA will specifically include how states can include various FIB sources such as wildlife and environment in QMRA modeling.

Issue 5.2.3 Other/New Methods and Indicators

Support for New Methods

Comment: Commenters supported EPA's accepting new or alternative indicator and/or enumeration method combinations, and explicitly including some flexibility in the draft RWQC for implementing superior tools in the near future.

Response: Thank you for your comment.

Comment: A commenter suggested states could develop alternative criteria using the qPCR method for *Enterococcus* spp.

Response: The RWQC provides a GM and STV for use with EPA *Enterococcus* spp. qPCR Method 1611 (U.S. EPA, 2012). For other methods, see section 6.2 of the RWQC for a discussion of how to proceed.

Microbial Source Tracking and Fate and Transport

Comment: Commenters proposed MST as a relevant tool for determining the origin of fecal pollution in waterbodies or for determining the extent of human pollution before initiating QMRA studies. MST should be added to the final RWQC document and described in detail as a useful tool for determining the sources of fecal pollution in waterbodies.

Response: MST can be used as part of the weight of evidence approach needed to justify the use of site-specific criteria for a particular waterbody. EPA is collaborating with SCCWRP to evaluate the use of sanitary surveys, fecal source tracking including MST and QMRA to evaluate the development of protective yet scientifically-defensible and achievable site-specific criteria at an urban runoff impacted beach in Southern California. The results of this work will be provided in TSM upon completion of the study and could serve as the basis for similar consideration in other locations.

Comment: A commenter urged EPA to support a microbial transport and fate program, including an improved understanding of molecular marker transport and degradation. A commenter proposed the development and use of community fingerprint approaches which will aid in source identification and ultimately quantitative source allocation, which will impact TMDL implementation programs.

Response: Thank you for the comment. EPA will consider these recommendations as potential areas of future research.

Models

Comment: A commenter expressed hope that EPA's new or alternative indicator and/or enumeration method combinations would include the development of models to better indicate the geographic extent of primary contact waters.

Response: States determine designated uses for waterbodies, so this suggestion is beyond the scope of the RWQC.

Comparative Analysis

Comment: A commenter recommended EPA conduct or fund *E. coli* culture Method 1603 and *E. coli* qPCR side-by-side monitoring studies in a variety of fresh waters to determine qPCR GM and STV values equivalent to the acceptable culture-based values.

Response: *E. coli* qPCR could be a candidate for alternative site-specific criteria for alternative indicator/methods. EPA will provide TSM to help states conduct studies such as the one suggested.

Comment: A commenter encouraged comparative analyses prior to considering implementation of either alternative indicators or methods.

Response: The TSM for alternative indicator/methods will include steps for conducting comparative analyses.

Uncertainty Surrounding the Use of New Methods and Indicators

Comment: A commenter cautioned against EPA's allowing the use of "new technologies" for quantifying fecal pathogens or fecal contaminant indicators that have not been validated for the ambient waters or wastewaters for which they might be applied.

Response: Pursuant to EPA's implementing regulations at 40 C.F.R. Part 131.11(b), states have the flexibility to adopt alternative WQC state-wide, or on a site specific basis. WQC in a State WQS using a different indicator or analytical method that is different from the final RWQC would need to be scientifically defensible and protective of the designated use. EPA would review technical information provided by the state with any WQS submission. Information on demonstrating the relationship between two-indicator method combinations can be found in TSM.

Comment: A commenter expressed concern that allowing the use of "any other equivalent method" will cause difficulties for laboratories and laboratory auditors as they will need to review additional quality control data to ensure that methods utilized meet the quality control requirements of the "lab-approved" method. The commenter urged EPA to include a procedure to determine equivalency for the option of "any equivalent method" to result in data meeting 40 CFR Part 136 Measurement Quality Objectives. A commenter suggested that EPA provide clear requirements and guidelines on new and equivalent methods, performance standards, method verification and expectations for approval, especially given that timeline of the TSM for this topic is not clear.

Response: At the current time, because no qPCR method is approved in 40 CFR Part 136, stakeholders may use any equivalent method. EPA does not currently have an alternative test

procedures protocol (which would only apply to approved methods) for genetic methods which would specify how side-by-side testing should be completed, but may develop one in the future. The upcoming TSM will detail how to demonstrate a consistent and predictable relationship between methods with one being an EPA recommended method.

Need for Guidance

Comment: A commenter suggested it is not clear from the draft RWQC how a state might utilize other indicators and/or test methods.

Response: EPA is developing TSM on alternative indicators and methods.

Issue 6.0 Implementation

Concerns with when TSM will be issued to Users

Comment: A commenter expressed concern that the guidance and TSMs would not be published until after the final RWQC. Commenters requested that guidance be published within the comment period for the RWQC. They argued that it was difficult to assess the new criteria while lacking guidance about implementation. Commenters requested that guidance be published concurrently with the final RWQC, to aid in the implementation of the new criteria and ensure that it is adopted uniformly between states. Waiting until late 2013 to release these documents will lead to confusion, inconsistencies, and misinterpretation of RWQC. A commenter suggested EPA should delay adoption until the criteria are revised (to allow exceedances due to uncontrollable sources, calculation of site-specific exceedance frequencies, until clarification is provided regarding how WQS can be implemented during wet weather conditions, and consideration of use intensity).

Response: EPA is developing a number of technical tools and documents to aid states implement the final RWQC. EPA plans to provide information on sanitary surveys, development of site-specific criteria, EPA's qPCR method and other topics in its upcoming beach guidance and other TSM documents. Once completed, EPA will make the TSM documents available on the EPA RWQC web site. EPA must publish the final RWQC by November 30, 2012, so RWQC cannot be delayed to wait for the TSM documents.

Issue 6.1 Current State Standards - Implications

No comments were associated with this issue.

Issue 6.2 Beach Grant Issues

Comment: Commenters raised concerns about beach grant funding and implementation.

Response: Implementation of beach grants is beyond the scope of the RWQC.

Issue 6.3 Monitoring/Sampling Concerns

Concerns with Costs

Comment: Commenters expressed concern over the monitoring, monitoring plans, and sampling cost of transitioning to and implementing the new criteria, especially in light of the end of funding from the Beach grants program.

Response: Monitoring, monitoring plans, and cost implications for transitioning and implementing the new criteria are beyond the scope of the criteria.

Need for Guidance

Comment: Commenters questioned how they should interpret samples from urban runoff and storm water.

Response: The final RWQC recommendations are applicable to all waterbodies designated for primary contact recreation without regard to source.

Issue 6.4 Public Notification/Risk Communication

Suggestions for a Revised Public Notification System

Comment: Commenters expressed dissatisfaction with the current public notification system. Commenters suggested a national notification system, including input from local agencies and the public. Another commenter requested a simpler (binary) system, and another commenter requested a more nuanced approach that included warning levels at a beach that was still “open.” One commenter requested that primary water contact recreational areas (that are not beaches) also have public notification systems.

Response: These comments are beyond the scope of the RWQC.

Improving Risk Communication

Comment: A commenter requested that risk information be available in multiple languages and formats to reach more of the public.

Response: This comment is beyond the scope of the RWQC.

Need for Guidance/Clarification

Comment: Commenters expressed confusion over beach status decision-making criteria.

Response: This comment is beyond the scope of the RWQC.

Issue 6.5 qPCR Method – Guidance (Inhibition Concerns)

Guidance on Establishing Method Equivalency

Comment: Commenters supported the use of qPCR but requested clear guidance for establishing qPCR method competency while recognizing that qPCR may not be appropriate for use at some beaches. Therefore, these commenters requested that EPA add clarity on what constitutes "equivalency" between methods and establish clear guidance for appropriate use of qPCR for recreational water quality monitoring. Allowing replacement of methods at appropriate beaches should be a high priority.

Response: EPA has provided a discussion of how to use new analytical methods in section 6.2 of the RWQC. EPA also intends to provide TSM on this topic.

Guidance on Implementation and Training

Comment: Commenters thought that EPA did not provide a clear path to facilitate implementation of qPCR in the current RWQC and that more guidance will needed on implementation and training. Another commenter noted that guidance on evaluating results with respect to interference is needed before states attempt to implement qPCR technologies and that this guidance is needed in the very near future (e.g., 2013).

Response: In addition to posting *Enterococcus* spp. qPCR Method 1611 (U.S. EPA, 2012), EPA intends to issue several documents to facilitate qPCR use. EPA intends to issue a tool to convert machine results (i.e., CT) to reporting unit results (cce per 100 mL) at the same time as the final RWQC and a troubleshooting guide in 2013. Training is also being developed. Finally, the revised beach guidance is expected to discuss considerations for use of qPCR in beach programs.

Comment: A commenter recommended that a laboratory be properly evaluated before using qPCR for compliance monitoring and some commenters asked EPA to be more descriptive with their implementation timeline.

Response: EPA does not certify or evaluate laboratories. EPA relies on the user to closely adhere to the method, including the performance acceptance criteria.

Comment: A commenter specifically requested guidance on implementing qPCR during the peak swimming season, implementing qPCR at heavily-used beaches, using qPCR after a rainfall and after a sewage spill to potentially open a beach to the public sooner, and recommendations for appropriate locations where qPCR should be used (e.g., populated beaches, beaches that are not remote).

Response: Implementation issues are beyond the scope of the RWQC.

qPCR Inhibition

Comment: A commenter thought that site-specific inhibition is too problematic for confidence in qPCR at this time and therefore did not support the recommendation to incorporate rapid testing methods for measuring water quality.

Response: EPA has provided information on qPCR, but has not included it in the recommended criteria.

Comment: Commenters pointed out that EPA did not cite any studies that show problems with qPCR technology, or examples of waterbody types in which qPCR has been found to be ineffective and asked EPA to conduct their own assessment of the benefits of adopting qPCR for evaluating the RWQC.

Response: The final RWQC discusses the problems with interference that EPA encountered at Boquerón, Puerto Rico.

Issue 6.6 qPCR Related Costs of Implementation

qPCR is a Burden To States

Comment: Commenters cited budget concerns and found that the use of side-by-side testing (i.e., qPCR and culture) both methods would cause a financial burden to states. A commenter theorized that a period of eight to 12 weeks of running simultaneous culture and qPCR methods would be adequate for determining how the two methods compare. This could be viewed as a potential disincentive for deploying qPCR in their monitoring programs because states will be responsible for costs associated with rapid methods and costs associated with the routine use of standard methods.

Response: The RWQC does not establish side by side testing as a prerequisite to the use of qPCR in beach notification programs or adoption into state standards. Overall testing of the qPCR method with different types of ambient waters, and by different laboratories, remains limited and EPA anticipates that there may be situations at some locations where the performance of the qPCR method may be inconsistent. Therefore, EPA suggests that states evaluate the qPCR method with respect to laboratory performance and sample interference in their prospective waters prior to use in a beach notification program or adoption of WQS based on the method.

Issue 6.7 Other Costs of Implementation

Comment: Commenters were concerned about the costs of implementing and transitioning to the new criteria and thought that cost should be considered in the process of developing new criteria. In particular, commenters mentioned the cost to WWTPs for changing the indicator of

effluent quality. The new standards could change impairment levels. Commenters requested funding for infrastructure upgrades to assist in compliance with the new criteria. In particular, commenters were concerned about old sewer systems. They requested flexible criteria to allow site-specific implementation and to take into account use levels of different waterbodies so as to prioritize spending (within and between states) to maximize public health benefit, and expressed concern with false negatives or false positives regarding actual risk, from effects such as storm water runoff or warm climates. Finally, commenters expressed concern over the cost of QMRA and epidemiological studies.

Response: The final RWQC indicators (*E. coli* and enterococci) have not changed since the 1986 recommended criteria. The approved analytical test methods for these indicators in 40 CFR Part 136 would still be the relevant test methods if states revise their WQS based on EPA's RWQC recommendations. Thus, there would be no additional cost to dischargers to monitor for these fecal indicators assuming that the applicable WQS includes WQC for *E. coli* or *Enterococcus* spp. as measured by a culture method. EPA does acknowledge that the adopted recommended criteria could change §303(d) listings for some state surface waters because EPA's recommended criteria include both GM and STVs, and if adopted in state standards, both values would be relevant components of the applicable WQS, which is used in §303(d) listing.

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