Overview of Technical Support Materials: A Guide to the Site-Specific Alternative Recreational Criteria TSM Documents

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Acronyms

ATP	Alternate Test Procedure
CFU	colony forming units
CFR	Code of Federal Regulations
CWA	Clean Water Act
E. coli	*Escherichia coli*
EPA	Environmental Protection Agency
FIB	fecal indicator bacteria, (e.g. fecal coliforms, *E. coli*, enterococci, *Enterococcus* spp.)
GI	gastrointestinal
GIS	geographic information system
GM	geometric mean
mL	milliliters
MPN	most probable number
MTF	multiple tube fermentation
MST	microbial source tracking
NEEAR	National Epidemiological and Environmental Assessment of Recreational Water
NGI	NEEAR-GI illness
NRC	National Research Council
QMRA	quantitative microbial risk assessment
qPCR	quantitative polymerase chain reaction
RWQC	recreational water quality criteria
TSM	technical support materials
U.S.	United States
WQ	water quality
WQC	water quality criteria
WQS	water quality standard(s)
WWTP	wastewater treatment plant

About EPA's Technical Support Materials

This Guide to the Technical Support Materials (TSM) documents is designed to help users evaluate site information and decide which tools would best support the development of site-specific alternative water quality criteria (WQC) that are scientifically defensible and protective of the recreational designated use. The Environmental Protection Agency's (EPA) nationally recommended recreational water quality criteria (RWQC) are broadly applicable for ambient waters designated for primary contact recreation. However, there are waterbodies with conditions that differ from those studied and used to inform EPA's 2012 RWQC. Water quality managers may want to consider WQC reflective of specific conditions or may want to use a different indicator of fecal contamination and/or enumeration method.

Text Box 1: Clean Water Act and Establishing WQC

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

States establish WQC and water quality standards (WQS) under the Clean Water Act (CWA) (see Text Box 1). EPA has previously indicated that States and Territories can use scientific approaches to propose alternative criteria. For example, EPA's 2004 *Water Quality Standards for Coastal and Great Lakes Recreation Waters Rule* indicates that States and Territories must apply the *Escherichia coli* (*E. coli*) and enterococci criteria to all coastal recreation waters. If, however, sanitary surveys and epidemiological studies show the sources of the indicator bacteria to be non-human and the indicator densities do not indicate a human health risk, then it is reasonable for the State or Territory not to consider those sources of fecal contamination in determining whether the standard is being attained (U.S. EPA, 2004). This approach was also included in the 1986 criteria document (U.S. EPA, 1986). EPA also previously indicated that it would be reasonable for a State or Territory to use existing epidemiological studies rather than conduct new or independent epidemiological studies for every waterbody if it is scientifically appropriate to do so (U.S. EPA, 2004). These flexibilities are included in the Code of Federal Regulations (CFR).[1]

[1] Footnote ''e'' to 40 CFR 131.41(c)(1) and footnote ''c'' to 40 CFR 131.41(c)(2) state: "These values apply to [*E. coli* or enterococci] regardless of origin unless a sanitary survey shows that sources of the indicator bacteria are non-human and an epidemiological study shows that the indicator densities are not indicative of a human health risk."

The 2012 RWQC recommends fecal indicator bacteria (FIB) levels (Table 1 in U.S. EPA, 2012a) that appear similar to the 1986 water quality criteria (U.S. EPA, 1986). However, two fundamental differences exist between these criteria that contribute to the scientific foundation of the approaches for derivation of site-specific WQC in Section 6.2 of the 2012 RWQC. These differences were informed by the scientific progress made over the last few decades that contributed to our understanding of microbiology, water quality, risk management, and public health protection. Although states have always had the option of developing WQC tailored to their specific waters, demonstrating the scientific defensibility and protection of the designated use has, until now, been a difficult and potentially burdensome task.

First, our understanding of the health effects associated with the historical levels of water quality recommended for public health protection has substantially progressed since 1986. Health studies informing the development of the 2012 RWQC and previous recommendations were conducted at sites predominantly affected by human fecal contamination in the form of secondary treated and disinfected effluent. There is a body of scientific evidence that indicates enteric viruses most likely caused the illnesses reported in those studies (Cabelli, 1983; Dufour, 1984; Soller et al., 2010a). The sources of fecal contamination determine the level and diversity of pathogens, and hence, the potential human health risks, which can be present in water.

Similar health studies conducted at sites affected by non-human sources of fecal contamination have not provided a clear linkage between water quality measured by FIB and health effects. Although waters impacted by non-human fecal contamination have long been considered to confer less potential for health risks compared to human impacted waters, the ambiguous results of the health studies did not provide risk managers evidence of the potential health implications of recreational exposure to waters containing animal feces relative to waters containing human feces. Recent advances in human health risk assessment methodologies, source identification techniques, and microbiology have now provided the linkages that allow for the derivation of source- and site-specific WQC (Schoen and Ashbolt, 2010; Soller et al., 2010b; Wuertz et al., 2011).

Second, the 2012 RWQC rely on a fundamentally different approach to derive the recommended values. The 1986 criteria recommended values for the culturable fecal indicator bacteria, enterococci and *E. coli*, were derived based on a proportional translation from the previous fecal coliform recommendations of 200 colony forming units (CFU) per 100 milliliters (mL). The reader is referred to the 2012 RWQC and other references for more discussion on the mathematics of this translation (Dufour and Schaub, 2007; U.S. EPA, 2012a). The values for enterococci and *E. coli* resulting from this translation were not directly linked to a specific illness rate, nor did they represent a potential risk management target. The 1986 criteria values simply represented an effort to carry forward historically accepted levels of water quality in terms of alternative fecal indicator bacteria (i.e., enterococci and *E. coli*) that the best available science at the time concluded were more effective at indicating potential fecal contamination. The health studies conducted by Cabelli (1983) and Dufour (1984) informed risk managers

about the potential for human illness that might occur following recreational exposure to waters containing levels of enterococci or *E. coli* at the recommended levels.

In contrast, the 2012 RWQC recommendations have an underlying health basis. Using the results of National Epidemiological and Environmental Assessment of Recreational Water (NEEAR) study, EPA derived the current recommendations based on an adjusted odds ratio of gastrointestinal (GI) illness below which there was no observed statistically significant increase in swimming-associated illness (U.S. EPA, 2012a). This significant increase in illness was first observed to occur at a geometric mean (GM) of 30 CFU enterococci per 100 mL, corresponding to 32 NEEAR-GI illness (NGI) per 1000 recreators. There was no significant difference between the swimming-associated illness rate at a GM of 30 CFU enterococci per 100 mL and a GM of 35 CFU enterococci per 100 mL, corresponding to 36 NGI per 1000 recreators. The 2012 RWQC recommendations for water quality based on an observed increase in illness provides the risk 'anchor' for evaluating the use protection of the alternative WQC.

The 2012 RWQC document includes tools that can be used by states to develop site-specific alternative WQC for inclusion into WQS packages to be submitted to and evaluated by EPA. Site-specific alternative WQC need to be scientifically defensible and protective of the designated use. Further, it is incumbent upon the state to substantiate those attributes in their proposed WQS packages. Site-specific alternative WQC should reflect the conditions of the watershed including current land uses and potential sources of fecal contamination and thus, should be revisited no less frequently than triennially to ensure the site-specific alternative WQC remain protective of the designated use. For example, if a substantial source of fecal pollution [e.g., wastewater treatment plant (WWTP)] is added, drainage is altered, or further human growth occurs (e.g., new buildings) the site-specific alternative WQC should be reviewed. This guide will help you decide if your waterbody is a candidate for site-specific alternative criteria and determine which set of tools would be amenable for you to use in deriving site-specific WQC.

For over a century, FIB have been used to protect public health (NRC, 2004). FIB have been used as water quality indicators because, among other things, they tend to be more numerous than pathogens in human fecal material, thus are a cheaper, safer, and easier target to enumerate for gauging ambient water quality. However, increasing numbers of scientific studies have demonstrated the existence of non-fecal sources of FIB in environmental matrices (Fujioka and Byappanahalli, 2003; Stewart et al., 2008; Byappanahalli et al., 2011; Yan et al., 2011). Notable examples of potential non-fecal sources of FIB include sands and soils (Yamahara et al., 2007; Yan et al., 2011), plant and periphyton-associated species (Ksoll et al., 2007; Badgley et al., 2010a,b; Ferguson, 2012), and growth in biofilms (Ferguson, 2006; Skinner et al., 2010). The relationship of the FIB from non-fecal sources to the occurrence and distribution of enteric pathogens and the potential for those microbes to predict human health effects in these examples has not been demonstrated (Halliday and Gast 2011; Viau et al., 2011; Shibata and Solo-Gabriele, 2012). Fecal, but non-human, sources of FIB also exist, but can co-occur with a different enteric pathogen profile relative to secondary treated and disinfected human wastewater effluent (i.e., the predominant source of fecal contamination impacting the

epidemiological studies informing EPA's 2012 RWQC). These profile differences can result in differences in potential relative health impacts (Schoen and Ashbolt 2010; Sinigalliano et al., 2010; Soller et al., 2010b; U.S.EPA, 2010a). Traditional culturable FIB have been crucial and successful in protecting public health and as advancements in science and technology occur, additional options become possible. The tools mentioned in this guide and discussed in more detail in the respective TSM documents present scientifically defensible and consistent approaches for understanding your site-specific information in context with water quality and human health risks. The TSM documents also discuss how you can use that information in the development of site-specific alternative water quality criteria.

This guide provides an overview of the set of TSM documents that EPA is providing for development of site-specific alternative criteria (as discussed in Section 6.2 of EPA's 2012 RWQC document). This set of TSM documents discusses tools related to the following areas:

1. alternative health relationships (Section 6.2.1 in RWQC "Epidemiological Studies")
2. non-human fecal sources (Section 6.2.2 in RWQC "Quantitative Microbial Risk Assessment")
3. alternative indicators and methods (Section 6.2.3 in RWQC "Alternative Indicators or Methods")

EPA plans to publish TSM documents corresponding to each set of these tools. The TSM documents will provide the detailed information that users need to determine which set of tools may be germane for their needs. They will also provide suggestions for gathering information and data to support the approach, conducting analyses, deriving site-specific alternative criteria, and preparing documentation for water quality standards packages. A brief synopsis of each set of tools follows. More detailed information can be found in each TSM document. These TSM documents will allow states to take advantage of the rapid and continuing advancements in the science of microbial water quality for use in their WQS.

Alternative Health Relationships

Recreational water epidemiological studies describe the probability of illnesses associated with exposure to fecal contamination as measured by FIB. It is important to note that the FIB do not necessarily cause illness themselves. Instead they are used to gauge the magnitude and extent of fecal pollution in a waterbody. Epidemiological studies with or without quantitative microbial risk assessment (QMRA) could be used to develop an alternative health relationship for a water quality metric. This alternative health relationship could inform the basis of site-specific alternative criteria.

EPA's NEEAR epidemiological study was conducted in water primarily impacted by human fecal contamination, with the exception of one site that was impacted by urban runoff (U.S. EPA, 2010b; Wade et al., 2006, 2008, 2010). Statistically significant associations between water quality, as determined using EPA's *Enterococcus* spp. quantitative polymerase chain reaction (qPCR) Method 1611 (U.S. EPA, 2012b), and reported GI illness were observed in the temperate marine and fresh water beaches impacted by WWTP. In the United States (U.S.) other agencies

have also conducted recreational water epidemiological studies. For example, epidemiological studies of recreational water exposures have been conducted in Southern California (Colford et al., 2012), Southern Florida (Fleming et al., 2006, 2008; Sinigalliano et al., 2010), and Ohio (Marion et al., 2010).

Several factors can influence the potential epidemiological relationship between indicator density and the potential for human illness. Some of the potentially important factors include the source of fecal contamination, age of the fecal contamination, solar radiation, water salinity, turbidity, dissolved organic matter, water temperature, and nutrient content. Additionally, numerous factors also affect the occurrence and distribution of FIB and pathogens, including but not limited to: predation of bacteria by other organisms; differential interactions between microbes and sediment, including the release and resuspension of bacteria from sediments in the water column; and differential environmental effects on indicator organisms versus pathogens (U.S. EPA, 2010b; WERF, 2009).

States or local agencies may choose to conduct epidemiological studies in their waterbodies and use the results from those studies to derive site-specific alternative criteria. To derive scientifically defensible alternative WQC for adoption into state standards, ideally the epidemiological studies should be rigorous, comparable to those used to support the 2012 RWQC, and peer-reviewed. However, smaller scale epidemiological studies may also provide a scientifically defensible foundation for alternative criteria. Additionally, QMRA (see section 6.2.2) can enhance the interpretation and application of new or existing epidemiological data (Boehm et al., 2009; Dorevitch et al., 2011; Soller et al., 2014). QMRA can supplement new or existing epidemiological results by characterizing various exposure scenarios, interpreting potential etiological drivers for the observed epidemiological results, and accounting for differences in risks posed by various types of FIB sources. The additional insights QMRA can provide in these situations may help inform site-specific alternative WQC development.

The *Site-Specific Alternative Recreational Criteria Technical Support Materials for Alternative Health Relationships* document discusses approaches that can be used to document potential human health effects from exposure to feces-contaminated recreational waters. This TSM could be used for documenting the health relationship of new or existing indicators of fecal contamination and their associated enumeration methods to levels of reported illness, or for determining the site-specific health relationship at any site where site-specific epidemiological studies and/or QMRA are conducted. The TSM includes examples of how epidemiological data and QMRA can be used to derive site-specific alternative WQC. Special circumstances related to the waterbody characteristics (i.e., waterbody biology, chemistry, or physics), the demographics of bathers, or the nature of the source may lead to exploration of health relationship based site-specific alternative criteria.

Non-Human Fecal Sources

EPA believes the 2012 RWQC are protective of the primary contact recreational designated use for waterbodies affected by any source of fecal contamination. The 2012 RWQC was informed by studies conducted in WWTP effluent-impacted waters. Since all pathogens in human feces

are potentially infectious to humans, developing criteria recommendations based on these studies represents a prudent and health protective benchmark. However, there are scenarios of contamination from non-human sources and non-fecal sources of FIB that potentially present markedly different probability of illness relative to human sources. QMRA can be used as a basis to develop site-specific alternative criteria, where sources are characterized predominantly as non-human or non-fecal (U.S. EPA, 2009). EPA's research indicates that understanding the predominant source of fecal contamination could help characterize the human health risks associated with recreational water exposure. QMRA studies have demonstrated that the potential human health risks from human and non-human fecal sources could be different due to the nature of the source, the type and number of pathogens from any given source, as well as variations in the co-occurrence of pathogens and fecal indicators associated with different sources (Till and McBride, 2004; Roser and Ashbolt, 2006; Schoen and Ashbolt, 2010; Soller et al., 2010b; Wuertz et al., 2011).

Further, research demonstrates that swimming-associated illnesses can be caused by different pathogens, which depend on the source of fecal contamination. For example, in human-impacted recreational waters, human enteric viruses appear to cause a large proportion of illnesses (Soller et al., 2010a). In recreational waters impacted by gulls and agricultural animals such as cattle, pigs, and chickens, pathogenic bacteria and protozoa are the likely etiologic agents of concern (Roser and Ashbolt, 2006; Schoen and Ashbolt, 2010; Soller et al., 2010b). The relative level of predicted human illness in recreational waters contaminated by non-human fecal sources can also vary depending on whether the contamination is direct or via runoff due to a storm event (Soller et al., 2010b; U.S. EPA, 2010a; Soller et al., 2014).

To derive site-specific alternative criteria that are considered scientifically defensible and protective of the designated use, QMRA studies should be well documented, transparently presented, follow accepted practices, and rely on scientifically defensible data. A sanitary characterization can provide detailed information on the source(s) of fecal contamination in a waterbody to determine whether the predominant source is human or non-human. EPA developed a QMRA-specific sanitary survey[2] application, which could be included in a sanitary characterization, to capture information directly applicable to a QMRA.

At sites where non-human sources predominate, QMRA can be used to determine a different enterococci or *E. coli* criteria value that is equally protective as the recommended 2012 RWQC. Fundamental to this approach is a thorough understanding of the potential sources of fecal contamination impacting your waterbody. The TSM, *Site-Specific Alternative Recreational Criteria Technical Support Materials for Predominantly Non-Human Fecal Sources,* describes the process that can be used to document likely sources of fecal contamination impacting a waterbody. Fecal source tracking and identification methods can be used to substantiate the findings of the sanitary survey (i.e., human sources do not predominate). As described in the TSM, a sanitary characterization consists of conducting a sanitary survey and substantiating water quality data. The results of monitoring for pathogens and indicators can be used to

[2] See: *Site-Specific Alternative Criteria Technical Support Materials for Predominantly Non-Human Fecal Sources,* Volume A, Appendix A.

conduct QMRA. EPA provides QMRA results from several conservative (health protective) scenarios where the predominant sources are from one or more of the following: gulls, pigs, chickens, and non-pathogenic sources. If users document that their site fits one of EPA's conservative scenarios, then EPA provides potential criteria values. Users also have the option of conducting QMRA for other non-human fecal sources and other site-specific parameters documented at a site.

Alternative Indicators and Methods

EPA anticipates that scientific advancements will provide new technologies for enumerating fecal pathogens or FIB. New technologies may provide alternative ways to address methodological considerations, such as rapidity, sensitivity, specificity, and method performance. As new or alternative indicator and/or enumeration method combinations are developed, states may want to consider using them to develop site-specific alternative criteria for adoption in WQS or as the basis for beach notification when a state does not plan to modify existing WQS. The TSM, *Site-Specific Alternative Recreational Criteria Technical Support Materials for Alternative Indicators and Methods*, describes a process for comparing enumeration methods that may allow users to take advantage of the rapid and continuing advancements in the science of microbial water quality. Text Box 2 contains examples of potentially useful newer enumeration methods and indicator organisms.

Text Box 2: Newer Enumeration Methods and Indicators

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

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

The evaluation of multiple FIB and enumeration methods has been used to describe a common level of water quality. For example, the derivation of EPA's 1986 criteria values was fundamentally based on the proportional comparison of multiple FIB: fecal coliform, enterococci, and *E. coli*. In those specific cases, comparisons were made among membrane filtration methods specific to each target organism. EPA has also approved other culture-based methods for the detection of enterococci and *E. coli* based on how those methods compare to EPA published methods. In this comparison, results from a membrane-filtration method were compared to another most probable number (MPN) method that relies on substrate-utilization and multiple tube fermentation (MTF). Rapid methods, such as *E. coli* enumerated by qPCR,

have already been evaluated against culturable methods and have demonstrated utility on a site-specific basis (Lavender and Kinzelman, 2009).

If a state adopts WQS using alternative indicator/method combinations, EPA will review those standards, including any technical information submitted to determine whether such standards are scientifically defensible and protective of the primary contact recreation use. To facilitate consideration of such standards, states may gather water quality data over one or more recreational seasons for the indicator/method recommended in the 2012 RWQC and the proposed alternative indicator/method combination. A robust relationship need not be established between EPA's recommendation and alternative indicator(s) for the whole range of indicator densities (U.S. EPA, 2010c). It is, however, important that a consistent and predictable relationship exist between the enumeration methods and an established indicator/health relationship in the range of the recommended criteria. If a state wishes to use an alternative indicator method without modifying existing WQS, then the alternative method should be a reliable predictor of the likelihood of an exceedance of the applicable WQS.

As technology advances there may be newer indicators or methods that offer advantages over the EPA published methods. With this approach, a new indicator-method combination can be statistically compared to an EPA method recommended in the RWQC (Methods 1600, 1603, and 1611 or equivalent). This approach uses site-specific water quality data to demonstrate the statistical correlation and may be useful for new methods that will be developed in the future, if that method correlates with EPA's methods at the site under consideration. This TSM approach is different from EPA's Alternate Test Procedure (ATP) program because it is limited to site-specific use, allows different analytes to be compared, and uses actual environmental monitoring for comparing methods.

Questions and Answers[3]

The following questions should help users determine which TSM best fits their needs. For clarity and ease of use, the format of this section is in a question and answer format.

Why would I want to use these TSM documents?

EPA's recommended RWQC can be applied nationally and are scientifically defensible and protective of the use. These criteria describe a condition that is protective of human health at a given level of water quality. The linkage between WQ and health protection in the RWQC was informed by studies conducted at sites with specific characteristics. EPA recognizes that there are site-specific characteristics and conditions that differ from those used to support the 2012 RWQC. EPA encourages states to improve and update their WQS to reflect the latest science and information.

[3] In this format, the question is presumed to be posed by someone who may use the TSMs to develop alternate site-specific alternative criteria and WQS (the use of "I" in many instances). The answer is a response to the user's question (the use of "you" refers back to the person who is interested in developing alternate site-specific criteria).

These TSM documents provide states with approaches to fine-tune EPA's recommendations to reflect site-specific characteristics and conditions, while maintaining equivalent public health protection. WQC that reflect site-specific conditions allow states to account for differences in their waterbodies or preferred enumeration method-indicator, while protecting public health. WQS reflective of site-specific conditions are better for determining attainment.

Who can use these Technical Support Materials?

These TSMs were created for states[4] who are interested in deriving site-specific alternative water quality criteria for inclusion in their WQS. The TSM also provide a transparent process that should allow EPA to evaluate and approve these WQS more easily.

Is my site a candidate for site-specific alternative water quality criteria?

The nationally recommended RWQC are designed to be scientifically defensible and protective of the designated use for all waters, and were informed by epidemiological data from sites where WWTP effluent impacts the recreational waterbody. You might consider site-specific alternative criteria if your site is not predominantly impacted by WWTP effluent or if you are interested in developing criteria using an alternative indicator or newer method. The national RWQC values are based on the fecal indicator bacteria enterococci and *E. coli* (Methods 1600, 1603, 1611 or equivalent). The TSM approaches can help you develop different enterococci or *E. coli* values, or derive criteria based on a different indicator or method.

How do I decide which TSM to use?

A sanitary characterization allow you to gain a better understanding of the potential sources of contamination impacting your waterbody and decide which TSM approach would be most useful for your situation. For more information on watersheds and approaches to watershed management, please see EPA's watershed website (http://water.epa.gov/type/watersheds/). Table 1 summarizes how the sources of fecal contamination and the type of method influence which TSM you should consider.

The sanitary characterization is a process that includes 1) compiling information on sources, water quality, and historical trends within your watershed, 2) evaluating this information against this guide and the related TSM documents, 3) identifying and addressing important data gaps relevant for the TSM approach you are considering, 4) collecting information to confirm the conclusions made in the first step. These steps are iterative and should be revisited by risk managers throughout the characterization process.

If you do not think that enterococci or *E. coli* provide the best water quality information and you are interested in developing a health relationship for a different indicator, refer to *Site-Specific Alternative Recreational Criteria Technical Support Materials for Alternative Health Relationships.*

[4] Anyone can prepare WQS and submit to the state. The state submits to EPA for review and approval.

Table 1. How do source and indicator method influence which TSM I should choose?

TSM	Sources of fecal contamination	Enumeration methods
Alternative Health Relationship	Any	Any
Alternative Fecal Sources	Predominantly non-human	EPA Methods 1600, 1603 or 1611 (or equivalent[5])
Alternative indicator-method	Any	New method has predictable consistent relationship with EPA Methods 1600, 1603 or 1611 (or equivalent)

If the sanitary characterization of your waterbody indicates that there are predominantly non-human fecal sources affecting it, then you may consider using QMRA to determine the potential probability of illness associated with recreating. Please refer to *Site-Specific Alternative Recreational Criteria Technical Support Materials for Predominantly Non-Human Fecal Sources* for information on what site-specific data is needed, how to conduct QMRA, and how to select alternative criteria values for enterococci or *E. coli.*

If you are interested in using an alternative indicator or method, possibly because of cost, speed, or other methodological advancements, refer to the *Site-Specific Alternative Recreational Criteria Technical Support Materials for Alternative Indicators and Methods*. The TSM for alternative indicators and methods explains how to demonstrate whether a consistent predictable relationship exists between the new method and one of EPA's methods for enumerating enterococci or *E. coli* (EPA methods 1600, 1603, 1611 or equivalent). This approach differs from EPA's ATP process in the following ways: 1) ATP is for national or limited use, whereas the TSM is for site-specific use only, 2) ATP is for methods with the same analyte only, whereas the TSM can be used for different indicators, 3) ATP is for new methods for 40 CFR 136 (for CWA uses) or 40 CFR 141 (for drinking water), whereas the TSM is for new methods for ambient water monitoring, and 4) ATP determines correlations by utilizing spiked samples in a laboratory, whereas the TSM determines correlations by environmental monitoring. The TSM approach is for comparing method performance on a site-specific basis and does not include the development of a health relationship with the new method.

Can I use these TSMs to develop site-specific alternative criteria for other designated uses?

The set of tools discussed in the TSM documents is designed to evaluate potential impacts to human health from exposure to fecal contamination in ambient surface waters designated for primary recreational contact. Any site-specific alternative WQC derived from using these tools

[5] In this context, "equivalent" refers to methods that are approved under EPA's ATP.

should be scientifically defensible and protective of the recreational designated use. These TSM tools are not designed to be used to characterize potential human health risks associated with other designated uses.

If you are interested in assessing human health risks for other stressors/agents or exposure scenarios, refer to other frameworks such as EPA's *Framework for Human Health Risk Assessment to Inform Decision Making* (U.S. EPA, 2014) and the interagency *Microbial Risk Assessment Guideline Pathogenic Microorganisms with Focus on Food and Water* (U.S. EPA/USDA, 2012).

What kind of information is useful in the sanitary characterization?

Once you decide to explore whether site-specific alternative criteria would be desired, the first step is to conduct a sanitary characterization. A sanitary characterization for this purpose includes gathering relevant information about the potential sources of contamination in the waterbody and other information related to source dynamics. As mentioned above, the sanitary characterization is a multistep process for understanding your watershed. Depending on which TSM you choose, the sanitary characterization can include information such as:

- Historical information – This includes information from previous FIB or pathogen monitoring. The history of best management practices and other mitigation efforts can be included.
- Sanitary survey information – This can be gathered with the marine and Great Lakes sanitary guides[6] or the QMRA sanitary survey.[7]
- Microbial source tracking (MST) – If any information is available from MST monitoring, this information can be very helpful in identifying sources of FIB.
- Wildlife survey – The occurrence of wildlife that could be a source of FIB or pathogens (e.g., warm-blooded animals) should be discussed. If there are seasonal differences and other discernible patterns for wildlife, those aspects can be included.
- Geographic information system (GIS) mapping – A map should be included in the sanitary characterization. If there are outfalls or other features that could contribute to FIB, those should be included on the map.
- Hydrological data – If information on currents and tidal effects is available, it can help characterize how the FIB are moving throughout the waterbody. In some cases, this information may be available in map format.

These components can be prioritized based on available resources and the relative usefulness of the information. For more information on how to utilize sanitary characterization for the development of site-specific alternative criteria, see the TSM documents.

[6] Visit EPA's Beach Sanitary Surveys website to find FAQs, guides, forms, and examples (http://water.epa.gov/type/oceb/beaches/sanitarysurvey_index.cfm)

[7] See *Site-Specific Alternative Recreational Criteria Technical Support Materials for Predominantly Non-Human Fecal Sources*

Conclusion

The three TSM documents will help users collect data, derive site-specific alternative criteria, and prepare WQS. EPA considers that the approaches in these documents reflect the state of the science and provide public health protection in a practical and cost effective manner.

States can adopt site-specific alternative criteria to reflect local environmental conditions and human exposure patterns. An alternative WQS may involve the adoption of different numerical value(s) that are based on the approaches described in the set of TSM documents. EPA recommends that alternative criteria reflect the same risk management decision regarding illness rate that are the basis of the 2012 RWQC. Such alternative criteria should be scientifically defensible, protective of the use, and reviewed and approved by EPA under CWA §303(c).

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