

CRITERIA DEVELOPMENT PLAN & SCHEDULE

RECREATIONAL WATER QUALITY CRITERIA



Office of Water
Office of Research and Development

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PURPOSE AND BACKGROUND

This *Criteria Development Plan* (CDP) describes the process and timeline EPA will follow in developing and publishing new or revised water quality criteria for pathogens and pathogen indicators for recreational waters (referred to in this document as "recreational water quality criteria" or "recreational criteria").

The CDP reflects decades of EPA experience with the steps that are necessary and the time that is needed to produce scientifically sound water quality criteria recommendations and other significant national environmental policy and guidance documents. EPA's new or revised recreational water quality criteria are expected to be particularly significant. Once developed and published, states are expected to revise their water quality standards (WQS) taking into account EPA's recommendations; these WQS will impact thousands of communities across the Nation and millions of visitors to our Nation's beaches. Producing criteria that both ensure protection of public health and represent sound public policy involves significant effort and many steps, including the following:

- (1) Conduct scientifically sound research and studies;
- (2) Carefully and thoroughly evaluate, analyze, synthesize, and, obtain scientific review of the data generated by the research and studies and the analyses;
- (3) Formulate options
- (4) Obtain input from a wide range of stakeholders including other federal agencies and various levels of government (e.g., local and state) on the policy options
- (5) Draft and publish the proposed criteria for broad public input and review; compile and make available to the public supplementary information that provides the scientific and policy bases for EPA's recommendations
- (6) Carefully consider all comments and views on the proposed criteria and make revisions as needed
- (7) Publish the final criteria

A number of the steps in the Criteria Development Plan include consultation and coordination with appropriate federal, state, tribal, and local officials (including local health officials), and other interested persons and organizations, consistent with Sections 304(a) and 304(a)(9)(A) of the Clean Water Act.

In addition, long experience at EPA in producing significant regulations and guidance such as new or revised recreational criteria has resulted in EPA's establishment of a formal process to ensure that EPA produces scientifically sound and technically rigorous regulations and guidance in the shortest time feasible. The steps in the CDP are generally consistent with this process. The formal process EPA follows for "significant"

EPA actions are fully described in "Overview of EPA's Action Development Process (ADP)" (<http://intranet.epa.gov/adplibrary/adp/index.htm>).

This process ensures that the Agency uses quality information and analyses to support its actions and ensures that scientific and policy issues are adequately addressed. The process is designed to ensure that actions such as the development of recommended recreational water quality criteria:

- Achieve environmental and public health protection objectives;
- Are consistent with legal requirements, executive orders, directives, Agency guidance, and national policies;
- Reflect EPA-wide involvement when necessary;
- Reflect appropriate consideration of the views outside EPA;
- Consider multimedia effects;
- Consider pollution prevention principles and innovative alternatives during the investigative and development process;
- Are based on sound scientific, legal, policy, and technical analyses;
- Can be efficiently implemented and effectively enforced;
- Are clear, concise and written in plain language; and
- Are timely.

Plan and Timeline for the Development of New or Revised Recreational Water Quality Criteria

I. Ongoing Scientific Research July 2007 – December 2010

The foundation for the development of new or revised recreational water quality criteria is the relevant research and studies that EPA and others have completed prior to 2007 and the research and studies that EPA (and others) will undertake between 2007 and the end of 2010. These studies and the timelines for completing these studies are fully described in EPA's "Critical Path Science Plan for the Development of New or Revised Recreational Water Quality Criteria" (CPSP). See Tables 3-1 and 3-2 (attached) from the CPSP for descriptions of the research activities EPA plans to complete by 2010 and the timeline for their completion.

Briefly, between 2007 and the end of 2010, EPA will be undertaking substantial scientific studies including:

- (1) conducting or supporting epidemiologic studies involving thousands of beach goers at marine beaches in Alabama, Rhode Island and California (and possibly other marine locations depending upon the results in Alabama, Rhode Island and California);

- (2) conducting epidemiologic studies or completing quantitative microbial risk assessments for waters impacted by animal sources of fecal contamination and/or urban runoff;
- (3) collecting data for use in quantitative microbial risk assessments to ensure that these risk assessments represent the diversity of locations nationally;
- (4) studying possible indicators of the presence of pathogens and developing and testing analytical methods (including rapid methods using molecular biology techniques) for measuring these indicators in different types of waters to ensure that the indicators and methods will be suitable for the range of Clean Water Act purposes and that the indicators and methods will provide reliable and reproducible results for the diversity of waters nationally;
- (5) developing data and producing protocols or tools for communities to conduct sanitary surveys to identify sources of fecal contamination;
- (6) evaluating genetic markers for fecal material from certain animals; and
- (7) collecting data and information to refine and validate water quality models.

The additional epidemiologic studies that EPA intends to conduct are expected to further define the relationship between exposure to fecal contamination in recreational waters and illness in humans. Several indicators and methods will be included in the epidemiologic studies (as described in the CPSP) to determine their performance characteristics and to identify those that are best suited for use in the range of CWA programs and for a range of geographical and climatic conditions. For each study, EPA intends to examine the illness response in adults as well as in children. The Agency also intends to explore the impact of different sources of fecal contamination on illness response to better understand whether there are differences and the magnitude of any differences. Simultaneously, test methods for measuring indicator organisms will be further developed and validated for the purpose of providing measurement tools that are reliable and provide reproducible results.

As studies are completed, some interim analyses will be performed to evaluate the adequacy of the data to answer the underlying science questions that the studies are intended to answer. As the results unfold, they may suggest the need for additional studies or modifications to the planned studies as they appear in the CPSP. The interim or early results (prior to the completion of all of the necessary studies) will also be used to begin the process of scoping out possible approaches for the structure and content of the criteria.

II. Analysis and Synthesis of All Study Results and Development and Publication of New or Revised Recreational Criteria and Supplementary Information – January 2011 –December 2012

A. Analysis and Synthesis of Data and Peer Review of Results and Analyses – January 2011-March 2011

After the completion of the studies in the CPSP, EPA will need to analyze and synthesize the study results. This will require evaluation, synthesis, summarization, statistical analysis and external scientific peer review before the studies can be used in the development of a new or revised criteria document. The studies described in the CPSP (epidemiological studies, site characterization, models) are expected to yield the largest data set of its kind related to the problem of fecal contamination. Due to the magnitude of the information and the complexity of the problem, (e.g. different organisms, endpoints, diverse geographic locations and aquatic conditions) conducting an analysis and synthesis of all of the study results (including literature reviews) will be a significant exercise. In this phase, EPA expects to conduct statistical analyses to determine whether these individual study data sets can be combined and if so, EPA expects to combine the data sets to provide for a more robust understanding of the relationships between different indicator levels and illness rates. EPA expects to produce exposure-response relationships to provide a reliable basis for estimating the level of human health risks associated with various indicator organisms and levels of indicator organisms in waters.

After the completion of this analysis and synthesis of the studies (including independent scientific peer review), EPA will move forward to begin the formulation of the new or revised criteria through the following process. The steps in the process and the estimated timeframes are provided below. EPA indicates an “approximate” time for some steps in recognition of the fact that a particular stage in the process may be somewhat shorter or somewhat longer depending upon the specific circumstances.

B. EPA Workgroup Development of Options for Overall Structure of Criteria and Preliminary Decision-making on Options for Overall Structure (approximately 6 weeks)

An EPA Workgroup will be formed and will consist of staff level representatives from throughout EPA, including representatives from offices that manage various Clean Water Act Programs such as the NPDES Permitting Program, the TMDL Program, and the Beach Monitoring and Advisory Program; the Office of Research and Development; the Office of Enforcement and Compliance Assurance; and the Office of General Counsel. The EPA Workgroup will develop options for the overall structure and content of the criteria, based on the individual and combined analyses and syntheses of the study results and the outcome of the scientific peer review process. This is a critical

step in the CDP that requires significant individual and group work to develop and refine ideas and options for the structure and content of EPA's criteria recommendations. Depending upon the results of the studies and the analyses, the Workgroup could recommend that EPA develop criteria recommendations based on a suite of inter-related indicators that can be used for various Clean Water Act programs. It is important that the EPA Workgroup include representatives from across EPA to permit full consideration of all issues and potential concerns regarding the options under consideration and to understand the strengths and potential pitfalls of each option. Options analysis and workgroup recommendations will need to be brought to EPA management for preliminary decision making during this stage of the process, to allow for the initial drafting of the criteria document by the workgroup, led by the Office of Water.

C. EPA Workgroup Drafts Initial Criteria Document (approximately 4 months)

The criteria drafting phase typically involves the identification and resolution of many additional science policy issues and public policy issues associated with establishing new or revised recommended criteria. This phase also involves the drafting of the criteria document, which is expected to include EPA's criteria recommendations and a significant amount of supplementary information such as explanations of the scientific basis of the criteria and any policy decisions that were made during the development of the criteria recommendations. During this stage of the process, the EPA Workgroup is also expected to propose options to the appropriate levels of management within EPA for decisions on issues such as the level of human health risk reflected in the criteria recommendations (e.g., 8 illnesses per 1,000 people, 10 illnesses per 1,000 people, etc.) and to incorporate these decisions and the basis for them into the draft criteria document. The workgroup is expected to also propose options for resolving the issue of the appropriate target population(s) for protection (e.g., adults, children, the elderly, etc.). Depending upon the structure of the criteria, the EPA workgroup may develop and propose an approach for factoring in the source of fecal contamination. If EPA decides to recommend criteria based on more than one indicator and/or method, the workgroup would be expected to include in the draft document an analysis of comparability between recommended indicators and/or methods. The draft criteria document is expected to be a standalone document that not only communicates what the new or revised recommended criteria are, but also, the complete scientific and policy rationale for EPA's recommendations. Importantly, states will use not only EPA's criteria recommendations, but also this supplementary information to develop and successfully adopt into state law water quality standards that are scientifically defensible and protective of the swimming use.

D. External Expert Peer Review of Initial Draft Criteria Document (6 weeks)

EPA considers external independent expert peer review of the draft criteria document by three to five independent external experts as essential to ensuring that EPA's new or revised criteria are scientifically sound and understandable. While EPA will develop a draft criteria document that is based on the best efforts of its Program scientists and regulatory experts, long experience at EPA has demonstrated that external peer review of draft recommended water quality criteria is very beneficial in helping to ensure that data have been interpreted correctly, and that the draft criteria are comprehensible by State and local governments and agencies, as well as regulated entities and the public. EPA can cite many examples where external expert peer review resulted in an important and substantive improvement in EPA's recommended criteria. In this case, a thorough peer review of this criteria document is expected to require extensive effort on the part of the peer reviewers to understand the underlying data (which is expected to be substantial), the goals of the criteria, and the manner in which the information has been used in criteria development. The timeframe of six weeks for this step is the minimum time needed to permit a thoughtful, thorough evaluation of all of the information presented.

E. EPA Workgroup Compilation and Analysis of Peer Review Comments on Initial Draft Criteria and Modifications to Initial Draft Criteria Document Based on Peer Review Results (approximately 2 months)

When the external peer review of the draft criteria document is completed, the EPA Workgroup will compile and distill the comments received from the peer reviewers and propose to EPA management, for decision making, any recommended changes to the criteria based on the outcome of the peer review process. A careful analysis of the substance of the comments will be necessary to determine which changes (if any) will be adopted. In some cases, further dialogue with one or more peer reviewers may be necessary in order for EPA to fully understand a comment or suggested change. A Response to Comments document (RTC) will be developed outlining the peer reviewers' comments, how the Agency responded to them, and will include an explanation of the rationale for each response. EPA will modify the draft criteria document where appropriate, based on the results of the peer review process. This step may also include additional data analysis, editing, and reconsideration of criteria form or approach, depending upon the nature of the comments made by peer reviewers.

F. Formal Intra-Agency Review of Draft Criteria Document and Revisions Based on Intra-Agency Review (approximately 1 month)

After any revisions are made based on the results of the external peer review process, all relevant EPA Offices will be provided with an opportunity to formally review and comment/concur on the criteria document prior to publication for public review and

input. This step in the process ensures that senior management and policymaking levels across all of EPA (for example the Office of Enforcement and Compliance Assurance, the Office of General Counsel, the Office of Research and Development, and the Office of Policy and Environmental Innovation) review important national policy and regulatory documents for issues and technical/scientific rigor before EPA sends documents out for public review and input. Long experience at EPA has demonstrated that involving senior officials from other Offices at EPA in a formal process that provides for review and comment so that all offices concur with the action, helps ensure that relevant additional policy and technical expertise within EPA that exists outside the originating Program Office (in this case, the Office of Water) is considered and reflected in the action. This step also provides an opportunity to identify concerns and conflicts that may exist with regard to cross-Office regulatory efforts. EPA will modify the draft criteria document where appropriate, based on the outcome of the intra-Agency review process. The outcome of this process may call for additional data analysis, editing, and reconsideration of EPA's draft criteria recommendations, depending upon the nature of the comments during intra-Agency review.

G. Inter-Agency Review of Draft Criteria Document and Revisions Based on Inter-Agency Review (2-3 months)

After any revisions are made based on the results of the intra-Agency review process, EPA will provide all relevant governmental Agencies outside EPA that have an interest in the criteria recommendations or have expertise to contribute with an opportunity to formally review and comment on the criteria document. This step in the process is in accordance with Executive Order 12866 and ensures that senior management and policymaking levels in other federal agencies (for example, the Centers for Disease Control, the National Institute for Environmental Health Studies, and the United States Geological Survey) review important policy and regulatory documents for issues and technical rigor before EPA sends documents out for public review and input. Long experience at EPA has demonstrated that providing senior officials from other executive branch agencies a formal opportunity to review and comment on important regulations, policies and guidance helps ensure that relevant additional policy and technical expertise within the federal government that exists outside the originating Agency is brought to bear to ensure a quality product. This step also provides an opportunity to identify concerns and conflicts that may exist with regard to cross-federal government regulatory efforts. EPA will consider the comments of other federal agencies and determine whether to modify the draft criteria document based on those comments. The outcome of this process may call for additional data analysis, editing, and reconsideration of EPA's draft criteria recommendations, depending upon the nature of the comments during Inter-Agency review.

H. Publish Draft Criteria for External Views (2-3 months)

During this step, EPA will publish the draft criteria for public review and input. EPA expects that this will be done by publishing EPA's proposed criteria recommendations and supplemental information in the Federal Register (or by publishing a Notice of Availability in the Federal Register and making the proposed document(s) available on EPA's Website). A public comment period at this phase provides an opportunity for the full range of interested persons and organizations to identify issues that may still need to be addressed and/or provide comments on EPA's proposed criteria recommendations. Long experience at EPA has demonstrated that public review and comment on significant guidance and policy documents, and regulations helps ensure better Agency actions. In this particular case, these criteria will affect thousands of communities and millions of beachgoers; it is essential that these new criteria be fully vetted with the public before EPA makes its final recommendations.

EPA expects and hopes that State officials in particular will carefully review these new draft criteria and offer comments and input during this stage of the process. States are expected to adopt Water Quality Standards for the pathogens and pathogen indicators to which EPA's new or revised criteria are applicable and there are many other entities that will be affected by those new standards: local governments, State and local public health agencies, wastewater treatment facilities and other regulated entities. In particular, because local public health officials are the primary managers of Beach Advisory Programs, EPA expects the draft criteria to be thoroughly reviewed and commented upon by these entities. In the past, States in particular have been very instrumental in identifying issues that EPA needs to address in its new or revised criteria prior to finalizing the criteria. EPA also expects that the regulated community and environmental and public health organizations will carefully and thoroughly review these new or revised criteria.. Based on past experience, EPA expects to receive a substantial amount of comments and input on its draft criteria document during this step in the process.

EPA expects that the comment period will be 60 to 90 days in order to provide the public with enough time to consider EPA's criteria recommendations and supporting information and prepare meaningful comments. Adequate time for public comment is especially important for EPA's new or revised recreational criteria because of the expected complexity of the scientific basis of the criteria recommendations.

I. Workgroup Compiles and Analyzes Public Comments and Produces Revised Criteria (As Needed) (approximately 3 months)

The EPA Workgroup will consider the comments received during the public review and input stage of the process and obtain decisions from EPA management on any proposed changes. EPA will modify the draft criteria document where appropriate, based on the

results of public review and input. This step may include additional data analysis, editing, and reconsideration of criteria form or approach, depending upon the nature of the comments. EPA will prepare a Response to Comment document (RTC) that includes the comments received and the Agency's response to those comments, including a rationale for the response. Because EPA expects an unusually large volume of comments, organizing and responding to comments will take a considerable amount of time.

J. Combined Intra-Agency and Inter-Agency Review (if Significant Changes to Criteria Occur as a Result of Public Review and Input) (2-3 months)

After any revisions are made to the new or revised criteria document based on the results of the public review and input process, EPA will conduct Intra-Agency and Inter-Agency reviews of the final criteria recommendations. The purpose of these reviews is discussed in sections F and G above. EPA expects the reviews at this stage of the process to take less time for the final criteria document because the reviewers will be expected to focus their review only on changes made to the proposed criteria recommendations and supplementary information as a result of the public review process.

K. EPA Workgroup Makes Any Final Revision to Criteria Recommendations and Supplementary Information Based on Final Intra and Inter Agency Review (1 month)

After the final criteria document has undergone any additional Intra-Agency and Inter Agency reviews, the EPA Workgroup will consider the comments received during this stage of the process and obtain final decisions from EPA management on any changes. The outcome of this step may call for additional data analysis, editing, and reconsideration of aspects of the criteria recommendations, depending upon the nature of the comments. The Workgroup will then revise the document accordingly.

L. Agency Signature of Final Criteria Document (2-3 weeks)

After the Workgroup revises the criteria document based on Intra-Agency and Inter-Agency reviews, the document is prepared for signature by a Senior Agency Executive. Typically, water quality criteria documents are signed by the Office Director, Office of Science and Technology, in the Office of Water. Prior to Office Director level signature, certain senior Agency officials, such as the General Counsel, are required to concur on the final document.

M. Publish Criteria Document (or Publish Notice of Availability) in the Federal Register

Table 3-1. Science Plan Research Activities and Projects

GOALS ADDRESSED BY RESEARCH	PROJECT TITLE	RESEARCH DESCRIPTION	START DATE/ END DATE
Epidemiology Studies/QMRA			
1 — 4	Conduct epidemiologic studies at POTW-impacted marine beaches in Fairhope, Alabama and Goddard, Rhode Island (P1, P2)	Prospective cohort epidemiology studies designed to evaluate the ability of rapid and novel indicators of recreational water quality to predict swimming-associated illness at marine beach sites impacted by treated wastewater effluent discharge. The study design is nearly identical to the recently completed Great Lakes studies (Wade et al., 2006), and very similar to studies recently completed and ongoing in California (Colford, 2007). Water samples are tested for <i>Enterococcus</i> using qPCR, <i>Enterococcus</i> using standard culture method, <i>E. coli</i> using qPCR, <i>Bacteroides</i> using qPCR (not human specific), <i>Bacteroides</i> using qPCR (human specific), and male-specific coliphages by antibody assay. Additional tests include over 30 pharmaceuticals and industrial chemicals. Water quality measures will be compared to illness rates to derive exposure-response relationships between indicator measures and illness reported among beachgoers. Study will have a multi-station sampling grid with multiple samples taken each day to capture local temporal and spatial variability.	2007 □ 2009
1 — 4	Support epidemiologic study at a beach in Avalon, CA considered to be impacted primarily by untreated human fecal contamination (P3)	Prospective cohort epidemiology study being conducted by SCCWRP with EPA support to assess health risks and illness/indicator relationship in marine beach primarily impacted by untreated human wastewater (as compared to treated human sources from other marine studies). Avalon beach is affected by a mix of sources of fecal contamination including bird droppings, urban runoff and leaking sanitary sewers (including failing infrastructure and leaking collection systems). Water samples are tested for <i>Enterococcus</i> qPCR, <i>Bacteroides</i> qPCR, <i>Bacteroides thetaiotamicon</i> qPCR, and coliphage by antibody assay. The study design is based on EPA's current marine study design. The intent is for data to be combined for future analysis. This study is part of a three beach "suite" in California. SCCWRP will ultimately have data from a beach that is predominantly impacted by animal fecal contamination (Doheny) and a beach predominantly impacted by a mixture of animal and human fecal contamination (Malibu). This data set could help EPA understand differences in illness rates under different source conditions in the same geographic/climatic region. The SCCWRP studies are receiving EPA technical input to ensure the usability of the information developed. Study will have a multi-station sampling grid similar in design to the NEEAR studies with multiple samples taken each day to capture local temporal and spatial variability.	2007 □ 2009
1 — 4	Conduct epidemiologic study (ies) and/or QMRA to characterize the indicator-illness relationship at a freshwater beach impacted by agricultural animal sources of fecal contamination for comparison to those obtained at POTW-impacted beaches (location to be determined) (P4)	Evaluate the ability of indicators to predict swimming-associated illness and compare the results with those at POTW-impacted beaches. Use a prospective cohort approach where feasible. Collect information to support predictive modeling. Study will have a multi-station sampling grid with multiple samples taken daily to capture local temporal and spatial variability.	2009 □ 2010
1 — 4	Conduct epidemiologic study in fresh or marine waters	Evaluate the ability of indicators to predict swimming-associated illness and compare the	2009 □ 2010

GOALS ADDRESSED BY RESEARCH	PROJECT TITLE	RESEARCH DESCRIPTION	START DATE/END DATE
	impacted by urban runoff and/or conduct QMRA analysis (P5)	results with those at POTW-impacted beaches. Use a prospective cohort approach where feasible. Collect information to support predictive modeling. Study will have a multi-station sampling grid with multiple samples taken daily to capture local temporal and spatial variability.	
1 — 4	Conduct epidemiology study on POTW-impacted marine waters (location to be determined) (P6)	Conduct epidemiologic study at a POTW-impacted beach to increase statistical power, and/or at a location similar to one of the previous marine studies or at a location in -between to account for geographic differences to assess indicator illness. Utilize the same prospective cohort approach and same study design. Study will have a multi-station sampling grid with multiple samples taken daily to capture local temporal and spatial variability.	2008 <input type="checkbox"/> 2010
1, 4	Determine data/components needed (e.g., monitoring and exposure) for QMRA applications (P7)	The overall objective of this project is to identify the data and information that will be needed to use QMRA techniques to interpret and interpolate the epidemiologic data that EPA expects to have available by 2011, and if necessary extrapolate to conditions for which specific epidemiologic data have not been collected or are not planned. A research team experienced with QMRA and recreational water will collaborate with EPA scientists and epidemiologists to identify critical data and information to support QMRA, evaluating how data from epidemiologic studies can be utilized, and identify additional data could be collected in concert with the planned epidemiologic studies to leverage the interpretation of those studies via QMRA for interpolation and/or extrapolations. For example, epidemiologic studies of recreational waters typically relate water quality characteristics (density of indicator organisms) to the probability of illness among recreators, and to interpret these studies via QMRA, additional data (such as the volume of water ingested during recreational activities and the critical etiologic agents) may need to be collected as part of and/or in parallel with the planned epidemiologic studies. Study will consider site-specific spatial and temporal sampling conditions that will be required in QMRA to assess swimmer exposure to indicators/pathogens.	2007 <input type="checkbox"/> 2008
Site Characterization Studies			
2 — 4	Study various parameters that affect performance of qPCR signal for enterococci and compare with other methods and pathogens in treated wastewater mixed with ambient waters (enterococci, <i>E. coli</i> , <i>Cryptosporidium</i> , and enterovirus) (P8)	The objective of this project is to understand what happens to the <i>Enterococcus</i> qPCR signal during wastewater treatment, after release into the environment and relationship of the <i>Enterococcus</i> qPCR signal to other indicators and pathogens. This project is important because it will establish whether and under what conditions EPA could recommend that States use <i>Enterococcus</i> qPCR as an indicator/method in new or revised criteria that is scientifically defensible for the broad CWA uses of criteria, including NPDES permitting of wastewater treatment plans. Understanding if and how the qPCR signal changes as a result of different kinds of wastewater treatment, and the relationship between treatment and what is found in the water at end-of-pipe, will allow EPA to understand the controls that would need to be in place during treatment to meet the criteria at the beach. This study will evaluate the fate of enterococci, <i>E. coli</i> , and F-specific (F+) coliphage as well as specific pathogens (enterovirus and <i>Cryptosporidium</i>) through wastewater treatment. In addition, the decay of the indicators	2008 <input type="checkbox"/> 2009

GOALS ADDRESSED BY RESEARCH	PROJECT TITLE	RESEARCH DESCRIPTION	START DATE/END DATE
1 — 3	Collect data and conduct source and site characterization evaluations at potential study sites to determine the extent of specific animal sources, and factors influencing the extent to which they would contribute to fecal contamination at the beach (P9)	<p>will after treatment be examined after mixing with surface water under laboratory conditions.</p> <p>This project will generally address the need to characterize non-human sources, e.g. animals, and conditions in watersheds that can result in pathogen contamination of recreational waters. This activity would contribute to the hazard identification and exposure assessment steps of a QMRA. Simple models that correlate watershed activities (presence of treatment plant effluents, types of agricultural activities, and domesticated animals) and attributes (slope, soil type, vegetation cover, climate, soil moisture) will be used to determine the susceptibility of a watershed to pathogen impairment. Geographic Information System (GIS)-based software such as Digital Watershed and available beach survey data will be used to examine land use patterns in a watershed and help evaluate, for example, whether animal sources are present. Factors that modulate contributions of animal wastes to pathogen loads in watersheds and adjacent recreational waters coupled with meteorological factors (e.g., rainfall, wind speed/direction, etc.) will also be investigated. Source differentiation assays for human and bovine fecal matter being developed and evaluated as a part of this Science Plan, as well as other assays (e.g., avium) available in the published literature or being independently developed externally, could be used along with traditional fecal indicator measures, to characterize the potential fecal input from animal feeding operations and pastures. Short-term spatial and temporal variability will be captured by multi-sample station grids and multiple samples taken during the day that would impact on assessing exposure risks.</p>	2008 □ 2009
2 — 4	Expand spatial scale of collection of site-specific data at epidemiology study locations to characterize watershed and support research into development of predictive models and QMRA (P10)	<p>This project will build on the base studies to provide more extensive fecal indicator and hydrometeorological and biogeochemical data to develop predictive models that can be used to predict fecal indicator levels based on weather and physical/chemical water characteristics and provide the opportunity to assess any potential direct correlation between weather/physical water characteristics data and health effects being documented in the epidemiologic studies. This project will also allow for development of models which extrapolate potential for health effects in geographic areas which possess some common characteristics of the settings of epidemiologic study locations, based on correlations between weather and other data with health effects at epidemiology study sites. GIS-based software such as Digital Watershed and available beach survey data will be used to identify the sites for the expanded studies. Where possible, measurement of the hydrometeorological data will be automated with equipment that is compatible with data loggers to increase frequency and reduce man-hours required for data collection. Parameters such as current velocity and direction, water temperature, wave height, tides, irradiance, turbidity, salinity, carbonate dissolved organic matter, and chlorophyll all can be logged automatically. The project also will use data from nearby National Oceanic and Atmospheric Administration (NOAA) National Data Buoy Center observation stations and the Weather Service to help develop models that nowcast and forecast fecal indicator levels at the epidemiologic sites. Data will help inform the</p>	2007 □ 2009

GOALS ADDRESSED BY RESEARCH	PROJECT TITLE	RESEARCH DESCRIPTION	START DATE/END DATE
1 — 3	Conduct site and source characterization studies to better understand the factors influencing the contribution of untreated sources (e.g., urban runoff) to total fecal contamination to ambient waters (P11)	spatial and temporal variables impact beaches. These variables will be used to determine sampling locations and sampling times/frequencies for QMRA and new or revised criteria. If an additional epidemiologic study is necessary EPA will use the site/source characterization study to select the study location based upon the site selection criteria, and/or revise study design. Data will inform sampling requirements to capture spatial and temporal variability based on upstream fecal contamination.	2008 <input type="checkbox"/> 2009
3, 4	Design and evaluate a monitoring approach that will characterize the quality of beach waters that takes into account the spatial and temporal variability associated with water sampling (P12)	Utilize data from the literature, e.g., the EMPACT study, or develop new data, as needed for molecular methods, to provide sufficient information for use by a limited number of experts to design a sampling plan or plans at a focused workshop. Future EPA epidemiology studies and other related studies will incorporate multi-site grids with multiple samples taken each day in epidemiology studies. These will be used to determine how temporal and spatial sampling will be used for future ambient recreational water quality criteria.	2008 <input type="checkbox"/> 2009
3, 4	Develop, refine and evaluate quantitative sanitary investigation method - sanitary survey protocol for recreational waters (P13)	The sanitary survey protocol should provide users with a set of tools to help them determine sources of bacterial contamination. This information can be used to make better informed decisions on remediation. The protocol and set of tools should be broad enough and in modular form so that it can be applied to all geographies and beach environments, and flexible enough to provide a variety of tools to be used if resources are limited. Sanitary inspections will consider sampling of upstream waters to quantify the contribution of fecal contamination that will impact beaches and the spatial and temporal factors that will need to be considered in criteria informed by the sanitary inspections. The approach to develop these tools is: 1) Analyze results of Great Lakes Beach Sanitary Survey Pilot Project with some of the following questions in mind: -identification of specific avenues of investigation that produce results in the most cases, if there are any. -identification of structure of survey forms and database that is easiest to use and understand, 2) Assess on-going beach sanitary survey activities non Great Lakes waters. (two inland water beach sanitary surveys, three west coast marine, three east coast marine, and four tropical marine). -identify approaches in a variety of geographies and climates, -identify approaches with a spectrum of resource availability (national data coverage may or may not be available, local information on septic tanks or storm water infrastructure may or may not be available, manpower for field investigations may or may not be available). (In other words, does the simple stuff work as well as the high tech stuff?) 3) Combine results of above assessments into a nationwide protocol and set of tools.	2009/2009
2 — 4	Pilot sanitary survey in Great Lakes (P14)	This project is a 3-year effort to design and implement beach sanitary surveys in Great Lakes	2006 <input type="checkbox"/> 2008

GOALS ADDRESSED BY RESEARCH	PROJECT TITLE	RESEARCH DESCRIPTION	START DATE/ END DATE
		recreational waters. Major milestones include: (1) developing a draft sanitary survey form and receiving comments from Great Lakes Beach Managers and public health officials; (2) developing grant criteria and award grants to States to pilot and implementing sanitary surveys; (3) pilot testing Beach Sanitary Survey Tool; (4) piloting the use of a data entry template to ensure consistent data entry for ease of data analysis; and (5) evaluating pilot studies and publishing a final beach sanitary survey tool for use by beach managers. Studies will consider spatial and temporal factors from fecal contamination events that will contribute to similar spatial and temporal variability at impacted beaches as reflected in criteria.	
Indicators/Methods Development and Validation Studies			
2 — 3	Evaluate multiple indicator/method combinations to develop quantifiable relationships (P15)	Multiple indicator/method combinations are being or will be tested in the marine epidemiology studies. The illness response to exposure relationship for each method will be compared to develop a quantifiable relationship among the results derived using the various indicator/method combinations. The relationships derived will serve as a basis for ensuring that results using the differing approaches can be compared to determine that similar risk levels are being attained.	2008 □ 2009
2, 3	Study the effects of sample holding time, sample storage, and preservation on sample integrity for future use (P16)	The objective of the study is to determine feasibility of using freezer-archived samples for determining quantitative relationships between levels of target deoxyribonucleic acid (DNA) sequences from new and/or improved water quality indicators and health data from the NEEAR epidemiologic studies. The effect of holding time of fresh samples on detection efficiency by qPCR will also be investigated. Analyses will be performed on freezer-archived water sample filter retentates and DNA extracts of water sample filter retentates from NEEAR epidemiologic studies using previously employed assays for target DNA sequences. Additional analyses will be performed on replicate freezer-archived sample filter retentates from common water samples after storage for incremental time periods. The results will be used to assess comparability of performance levels of the initial and subsequent analyses. Time point analysis (up to overnight) to investigate the effect of holding fresh samples on the qPCR signal will also be studied.	2007 □ 2008
2 — 4	Develop, refine, validate, and publish new ambient and wastewater test methods (P17)	Once the epidemiologic studies identify those indicator/methods that are better at predicting swimming-related illness, those methods will be further developed and validated through single- and/or multi-lab validation studies for monitoring in ambient water and wastewater. This activity involves considering those methods for promulgation in 40 Code of Federal Regulations (CFR) Part 136. Additionally, this activity involves developing an Alternate Test Procedure (ATP) protocol to facilitate addition of new molecular methods to Part 136 as methods mature. Included in this approach will be elements of training of the participant labs to ensure proper levels of understanding of the validation plan and protocols.	2008 □ 2011

GOALS ADDRESSED BY RESEARCH	PROJECT TITLE	RESEARCH DESCRIPTION	START DATE/ END DATE
2 — 4	Evaluate the suitability of individual combinations of indicators and methods for different CWA programs (P18)	The overall objective of this project is to identify and evaluate indicator/method combinations for their strengths and limitations with respect to fecal source identification (human, animal); performance in different waterbody types. The important features of each indicator/method will be described and the strengths and weaknesses of those features will be explained and evaluated. The ideal set of features will be proposed so that the indicator/methods can be compared to a hypothetical ideal indicator/method. The indicators/methods under consideration will be ranked for each feature with respect to ability to differentiate fecal sources, performance in different waterbody types, and appropriateness for different CWA purposes. EPA plans to use the results of this evaluation to inform the decisions regarding which indicator/methods will be included in the new or revised criteria and under what conditions those indicators/methods will be recommended.	2007 <input type="checkbox"/> 2008
1 — 3	Develop new and/or evaluate previously published source-identifying assays (P19)	This project will develop human-specific qPCR assays and evaluate the performance of these assays and other currently available qualitative and quantitative PCR-based methods designed to discriminate between human and non-human sources of fecal pollution. Performance measures will include specificity, sensitivity, precision and range of quantification, as well as genetic marker geographic continuity and abundance within and between human populations. Top performing qualitative PCR assays, providing evidence of human fecal pollution, will be recommended for use in epidemiology study site characterizations. If possible, qPCR assays will be recommended that prove useful in calculating a meaningful ratio of human to non-human fecal load in environmental samples.	2007 <input type="checkbox"/> 2008
1 — 4	Evaluate human assays with water samples with different levels of fecal contamination from wide geographic range to supplement site characterization and quantitative sanitary investigation (P20)	This project will assemble a collection of human fecal impacted water samples from across a wide geographic range and compare detection levels between select human-specific PCR assays and currently recommended water quality fecal indicators. Water samples will be collected from both fresh and marine sites where applicable with the goal of analyzing samples from each EPA region. Parallel tests will also be completed to measure <i>E. coli</i> and enterococci cell densities. Results from PCR studies will be compared to bacterial cell counts to characterize any relationships between human-specific genetic methods and culture-based fecal indicator approaches.	2008 <input type="checkbox"/> 2009
1 — 3	Evaluate genetic markers for cows to supplement the site characterization and quantitative sanitary investigation (P21)	This project will evaluate the performance of currently available ruminant- and cow-specific qualitative and quantitative PCR assays. Top performing qualitative PCR assays and if possible qPCR assays will be recommended for use in epidemiology study site characterizations. Select host-specific qualitative and quantitative PCR assays (maximum of 8 methods) will be evaluated in regards to specificity, sensitivity, precision and range of quantification, as well as genetic marker geographic continuity and abundance within and between host populations.	2008 <input type="checkbox"/> 2009
1 — 4	Re-analyze archived NEEAR samples for other indicators (depending upon the outcome of P16 and the	Determine quantitative relationships between absolute and/or relative levels of target DNA sequences from new water quality indicators and health data from previous epidemiologic	2008 <input type="checkbox"/> 2009

GOALS ADDRESSED BY RESEARCH	PROJECT TITLE	RESEARCH DESCRIPTION	START DATE/END DATE
	nature of the indicator/method) (P22)	studies based on analyses of freezer-archived samples. As many as eight new indicators, including presumptive human-specific indicators, several new <i>Bacteroides</i> species, <i>C. perfringens</i> and <i>E. coli</i> may be analyzed for in frozen archived samples from 2003, 2004, 2005 and 2007 NEEAR epidemiologic studies.	
Modeling			
2 — 4	Pilot test Virtual Beach model for beach notification and advisories/closures (P23)	This project is pilot testing models in current use in the Great Lakes, including the Virtual Beach model, to provide early warnings about fecal indicator levels that pose health risks to beach communities. The synthesized system will forecast fecal indicator levels as a function of time and location. The project is limited to two beaches in Lake Erie and Lake Michigan where the models will be validated for predicting culturable <i>E. coli</i> or fecal enterococci. Statistical models for static and dynamic nowcasting of indicator bacteria at beaches will be refined using observations of variables by buoy/sonde, current instrumentation and optical systems and meteorological data. These observations include water quality and dynamic variables (temperature, turbidity, currents, density stratification), optical (UV and visible irradiance, light scattering) and meteorological (wave height, wind speed, rainfall) parameters. Other studies will be pursued in conjunction with NOAA forecasts of the environmental and meteorological variables that are used as model inputs, to forecast exceedance of recreational water standards a day in advance.	2007 <input type="checkbox"/> 2008
2 — 4	Refine and validate existing water quality models for freshwater beach notification and advisories/closures (P24)	This project will validate the ability of Virtual Beach and other selected statistically-based predictive models in current use from our base studies to provide early warnings about fecal indicator levels that pose health risks to a wider range of beach communities that are affected by POTWs around the Great Lakes. Five beaches in the Great Lakes will be selected for modeling in collaboration with Region 5 and local State and municipal beach managers. GIS-based software such as Digital Watershed and available beach survey data will be used to identify the POTW-impacted beaches. In all beaches, models will be developed for predicting either culturable <i>E. coli</i> , or fecal enterococci. One beach will be used for predicting culturable <i>E. coli</i> , fecal enterococci and <i>Enterococcus</i> qPCR detection methods. Models including the Virtual Beach model for static and dynamic nowcasting and forecasting of indicator bacteria at beaches, along with other modeling configurations being successfully used in the Great Lakes will be integrated to include observations of variables by buoy/sonde, current instrumentation, optical systems and meteorological data that will be automated where possible. Predictive models will be developed to evaluate concentrations of fecal indicator bacteria measured by culturable and qPCR methods at several points in a POTW-contaminated stream (Salt Creek) in a small catchment that runs into beach areas along southern Lake Michigan.	2007 <input type="checkbox"/> 2008
2 — 4	Refine and validate other existing water quality models for marine beach notification and advisories/closures (P25)	This project will evaluate the ability of Virtual Beach and other selected predictive models from our base studies to provide warnings with an acceptable level of statistical reliability about fecal indicator levels that pose health risks to coastal marine beach communities that are	2008 <input type="checkbox"/> 2009

GOALS ADDRESSED BY RESEARCH	PROJECT TITLE	RESEARCH DESCRIPTION	START DATE/ END DATE
		affected by POTWs and other sources. The project will be applied to at least two marine beaches to be selected in collaboration with Region 4, Region 9, and Region 10 (or others) and local State and municipal beach managers. GIS-based software such as Digital Watershed and available beach survey data will be used to identify the POTW-impacted beaches. Models will be developed at all study beaches for predicting (nowcasting and forecasting) culturable <i>E. coli</i> , fecal enterococci and one beach for predicting culturable <i>E. coli</i> or fecal enterococci and <i>Enterococcus</i> qPCR detection methods. The predictive models for static and dynamic nowcasting and forecasting of indicator bacteria at beaches will include in their statistic bases observations of variables by buoy/sonde, current instrumentation, optical systems and meteorological data that will be automated where possible. Observations to be made in the project include water quality and oceanographic variables (tides, salinity, temperature, turbidity, currents, density stratification, wave height), optical (UV and visible irradiance, light scattering) and meteorological (humidity, clouds, temperature, wind, rainfall) parameters. EPA will pursue other studies regarding the ability of NOAA forecasts of the environmental and meteorological variables that are used as model inputs to forecast exceedance of recreational water standards a day in advance. These studies will include evaluation of the accuracy of the forecasts as a function of distance of the weather station from the beach of interest relative to the parameters measured in situ during sampling events.	
4	Develop technical protocol for site-specific application of predictive models to be used in making beach advisory decisions (P26)	Develop a guide to assist States and localities in using Virtual Beach and other predictive models in their beach advisory programs to support criteria implementation.	2009/2009
Appropriate Level of Public Health Protection			
1 — 4	Compare 1986 to NEEAR to better understand the relationship between fecal contamination and illness in these data sets (P27)	Obtain raw data from the 1986 studies (if available). Conduct statistical analysis to control for known differences in the two studies such as recall period, age distribution background illness rates, and illness definition to attempt to create comparable definitions. Once comparable illness definitions are created, it may be possible to use this information to determine adjusted "new" acceptable risk levels that do not exceed those from 1986, accounting for differences in the studies.	2009 2010
3, 4	Evaluate applicability of NEEAR Great Lakes data to inland waters (P28)	Assess the similarities and differences between coastal freshwaters and inland freshwaters to establish whether there are or not significant differences to justify additional studies to support applicability of criteria to inland waters. Additional studies could include an epidemiology study or QMRA application in flowing inland water.	2008 2009
1	Conduct statistical analysis of children data from epidemiologic studies (P29)	Conduct statistical analyses of data collected for children during epidemiologic studies to determine if there is a significant difference in risk to children.	2007 2010
Literature Reviews			
1	Conduct state-of-the-science reviews of published	Search the epidemiologic literature (international and domestic journals and government	2007/2007

GOALS ADDRESSED BY RESEARCH	PROJECT TITLE	RESEARCH DESCRIPTION	START DATE/ END DATE
	studies to characterize relative risks from different sources (P30)	reports) for references to illness resulting from exposure to fecal materials from a variety of sources. Particular emphasis will be placed on animal-derived waste. The literature information will be evaluated to determine the extent to which it supports characterization of differences in illness resulting from exposure to waters contaminated with fecal material from different sources. While recreational exposures are the primary focus, attention should also be paid to contaminated drinking water and reported illness. Report detailing the studies identified and an evaluation of what they indicate relative to illness resulting from exposure to different sources of fecal contamination.	
1	Conduct state-of-the-science review on occurrence and cross-infectivity of specific pathogens associated with animals (P31)	Search available literature (international and domestic journals, waterborne disease outbreak surveillance reports, and other government reports) on organisms that occur in ambient waters that are pathogenic to humans, which of these organisms are also present in animal populations, and the extent to which strains found in animals can be transmitted to humans. The product will be a report discussing the issues above with an evaluation of the extent to which the information identified can be used to support the differentiation of risk from animal and human sources of fecal contamination.	2007/2007
4	Conduct literature review, and evaluate and interpret available data on indicator behavior in tropical climates (e.g., water, sand and sediments) (P32)	Determine the extent to which indicators perform differently in a tropical environment compared to a temperate environment, investigate the underlying cause if a difference is identified, and consider possible alternative indicators for future development as deemed appropriate. The domestic and international literature will be searched to identify relevant articles and reports that discuss and evaluate the extent to which indicator organisms and other accompanying organisms derived from fecal sources are impacted by temperature regime (e.g., temperate vs. tropical). In addition, the literature will also be queried for information on what other parameters, such as resuspension or regrowth, may impact the amount of indicators measured in compliance monitoring. Finally, the review will consider potential alternative indicators that may provide more meaningful results in tropical environments if the current indicators are determined to be limited in application in a tropical environment.	2007/2007

Note: Codes (P1–P32) refer to an arbitrarily assigned project number.

Table 3-2. Overview of Proposed Near-term Research Activities to Support Development of New or Revised Recreational Criteria¹

Broad Research Category	Completed	2007	2008	2009	2010
Epidemiology Studies/QMRA	Great Lakes NEEAR freshwater studies Incomplete marine study in Biloxi, MS			P1: Conduct epidemiologic study on POTW-impacted marine beach in Goddard, Rhode Island.	
				P2: Conduct epidemiologic study on POTW-impacted marine beach in Fairhope, Alabama.	
				P3: Support epidemiologic study at a beach in Avalon, CA considered to be primarily impacted by untreated human fecal contamination.	
				P4: Conduct epidemiologic study(ies) and/or QMRA to characterize the indicator-illness relationship at a freshwater beach impacted by agricultural animal sources of fecal contamination for comparison to those obtained at POTW-impacted beaches.	
Site Characterization	P14: Pilot Great Lakes sanitary survey			P5: Conduct epidemiologic study in fresh or marine waters impacted by urban runoff and/or conduct QMRA analysis.	
			P6: Conduct epidemiology study on POTW-impacted marine waters.		
			P7: Determine data/components needed (e.g., monitoring and exposure) for QMRA applications.		
			P8: Study various parameters that affect performance of qPCR signal for enterococci and compare with other methods and pathogens in treated wastewater mixed with ambient waters (enterococci, <i>E. coli</i> , <i>Cryptosporidium</i> , and enterovirus).		
			P9: Collect data and conduct source and site characterization evaluations at potential study sites to determine the extent of specific animal sources, and factors influencing the extent to which they would contribute to fecal contamination at the beach.		
			P10: Expand spatial scale of collection of site-specific data at epidemiologic study locations to characterize watershed and support research into development of predictive models and QMRA.		
				P11: Conduct site and source characterization studies to better understand the factors influencing the contribution of untreated sources (e.g., urban runoff) to total fecal contamination to ambient waters.	

¹ Note: The timeline for epidemiologic studies includes study design, study initiation and completion, data analysis, peer review, and publication.

Broad Research Category	Completed	2007	2008	2009	2010
Indicators/Methods Development and Validation	Test methods through epidemiology studies Conduct lab validation of enterococci qPCR in freshwater Publish wastewater culture method for enterococci and E. coli in 40 Code of Federal Regulations (CFR) Part 136	P12: Design and evaluate design a monitoring approach that will characterize the quality of beach waters that takes into account temporal and spatial variability associated with water sampling.			
		P13: Develop, refine and evaluate quantitative sanitary investigation tools/protocols.			
		P14: Pilot sanitary survey in Great Lakes.			
			P15: Study equivalency between enterococci qPCR and various indicators and methods.		
		P16: Study the effects of sample holding time, sample storage, and preservation on sample integrity for future use.			
			P17: Develop, refine, validate, and publish new ambient and wastewater test methods.		
		P18: Evaluate the suitability of individual combinations of indicators and methods for different CWA programs.			
		P19: Develop new and/or evaluate of previously published source-identifying assays.			
			P20: Evaluate human assays with water samples with different levels of fecal contamination from wide geographic range to supplement site characterization and quantitative sanitary investigation.		
			P21: Evaluate genetic markers for cows to supplement site characterization and quantitative sanitary investigation.		
			P22: Re-analyze archived NEEAR samples for other indicators (depending on the outcome of P16 and the nature of the indicator/method)		

Broad Research Category	Completed	2007	2008	2009	2010
Modeling	Virtual Beach model and other existing models	P23: Pilot test Virtual Beach model for beach notification and advisories/closures			
		P24: Refine and validate other existing water quality models for freshwater beach notification and advisories/closures.			
			P25: Refine and validate other existing water quality models for marine beach notification and advisories/closures.		
				P26: Develop technical protocol for site-specific application of predictive models to be used in making beach advisory decisions.	
Appropriate Level of Public Health Protection	Analysis of Great Lakes NEEAR freshwater epidemiology data for general population and subgroups (e.g., children and elderly)			P27: Compare 1986 to NEEAR data to better understand the relationship between fecal contamination and illness in these data sets.	
			P28: Evaluate applicability of NEEAR Great Lakes data to inland waters.		
		P29: Conduct statistical analysis of children data from epidemiologic studies.			
Literature Reviews		P30: Conduct state-of-the-science review of published studies to characterize relative risks from different.			
		P31: Conduct state-of-the-science review on occurrence and cross-infectivity of specific pathogens associated with animals.			

Broad Research Category	Completed	2007	2008	2009	2010
		P32: Conduct literature review and evaluate and interpret available data on indicator behavior in tropical climates (e.g., water, sand and sediments).			

Note: Codes (P1 – P32) refer to an arbitrarily assigned project number.

