CRITICAL PATH SCIENCE PLAN

FOR THE DEVELOPMENT OF NEW OR REVISED RECREATIONAL WATER QUALITY CRITERIA

Office of Water
Office of Research and Development

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ACRONYMS AND ABBREVIATIONS

AL	Alabama
ATP	Alternate Test Procedure
AWQC	ambient water quality criteria
BEACH Act	Beaches Environmental Assessment and Coastal Health Act
BMP	Best Management Practices
CA	California
CFR	Code of Federal Regulations
CPSP	Critical Path Science Plan
CWA	Clean Water Act
DNA	deoxyribonucleic acid
EMPACT	Environmental Monitoring for Public Access and Community Tracking Study
EPA	U.S. Environmental Protection Agency
GI	gastrointestinal
GIS	Geographic Information System
MS	Mississippi
NEEAR	National Epidemiological and Environmental Assessment of Recreational Water Study
NOAA	National Oceanic and Atmospheric Administration
NPDES	National Pollutant Discharge Elimination System
PCR	polymerase chain reaction

POTW	publicly-owned treatment works
QMRA	Quantitative Microbial Risk Assessment
qPCR	quantitative polymerase chain reaction
RI	Rhode Island
SCCWRP	Southern California Coastal Water Research Project
TMDL	Total Maximum Daily Load
URI	upper respiratory illness
U.S.	United States
USGS	United States Geological Survey
UV	ultraviolet
WQS	water quality standard
WWTP	Wastewater Treatment Plant

CHAPTER 1 INTRODUCTION

On October 10, 2000, the Beaches Environmental Assessment and Coastal Health Act (BEACH Act) was signed into law, amending the Clean Water Act (CWA). Two of the major provisions of the BEACH Act are CWA sections 104(v) and 304(a)(9), which together require the U.S. Environmental Protection Agency (EPA) to conduct studies associated with pathogens and human health and to publish new or revised recreational water quality criteria for pathogens and pathogen indicators based on those studies. These criteria will be used by States, Territories, and Tribes to develop their water quality standards (WQS). EPA has conducted a significant amount of research since the BEACH Act was enacted and is now in the process of defining what additional studies EPA will conduct in order to issue new or revised CWA criteria by 2012.

1.0 PURPOSE AND SCOPE

Since EPA issued its current recreational water quality criteria over 20 years ago, there have been significant scientific advances, particularly in the areas of molecular biology, virology and analytical chemistry. EPA believes these new scientific and technological advances need to be considered and evaluated for feasibility and applicability in the development of new or revised criteria for pathogens and pathogen indicators. To this end, EPA has conducted a significant amount of research including developing new methods for measuring microbiological organisms in water and conducting epidemiologic studies to provide the scientific foundation for new or revised criteria. However, these studies are only a part of what is needed. EPA's review of existing research and science has raised a series of significant questions that need to be answered in order for EPA to move forward with criteria development. These questions are presented and discussed in Chapter 3.

To address these questions, EPA has engaged a range of stakeholders representing the general public, public interest groups, State and local government, industry, and municipal wastewater treatment professionals. Based on their feedback as well as detailed input and recommendations from the scientific community, the Agency has developed a *Critical Path Science Plan for Development of New or Revised Recreational Water Quality Criteria* (CPSP or Science Plan). The purpose of the CPSP is to articulate the essential research and science that EPA will conduct between 2007 and the end of 2010 to establish the scientific foundation for new or revised recreational water quality criteria to protect swimming in waters designated by a State for that use (referred to in this document as "recreational water quality criteria" or "recreational criteria"). The CPSP also describes studies for which EPA is providing financial and/or technical support. The specific near-term critical research and science needs described in the Science Plan were informed by the individual input of the 43 international and U.S. experts who attended a scientific workshop held by EPA in March 2007 at the Airlie Center in Warrenton, Virginia. Near-term needs were defined as specific research and science activities that could be accomplished in 2 to 3 years to support development of new or revised criteria by 2012. The

Report of the Experts Scientific Workshop on Critical Research Needs for the Development of New or Revised Recreational Water Quality Criteria is available online at www.epa.gov/waterscience. The CPSP represents an integrated approach to answering the key questions that EPA believes need to be addressed to ensure that the new or revised criteria are scientifically sound. EPA recognizes, however, that the outcome of one study may affect the design and implementation of those that follow. Therefore, some contingencies have been identified in this Science Plan to accommodate unexpected outcomes, and it is acknowledged that others may arise that have not been foreseen.

1.1 STATUTORY BACKGROUND AND PURPOSE OF EPA'S RECOMMENDED WATER QUALITY CRITERIA

Section 304(a)(1) of the CWA directs EPA to publish recommended water quality criteria reflecting the latest scientific knowledge on the effects of the presence of pollutants in water on health and welfare. The criteria published by EPA under section 304(a) are intended to provide guidance to States in setting WQS to protect public health as well as to maintain and restore water quality and ecosystem integrity.

CWA section 303 requires each State to adopt WQS for all waters of the State and to review, and revise them as necessary, every 3 years. A WQS is a method of expressing the desired condition of a water body. Such standards consist of three main elements: (1) one or more designated "uses" of each of the State's waters, such as recreation or propagation of fish; (2) "criteria" expressed as pollutant concentration levels or narrative statements representing a quality of water that supports a designated use; and (3) an anti-degradation policy to protect existing uses and high quality waters. WQS serve the dual purposes of establishing the water quality goals for a specific water body and serve as the regulatory basis for the establishment of water-quality-based treatment controls and strategies beyond the technology-based levels of treatment required by sections 301(b) and 306 of the CWA. In the case of WQS for pathogens or pathogen indicators to protect the swimming use of waters, States also use WQS in their beach monitoring and notification programs.

The BEACH Act was enacted on October 10, 2000. It amended the CWA in part by adding Section 304(a)(9)(A), which provides:

> "Not later than 5 years after the date of the enactment of this paragraph, after consultation and in cooperation with appropriate Federal, State, tribal, and local officials (including local health officials), the Administrator shall publish new or revised water quality criteria for pathogens and pathogen indicators (including a revised list of testing methods, as appropriate), based on the results of the studies conducted under section 104(v), for the purpose of protecting human health in coastal recreation waters."

Section 104(v) of the CWA was also enacted as part of the BEACH Act. It provides that EPA "shall initiate, and not later than 3 years after the date of enactment" of the BEACH Act, "complete . . . studies to provide additional information for use in developing —

(1) an assessment of potential human health risks, resulting from exposure to pathogens in coastal recreation waters, including non-gastrointestinal effects;
(2) appropriate and effective indicators for improving detection in a timely manner in coastal recreation waters of the presence of pathogens harmful to human health;
(3) appropriate, accurate, expeditious, and cost-effective methods (including predictive models) for detecting in a timely manner in coastal recreation waters the presence of pathogens that are harmful to human health; and
(4) guidance for State application of the criteria for pathogens and pathogen indicators to be published under section 304(a)(9) to account for the diversity of geographic and aquatic conditions."

1.2 PURPOSE OF WATER QUALITY CRITERIA COMPONENTS OF STATE WATER QUALITY STANDARDS

Water quality criteria when adopted into State WQSs play a critical role in implementing a range of essential purposes and functions under the CWA.

Water Quality Assessments. Sections 303(d) and 305(b) provide that States are required to assess their waters on a regular basis to determine if they are meeting WQS. The States' water quality criteria are an essential baseline against which States determine whether particular waters are "impaired."

Total Maximum Daily Loads. Total maximum daily load (TMDL) calculations are required for all waters that have been listed as "impaired" under section 303(d). A TMDL specifies the maximum amount of a pollutant that a waterbody can receive and still meet WQS, and "allocates" pollutant loadings among point and non-point pollutant sources. TMDL calculations for impaired waters must be written to implement the applicable State WQS.

National Pollutant Discharge Elimination System (NPDES). NPDES permits are required under section 402 for point source discharges of pollutants to waters of the United States. NPDES permits must include effluent limitations more stringent than required by technology regulations if necessary to meet water quality standards, which include State water quality criteria.

Non-point Source Program. Water quality standards (including criteria) play a similarly important role under the CWA section 319 non-point source program as part of the listing and TMDL processes outlined above to determine whether best management

practices (BMPs) or other risk management control strategies are needed to address non-point source pollution.

Recreational Water Monitoring and Notification. A State's recreational water quality criteria are used in beach monitoring and notification programs. States and beach managers typically make decisions about whether to issue advisories or closure notices by measuring the results of their monitoring against their WQS.

1.3 GOALS OF EPA'S SCIENTIFIC RESEARCH

The studies that EPA is to conduct under CWA section 104(v) are to provide additional information for developing (1) an assessment of potential health risks resulting from exposure to pathogens; (2) appropriate and effective indicators of the presence of pathogens; (3) appropriate, accurate, expeditious, and cost-effective methods for detecting the presence of pathogens; and (4) guidance for State application of any new or revised criteria to account for diversity of geographic and aquatic conditions. The results of these studies will support EPA's development of new or revised water quality criteria under CWA 304(a) to protect public health in waters designated by States for swimming (i.e., recreational waters). Below is a general summary of the goals of EPA's scientific research which are consistent with the requirements of section 104(v).

1. **Assessment of Human Health Risk**. Conduct research (e.g., epidemiologic studies and quantitative microbial risk assessment [QMRA]) to allow for an assessment of potential human health risks (including non-gastrointestinal effects) in the general population, including children, from swimming-related exposure to different sources of fecal contamination (human versus non-human).

2. **Development of Indicators.**[1] Conduct research to identify appropriate indicators of fecal contamination to allow for a reliable correlation between indicator concentrations and health effects. Develop studies to evaluate temporal and spatial variability in indicator concentrations to appropriately characterize water quality and inform recreational water quality management decisions.

3. **Development of Methods.**[2] Conduct research to develop, evaluate and validate appropriate methods to measure indicators of fecal contamination to allow for a reliable correlation between indicator concentrations and health effects. Assess linkages between indicators and methods to ensure that they will be protective of the swimming use when implemented singly or in combination.

4. **Extrapolation of Research Results for Developing New or Revised Criteria.** Conduct appropriate studies to assess the influence of variability in geographic and aquatic

[1] Research on indicators and methods are discussed together in Chapter 3 (Section 3.2).
[2] Research on methods (including models) is discussed in Chapter 3 (Sections 3.2 and 3.3).

conditions on indicator and method performance, and assess the suitability of indicators and methods for various CWA purposes (e.g., beach monitoring, assessments, TMDLs, and permitting). Develop, evaluate and validate predictive models and tools to understand the extent to which data from epidemiologic study sites can be extrapolated to other geographic locations and aquatic conditions; and examine the role of models as a tool in predicting water quality problems to assist in new or revised criteria implementation.

The requirements in CWA sections 104(v) and 304(a)(9)(A) are for studies and water quality criteria related to "coastal recreation waters" as defined in section 502(23) of the CWA (i.e., marine coastal waters, coastal estuaries, and Great Lakes waters). However, some of the studies included in this Science Plan would be used to support the development of recommended water quality criteria that applies to both coastal recreational waters and inland waters designated for swimming.

CHAPTER 2 DEVELOPMENT OF THE CRITICAL PATH SCIENCE PLAN

2.0 SUMMARY OF EPA RESEARCH ALREADY COMPLETED

2.0.1 Early Studies

Current 304(a) recreational water quality criteria are based on epidemiologic studies conducted by EPA in the 1970s and 1980s. The currently recommended indicators are based on methods that involve culturing and enumerating fecal indicator bacteria (*Enterococcus spp*. or *E. coli)*. One shortcoming of these methods is that the bacteria require at least 18 to 24 hours to grow visible colonies for subsequent enumeration. Recent research indicates that the quality of water that is impacted by fecal contamination can change rapidly, and thus, criteria based on indicator organisms and associated methods that require 18 hours or more to produce results can lead to either unnecessary beach closings or the exposure of swimmers to water of poor quality.

Since the enactment of the BEACH Act, EPA has undertaken several significant studies designed to improve the scientific basis for recreational water quality criteria. Each study is discussed below.

2.0.2 National Epidemiological and Environmental Assessment of Recreational Water Study

EPA's National Epidemiological and Environmental Assessment of Recreation (NEEAR) Water Study is a collaborative research study between EPA and the Centers for Disease Control and Prevention (CDC). EPA also coordinated this study with the U.S. Geological Survey (USGS) and other interested agencies. A primary goal of this study is to establish a health-based relationship between indicators of fecal contamination and swimming-associated illness as measured by a variety of methods, including timely molecular methods. To date, four Great Lakes freshwater epidemiologic studies have been completed, one marine study[3] was started but halted due to hurricane conditions and two EPA-conducted marine epidemiologic studies (described in Chapter 3) are currently underway. The Great Lakes freshwater studies were the first to establish a relationship between the levels of fecal contamination in recreational waters (referred to in this document as "microbial water quality"), as measured by timely methods, and swimming-associated health effects occurring within 10 to 12 days after a beach visit. In these studies, molecular methods showed great promise for allowing beach managers to potentially make more timely decisions regarding the safety of beach waters on any given day.

[3]Marine study in Biloxi, Mississippi was halted because the beach study site was destroyed by Hurricane Katrina in 2005.

2.0.3 Environmental Monitoring for Public Access and Community Tracking Beaches Project

The Environmental Monitoring for Public Access and Community Tracking (EMPACT) Beaches Project (EPA, 2005) was designed to identify the characteristics of a beach environment that have a significant impact on microbial water quality monitoring results. Five beach environments were examined to determine the factors that most influence the measurement of microbial water quality at beaches. Two ocean beaches, an estuarine beach, a Great Lakes beach, and a riverine beach were selected to provide as broad a representation of beach environments as possible. The results indicated the following:

- The greatest single determinant of fecal indicator level was found to be the depth zone, or distance from the shoreline at which the sample was collected—fecal indicator concentrations were substantially lower as one moved from ankle-deep to knee-deep to chest-deep water;
- Significant declines in indicator densities from the morning to the afternoon were observed at four of the five study beaches; and
- There was significant variability over time so that measurements of indicators on any given day did not correlated to indicator levels on subsequent days.

2.0.4 Other Completed Studies

The following additional studies were critical to determining which indicators and methods were available for inclusion in the NEEAR study in the Great Lakes to provide timely quantification of fecal contamination.

- Method evaluation of off-the-shelf technologies for rapid methods for indicators of fecal contamination;
- Method development study of quantitative polymerase chain reaction (qPCR) methods for *Enterococcus* and B*acteroides*; and
- Completion of a chemical indicator study evaluating other chemical substances, including coprostanol, urobilin, caffeine, acetaminophen, cotinine and codeine as possible indicators of human fecal contamination (from wastewater).

EPA also completed related studies to allow for the use of the epidemiologic study results to: (1) develop a predictive modeling tool, and (2) understand whether the Great Lakes study results could be applied beyond the study locations to other freshwaters. These studies included:

- A study to develop a virtual beaches model intended to allow beach managers to collect and analyze explanatory variables and develop a beach prediction tool; and

- An evaluation of the aquatic matrix effects on the performance of the qPCR method in order to determine the method's applicability in freshwaters beyond the four Great Lakes test sites.

Additional information is needed to fulfill several important goals and objectives for new or revised criteria. For example, the relative health effects and associated risk levels from different sources of fecal contamination (e.g., human versus non-human sources of fecal contamination, and treated versus untreated or poorly treated human sewage) are not well understood and may vary significantly; the relationship between indicator organism concentrations and adverse health effects in different waterbody types are not well understood; the compatibility of existing culture methods with the newly developed rapid methods for indicator organisms is not sufficiently understood; and the optimization of sampling, recovery, and processing of samples using rapid methods is still under development.

2.1 CONSIDERATION OF STAKEHOLDER INPUT ON THE 1986 BACTERIA CRITERIA

Although EPA considers the science underlying the 1986 bacteria criteria to be superior to the science underlying the previously recommended criteria for fecal coliforms, some States have yet to adopt new or revised standards for inland waters based on the 1986 bacteria criteria. States and other stakeholders, including experts from the Experts Scientific Workshop have suggested that EPA consider the following recommendations in conducting studies and developing the new or revised criteria, based on their experience implementing the 1986 bacteria criteria.

- Provide clear, science-based guidance and flexibility regarding use of the single-sample maximum values (a feature of the 1986 criteria) and differing risk levels, or change the approach to include specific measures to assess water quality for both the short-term (beach closure/advisory decisions) and the long-term (attainment of the designated swimming use over a length of time).
- Consider the impact on transition from current criteria (e.g., fecal coliforms-based criteria or the 1986 bacteria criteria) to new criteria on impaired waters listings, existing bacteria TMDLs, and associated discharge permits; and develop tools, strategies, and policies to ease the transition.
- Develop EPA-approved analytical methods for use in both ambient and wastewater for the new indicator bacteria.
- Collect data or perform analysis to assess the applicability of the new bacteria criteria to flowing streams.
- Conduct research to quantify the risk associated with contributions from the range of non-human sources of fecal contamination, and incorporate flexibility to adjust the new criteria for water bodies that do not receive human sources of fecal contamination.
- Continue dialogue with States and other stakeholders during the development of the new bacteria criteria to keep them informed regarding the outcomes of the research and the effect on the criteria development approach.

2.2 EXPERTS SCIENTIFIC WORKSHOP AND REPORT

The *Experts Scientific Workshop on Critical Research and Science Needs for the Development of New or Revised Recreational Water Quality Criteria* took place at the Airlie Center in Warrenton, Virginia, from March 26 to March 30, 2007. Forty-three U.S. and international experts from academia, States, public interest groups, EPA, and other federal agencies, met to discuss the state-of-the-science on recreational water quality research and implementation issues.

The purpose of the workshop was for EPA to obtain input from individual members of the broad scientific and technical community on the "critical path" research and related science needs for developing scientifically defensible new or revised CWA Section 304(a)(9) recreational ambient water quality criteria in the near-term. Near-term needs were defined as those specific research and science activities that could be accomplished in the next 2 to 3 years so that results would be available to EPA in time to support development of new or revised criteria by 2012.

For additional information on the Experts Workshop Report and research identified by the experts, go to www.epa.gov/waterscience.

CHAPTER 3 KEY SCIENCE QUESTIONS EPA WILL RESEARCH UNDER THE CRITICAL PATH SCIENCE PLAN

3.0 PEER-REVIEW OF DRAFT CRITICAL PATH SCIENCE PLAN

In developing the Science Plan, EPA considered the research needs identified by the experts participating in the Experts Scientific Workshop. EPA then established its research priorities based on the most significant science questions, which EPA believes it can make significant progress toward answering in the next 2 to 3 years to support development of new or revised recreational criteria.

The research projects were described in a draft of the Science Plan which was peer reviewed by three scientific experts external to EPA.[4] The purpose of the peer review was to obtain expert feedback and comments on the clarity and scientific merit of the proposed research activities, and on the likelihood they can be completed in a 2- to 3-year period and meet EPA's goals and objectives for the new or revised criteria. In addition, EPA asked the peer reviewers whether or not the proposed research activities effectively addressed the science questions and research needs identified in the document, and to identify the noteworthy strengths and weaknesses of the proposed research activities. EPA requested that peer reviewers indicate any modifications that would improve upon any particular research project or upon the science plan in its entirety.

The reviewers provided beneficial and constructive input to EPA on the draft Science Plan. The reviewers confirmed that the epidemiologic studies, assay methodologies, fecal contamination source identification studies, QMRA methods, and other studies reflected a generally reasonable and effective approach to answering the research questions. They supported EPA's focus on research related to non-human sources of fecal contamination. They also indicated that the plan as outlined is achievable in the 2- to 3-year timeframe available. However, they suggested that EPA clarify the key goals and questions articulated in the Science Plan to increase understanding and transparency in the document (e.g., more clearly articulating the connection between the research projects and the goals, improving individual project descriptions and justifications, identifying how research results would be used and how the project results may interact). EPA concurred with many of these comments and has revised the Science Plan accordingly. EPA has clarified the key goals and key research questions as presented in section 1.3 as follows:

- Assessment of Human Health Risks (Goal 1, discussed in section 3.1)
    - *Key Research Question:* What is the risk to human health from swimming in water contaminated with human fecal matter as compared to swimming in water contaminated with non-human fecal matter?
- Development of Indicators (Goal 2) and Methods (Goal 3) (discussed in section 3.2)

[4] Peer review comments are available upon request.

  - *Key Research Question:* How well do culture and molecular methods for various indicators (singly or in combination) correlate with swimming-related illnesses?
- Extrapolation of Research Results for Developing New or Revised Criteria (Goal 4, discussed in section 3.3)
  - K*ey Research Question:* Are these indicators, methods and models suitable for use in different types of waters and for different CWA programs?

3.1 ASSESSMENT OF HUMAN HEALTH RISKS (GOAL 1)

EPA's current CWA 304(a) recommended criteria for bacteria are based on *E. coli* and enterococci as indicators of fecal contamination. These criteria were derived largely from the results of epidemiologic studies at beaches predominantly impacted by publicly-owned treatment works (POTWs) in the 1970's and 1980's. At that time, human sources of fecal contamination originating from POTWs were viewed as representing the highest relative risks to swimmers. While human fecal contamination may pose a higher risk, there are other sources of fecal contamination for which the risk is not well understood. These other sources include poorly- treated or untreated human fecal waste, and non-human sources of fecal contamination (e.g., fecal contamination from agriculturally important animals and wildlife in the watershed). Also, stormwater runoff in urban areas may represent a mixed source of human and animal fecal material. Animal sources in an urban setting may include domesticated and other animals such as geese.

There have been limited studies on poorly-treated or untreated human fecal contamination, and few studies on waters largely impacted by animal sources of fecal contamination. Many of these studies used different indicators of fecal contamination, various (qualitative to quantitative) approaches at differentiating sources of contamination, and different approaches or protocols to assess health effects in the study population. The lack of studies using similar study design and protocols focusing on various sources of fecal contamination represents a major data gap. As such, it is difficult to determine in a quantitative manner the relative risks of swimming-associated illness from various sources of fecal contamination. Specific uncertainties that EPA intends to address include:

- Understanding what human illnesses are caused by swimming in waters contaminated with human fecal matter from different sources, the levels of human fecal matter in these waters that cause human illness, and the relationship between different levels of human fecal matter in waters and human illness rates.
- Understanding what human illnesses are caused by swimming in waters contaminated with non-human fecal matter, the levels of non-human fecal matter in these waters that cause human illness, and the relationship between different levels of non-human fecal matter in waters and human illness rates.
- Understanding any differences in risk to children swimming in waters contaminated with fecal matter versus adults swimming in these waters.

3.1.1 Description of the Key Science Question

What is the risk to human health from swimming in water contaminated with human fecal matter as compared to swimming in water contaminated with non-human fecal matter?

The research described in this section addresses Goal 1 as outlined in section 1.3 and focuses on the following two areas:

- Risks from Human Sources of Fecal Contamination (Section 3.1.2)
- Risks from Non-Human Sources of Fecal Contamination (Section 3.1.3)

3.1.2 Risks from Human Sources of Fecal Contamination

3.1.2.1 Treated POTW Effluent

EPA conducted prospective cohort epidemiologic studies at four Great Lakes beaches impacted by treated wastewater discharges as part of the NEEAR studies. EPA included several indicators and methods of fecal contamination and assessed their relationship to the following non-enteric and enteric illnesses:

(1) gastrointestinal illness (GI) , defined as any of the following:
    a) diarrhea (3 or more loose stools in a 24-hour period), or
    b) vomiting, nausea and stomachache, or
    c) nausea or stomachache and impact on activity;
(2) upper respiratory illness (URI), defined as any two of the following: sore throat, cough, runny nose, cold, fever;
(3) rash;
(4) eye ailment, defined as either eye infection or watery eye; and
(5) earache.

Furthermore, EPA collected extensive demographic data which will allow for analysis of risk in various subpopulations, including children, relative to the general population.

Swimming-related GI rates were found to be significantly associated with fecal contamination (as measured by qPCR enterococci) in the Great Lakes NEEAR studies (Wade et al., 2006). EPA intends to conduct comparable studies (using the same site selection criteria and protocols and methods) at POTW-impacted marine beaches to determine if a similar indicator-illness relationship holds.

EPA initiated a marine epidemiologic study in Biloxi, MS in the summer of 2005 that was curtailed due to severe weather events caused by Hurricane Katrina. Although the study was insufficient in terms of sample size, it represents a source of additional data that can be analyzed along with data from ongoing and future epidemiologic studies. At this time, the lack

of similar epidemiologic studies in marine waters represents a data gap; EPA needs to determine whether the relationship between fecal contamination and illness, which was observed in the Great Lakes, is similarly applicable in marine waters. To address this gap, EPA intends to conduct the following research activities and projects:

- Conduct an epidemiology study at a POTW-impacted marine beach at Goddard, Rhode Island. (P1)[5]

- Conduct an epidemiology study at a POTW-impacted marine beach at Fairhope, Alabama. (P2)

- Conduct statistical analysis of children data (P29) to determine if there is a significant difference in risk in all epidemiologic studies.

- Compare 1986 to NEEAR data to better understand the relationship between fecal contamination and illness in these data sets (P27).

If the results of these studies do not yield sufficient statistical power or if the results between these studies (Alabama, Rhode Island, and Mississippi) are not consistent, then an additional epidemiologic study on POTW- impacted marine waters (P6) would be conducted.

When completed, these studies will fill a data gap and help EPA determine whether and how fecal contamination is associated with illness in marine waters. Detailed descriptions of each research activity can be found in Table 3–1, organized under a broad research category (e.g., epidemiology studies). Table 3–2 presents a timeline for these studies indicating when EPA expects to initiate and complete the studies. The timeline for epidemiology studies includes study design, study initiation and completion, data analysis, peer review, and publication.

3.1.2.2 Poorly Treated or Untreated Wastewater

Since past research efforts have largely focused on POTW-impacted waters, there have been few epidemiologic studies which have addressed the relative risks of illness associated with poorly or untreated human fecal matter. Addressing this gap has been the focus of the Southern California Coastal Water Research Project (SCCWRP). A prospective cohort epidemiology study is being conducted by SCCWRP with EPA support to assess health risks and illness-indicator relationships at a marine beach in California. 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). EPA is interested in this study as an example of a beach believed to be predominantly impacted by poorly/untreated human fecal contamination. Water samples are being tested for *Enterococcus* qPCR, *Bacteroides* qPCR, *Bacteroides thetaiotamicron* qPCR, and coliphage by antibody assay in addition to

[5] Codes (P1–P32) refer to an arbitrarily assigned project number.

traditional culture-based assays. The study design is largely based on EPA's current marine study design and the data could potentially be combined with EPA conducted studies for future analysis. Because the focus of this SCCWRP research is expected to help fill this gap, EPA does not intend to conduct any additional studies in this area.

SCCWRP is expected to ultimately generate data from two, other beaches: a beach that is predominantly impacted by animal fecal contamination (Doheny, CA), and a beach that is impacted by a mixture of animal and human fecal contamination (Malibu, CA). This data set could potentially help EPA understand differences in illness rates under different source conditions in the same geographic/climatic region. These other SCCWRP studies are receiving EPA technical input.

Summary of research activities and projects:

- Support an epidemiologic study at a beach in Avalon, CA believed to be impacted primarily by untreated human fecal contamination. (P3)

- Conduct statistical analysis of children data (P29) to determine if there is a significant difference in risk in the Avalon, CA epidemiologic study.

EPA will consider the results of the SCCWRP studies to determine whether risks associated with poorly treated or untreated human fecal matter differ greatly from risks associated with swimming in waters in proximity to POTWs and if the risks are different, what the relative difference is in risk of illness. A detailed description and a timeline for each study are provided in Tables 3–1 and 3–2, respectively.

3.1.3 Risks from Non-Human Sources of Fecal Contamination

3.1.3.1 Animal Sources and Stormwater

Human and animal feces can both potentially contain pathogens that cause human illness. Some human pathogens can be shed in feces by both humans and animals, while others such as viruses are typically host specific. As a result, the relative risks associated with animal fecal matter are dependent somewhat on the host species. As noted in the Experts Workshop Report (EPA, 2007), "it is widely believed that human feces pose a larger health risk than animal feces to swimmers and other primary contact recreational waster users. This belief derives from the basic concept that virtually all enteric pathogens of humans are infectious to other humans, while relatively few of the enteric pathogens of animals are infectious to humans…The bottom line is that there are few data to demonstrate whether animal feces pose a lower, greater, or equivalent heath risk to swimmers than human feces. If there is a difference, it would be important to know the magnitude of the difference, in order for EPA to make appropriate criteria recommendations. The only way to get a better sense of the health risk to swimmers posed by animal feces is to conduct targeted studies."

EPA plans on conducting several lines of research to support such targeted studies. Initially, EPA will conduct a state-of-the science review of published studies to identify major data gaps, outline current thinking on relative risks and target animals/pathogens of concern, and identify specific data collection needs that may influence the direction and design of field studies that would be conducted to help answer this question. Then, EPA will:

(1) develop new and/or evaluate previously published genetic biomarker methods (or assays) for identifying human and a particular source of animal contamination, and
(2) collect data and conduct source and site characterization evaluations at potential study sites.

Based on the findings from this research, EPA will conduct at least one epidemiologic study and/or conduct QMRA to characterize the indicator-illness relationship at a freshwater beach impacted by agricultural animal sources of fecal contamination for comparison to the relationship(s) obtained at beaches impacted by human fecal contamination.

The genetic biomarker assays will be useful in characterizing the sources of fecal contamination at recreational water sites, as an initial step prior to conducting epidemiologic or QMRA studies. Source and site characterization activities will be conducted concurrently with the use of the genetic biomarker methods to identify likely agricultural sources and site characteristics that may influence contributions of fecal contamination at the beach. While various assays are being researched which may in the future allow for differentiation among animal groups, only those that differentiate human fecal material from the total fecal material, and those that differentiate bovine fecal material from other animal fecal material, will be available given the 2- to 3-year timeframe for developing the new or revised criteria.

Source and site characterization activities will also be conducted to assess risks posed by urban stormwater sources of contamination. Based on these activities and an evaluation of the preliminary results of the proposed Doheny, CA, SCCWRP study, EPA will decide whether the potential differences in risks can be assessed through QMRA activities or whether an epidemiologic study is needed. If an additional epidemiologic study is warranted, EPA will use the site/source characterization study to develop site selection criteria, and/or revise study design if needed. The site/source characterization study activity will also potentially support the development of quantitative sanitary investigation tools/protocols.

Summary of research activities and projects:

- Conduct several state-of-the-science reviews of published studies focusing on:
  - sources of non-human fecal contamination (P30),
  - studies on occurrence and cross-infectivity of specific pathogens associated with animals (P31), and
  - components and data requirements for QMRA (P7).

- Develop new and/or evaluate previously published source-identifying assays (P19) or molecular biomarkers.

- 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)

- Evaluate genetic markers for cows to supplement the site characterization and quantitative sanitary investigation. (P21)

- 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)

- Conduct site and source characterization studies to better understand the factors influencing the contributions of untreated sources (e.g., urban runoff) to total fecal contamination to ambient waters. (P11)

- Conduct at least one epidemiologic study 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. (P4)

- Conduct epidemiologic study in marine or fresh waters impacted by urban runoff and/or conduct QMRA analysis. (P5)

These targeted studies will address current data gaps and uncertainties in assessing the relative risks associated with non-human sources of fecal contamination. A detailed description and a timeline of each study are provided in Tables 3–1 and 3–2, respectively.

3.2 DEVELOPMENT OF INDICATORS AND METHODS (GOALS 2 AND 3)

EPA's current CWA 304(a) recommended criteria for bacteria are based on methods that involve culturing and enumerating *E. coli* and enterococci as indicators of fecal contamination. One shortcoming of these methods is that the bacteria require at least 18 to 24 hours to grow visible colonies for subsequent enumeration. The need for appropriate and effective indicators and methods for timely detection of fecal pathogens is reflected in the EPA science Goals 2 and 3 described in section 1.3. As described in Chapter 2, EPA has conducted epidemiologic studies at four Great Lakes beaches and tested a suite of indicators and methods which were available at the time the studies were conducted and that met EPA performance criteria. The results of those studies indicate that *Enterococcus* qPCR is positively correlated with GI illness. EPA has also conducted a study evaluating the performance of this method in various settings. At present, EPA is testing a similar suite of indicators and methods in marine waters impacted by

human fecal contamination. The analysis of the marine studies will determine whether the same or a different indicator and method are most appropriate for marine environments.
EPA may identify or recommend more than one indicator or method, recognizing the different purposes served by criteria in the implementation of CWA programs (e.g., criteria are used to determine NPDES limits, to trigger beach advisories, and to define impaired waters). If EPA does recommend more than one indicator or method, EPA must understand the relationship between any separately recommended indicators and methods (for the various CWA purposes) and ensure that the recommended combination of indicators and methods will be, when implemented, protective of the swimming use.

Recent research indicates that indicator organism concentrations can vary at a given beach on time scales ranging from minutes to decades based on events such as changes in wastewater treatment, meteorological events (El Niño), strength or magnitude of rainfall events, tidal cycles, and UV-induced mortality. Of particular concern are the short-term (minute to hour) variability and heterogeneous mixing which can lead to moving hot spots of microorganisms. Additional research is needed to understand these processes and develop robust monitoring protocols that will allow for adequate characterization of microbial water quality.

EPA studies have demonstrated the utility of a new indicator and method (i.e., qPCR for enterococci) as a predictor of swimming-related illness in the Great Lakes. Whether this indicator and method is applicable to other settings or appropriate for use across the range of CWA programs is not fully understood. Data gaps include understanding how well the various indicators and methods perform in other settings (e.g., marine versus fresh water; human versus non-human sources of fecal contamination), and how they relate to one another. These data gaps led EPA to identify the following key science question.

3.2.1 Description of the Key Science Question

How well do culture and molecular methods for various indicators (singly or in combination) correlate with swimming-related illnesses?

The research activities described in section 3.2 aim to identify appropriate indicators of fecal contamination and related methods for use in new or revised criteria. This research addresses Goals 2 and 3 as outlined in section 1.3. The research related to indicators is not separate from the research related to methods. This is because in conducting epidemiologic studies to determine the relationship between illness and indicators, methods are used to detect and quantify the indicators. EPA will conduct health-based studies to identify those indicators/methods that show a positive correlation between indicator concentrations in the water and health effects. The research in this section focuses on the following three areas:

- Develop, Evaluate and Validate Indicators and Methods (Section 3.2.2)
- Assess Linkages between Indicators and Methods (Section 3.2.3)
- Characterize Temporal and Spatial Variability in Measurements (Section 3.2.4)

3.2.2 Develop, Evaluate and Validate Indicators and Methods

As discussed in Chapter 2, EPA conducted prospective cohort epidemiologic studies at four Great Lakes beaches impacted by treated wastewater discharges as part of the NEEAR studies. EPA included several validated methods available at that time and assessed their relationship to various illness endpoints described in section 3.1.2.1. Water samples were tested for *Enterococcus* using qPCR, *Enterococcus* using standard culture method, *E. coli* using a standard culture method, and *Bacteroides* using qPCR. The samples also were tested for over 30 pharmaceutical and industrial chemicals. Swimming-related illness rates and qPCR measures of enterococci were significantly associated in these studies. EPA is conducting comparable studies in marine waters impacted by POTWs to determine if a similar relationship holds at sites using the same site-selection criteria and protocols and methods used at the Great Lakes beaches. Additional indicators and methods included in the marine study sites (section 3.1) are *E. coli* using qPCR, *Bacteroides* using qPCR (not human-specific), *Bacteroides* using qPCR (human-specific), and male-specific coliphages antibody assay. EPA will evaluate each of the indicators/methods, and should any of these prove superior to enterococci qPCR, those methods will be further studied.

Archived samples on frozen filters from the Great Lakes epidemiologic studies will be analyzed if appropriate for indicators and methods not originally available, but that showed promise in marine studies, to determine whether a better correlation can be established with swimming-associated illness. In addition, EPA is refining several indicators/methods (e.g., *Bacteroides*) and plans to include improved techniques in any re-analysis. However, prior to analyzing any archived samples, EPA plans to conduct a study to assess the effects of sample holding time, sample storage, and preservation on sample integrity for future use (P16).

Summary of research activities and projects:

- Study the effects of sample holding time, sample storage, and preservation on sample integrity for future use. (P16)

- Re-analyze archived NEEAR samples for other indicators (depending on the outcome of M0 and the nature of the indicator/method). (P22)

- Develop, refine, validate, and publish new ambient and wastewater test methods. (P17)

3.2.3 Assess Linkages Between Indicators and Methods

Recognizing that any single indicator or method may not be suitable for all CWA purposes, EPA intends to conduct scientific studies to explore correlations and linkages between available indicators and methods to ensure that they provide for equivalent or comparable public health protection. EPA plans to analyze each indicator and method relative to its relationship with swimming-associated risk of illness. Additionally, EPA plans to use this information to develop

water quality models that can be extrapolated from one waterbody type to another. (See also section 3.3).

Summary of research activities and projects:

- 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, *E. coli*, *Cryptosporidium,* and enterovirus). (P8)

- Evaluate multiple indicator/method combinations to develop quantifiable relationships. (P15)

- Pilot sanitary survey in Great Lakes. (P14)

3.2.4 Characterize Temporal and Spatial Variability in Measurements

The NEEAR studies used a detailed sampling protocol for collecting data at various locations and water depths at a beach several times each day. These data were evaluated to determine their relationship with observed rates of swimming-associated illness. The results of that evaluation provide insights on the variability that one may expect spatially and temporally at a beach. Recent research external to EPA supports these findings (EPA, 2007). Additional research is needed to understand the short-term (minute-to-hour) variability caused by various processes, such as tidal cycles, as well as the effects of these processes on monitoring data. Accounting for this variability will lead to more robust monitoring protocols that will allow beach managers to better characterize the water quality at their beaches.

Summary of research activities and projects:

- 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)

These studies will address the current data gaps and uncertainties in assessing the performance of various indicators and methods to detect pathogens in a time manner, and how various indicators and methods relate to one another in predicting risks. A detailed description and a timeline of each study are provided in Tables 3–1 and 3–2, respectively.

3.3 Extrapolation of Research Results for Developing New or Revised Criteria (Goal 4)

As described in section 3.1, EPA is conducting or supporting epidemiological studies at select sites. Environmental factors, such as meteorology or the physical and chemical characteristics of freshwater and marine environments, vary geographically and may influence the presence

and viability of indicators and pathogens. Consequently, they may also influence any observed indicator-illness relationship. Therefore, EPA intends to conduct studies to better understand what differences in geography and climate are significant in the context of development of new or revised criteria.

As described in section 3.2, EPA may identify or recommend more than one indicator or method. Individual CWA programs (e.g., beach monitoring, assessments, TMDLs, and permitting) have specific purposes that may influence the selection of indicators or methods. For example, timeliness of obtaining test results may be critical for effective beach monitoring and notification, but may not be essential for NPDES permitting. Understanding the specific attributes of various indicators and methods as they relate to different CWA programs represents another data gap.

The research activities described below address the major data gaps in understanding how variations in diverse geographic and aquatic conditions can influence indicator performance, and whether and how individual indicators and methods are suitable for various CWA programs. These data gaps lead EPA to identify the following key science question.

3.3.1 Description of the Key Science Question

Are the indicators, methods and models suitable for use in different types of waters and for different CWA programs?

This research addresses Goal 4 as described in section 1.3 and focuses on the following three areas:

- Assess Variability in Diverse Geographic and Aquatic Conditions (Section 3.3.2)
- Assess Methods Suitability to Different CWA Purposes (Section 3.3.3)
- Develop, Evaluate and Validate Predictive Models and Tools (Section 3.3.4)

3.3.2 Assess Variability in Diverse Geographic and Aquatic Conditions

EPA expects that differences between freshwater and marine environments present the greatest potential for variation in indicator performance. Other factors that are likely to influence variability include hydrometeorology, biogeochemistry, and temperature.

3.3.2.1 Fresh and Marine Waters

EPA has or will be conducting or supporting several epidemiologic studies in both fresh and marine waters. The same protocol is being used across all epidemiologic studies to allow for an analysis of any differences in indicator performance between waterbody types.

3.3.2.2 Temperature/Climatic Conditions

Temperature influences the general persistence and survival of indicators and specific pathogens deposited or discharged into the environment. As described in section 3.1, EPA has or intends to conduct or support epidemiologic studies at sites representing a range of temperature and climatic conditions. These include: freshwater temperate (Great Lakes), a marine subtropical beach (Fairhope, AL), a marine temperate beach on the Atlantic coast (Goddard, RI), and a marine temperate beach on the Pacific coast (Avalon, CA). The same protocol is being used across all epidemiologic studies to allow for analysis of any differences between temperature and climatic conditions and indicator performance as predictors of illness.

In the near term, EPA is not intending to conduct an epidemiology study in tropical waters. This is because available data indicate that the characterization of indicators and pathogens in tropical climates and the factors influencing their existence, persistence, and behavior (e.g., re-growth, naturally occurring sources) are not sufficiently characterized to pursue targeted research in the near-term. There has been extensive research in recent years in an attempt to understand the behavior of pathogens and pathogen indicators in tropical waters, but this research has yielded ambiguous results as to what may actually be influencing the presence and growth of indicators and pathogens. If EPA were to conduct an epidemiologic study in tropical waters within 2-3 years, and differences between tropical and temperate waters were observed, EPA would not be able to use its results in developing new or revised criteria without a better understanding of the factors influencing the presence and growth of indicators and pathogens. Additional research is needed to characterize organism ecology and fate before an appropriate study design can be developed for an epidemiologic study. (Refer to Chapter 4 for further discussion on deferred research at tropical beaches.)

Instead, EPA will conduct a comprehensive literature review to determine the extent to which indicators may perform differently in a tropical environment compared to temperate or subtropical environments, and to better understand the underlying causes for any differences. EPA is also open to evaluating epidemiologic and other data generated at tropical locations by other entities to determine if an alternative indicator is appropriate.

Summary of research activities and projects (for tropical waters):

- Conduct literature review, and evaluate and interpret available data on indicator behavior in tropical climates: (e.g., water, sand, and sediments). (P32)

3.3.2.3 Extrapolation to Other Fresh Waters

EPA is interested in evaluating whether it is scientifically valid to extrapolate results from studies conducted in Great Lakes freshwater environments to other freshwater environments that may differ from the Great Lakes.

Sites can vary in the type and magnitude of contamination sources and their relative contribution to the mix of individual pathogens, and they may differ with respect to site-specific environmental factors (e.g., hydrology, meteorology). Given the numerous factors to be considered, it is not feasible to conduct field studies that can adequately control for all parameters. Collecting weather information along with physical and chemical water characteristics data during epidemiology studies provides the opportunity to utilize water quality models to examine any correlation of these data with health effects. Utilizing existing or developing new predictive water quality models, one can evaluate whether and how the epidemiologic data can be extrapolated to estimate potential health effects across different geographic areas. (Refer to section 3.3.4 for research activities related to development, evaluation and validation of predictive models and tools.)

Summary of research activities and projects:

- Evaluate applicability of NEEAR Great Lakes data to inland waters. (P28)

- 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. (P10)

3.3.3 Assess Methods Suitability to Different CWA Purposes

Individual CWA programs (e.g., beach monitoring, assessments, TMDLs, and permitting) have specific purposes that may influence selection of indicators or methods. For example, timeliness of obtaining test results may be critical for effective beach monitoring and notification, but may not be essential for NPDES permitting. Understanding the specific attributes of various indicators and methods as they relate to different CWA programs represents a data gap.

Summary of research activities and projects:

- Evaluate the suitability of individual combinations of indicators and methods for different CWA programs. (P18)

3.3.4 Develop, Evaluate and Validate Predictive Models and Tools

Statistical models that relate water quality to environmental factors like wind speed, prior rainfall, and tide level are valuable tools for making beach closure or advisory decisions. Site-validated models predict water quality problems reliably and in a more timely fashion than traditional bacterial indicator monitoring alone. Once a model is site-validated, traditional water monitoring could be reduced and targeted.

As described in Sections 3.2 and 3.3.2, EPA is conducting research to understand those factors that contribute to variability of indicator and pathogen behavior across diverse aquatic

conditions including those that influence sources of indicators and pathogens, their persistence, and their concentrations at beaches. As a result of these studies, EPA intends to refine an existing predictive model (virtual beach) based largely on the Great Lakes studies for use in beach monitoring at specific sites. EPA intends to test and validate this model and other existing models in various freshwater and marine environments in different geographic conditions, and in waters impacted by a wide range of fecal sources of contamination for site specific application. A technical protocol for site-specific application of the model(s) would then be developed to assist States and tribes with implementation of new or revised criteria. In addition to predictive models, EPA intends to develop tools such as sanitary surveys to facilitate the collection and evaluation of data for site-specific applications.

The research activities described below provide useful tools for extrapolating data from epidemiologic study sites to other geographic locations and aquatic conditions, and predicting water quality problems to assist in beach monitoring and notifications programs. Potentially, these tools may also prove useful in predicting water quality problems in other CWA programs for which criteria are intended.

Summary of research activities and projects:

- Pilot test Virtual Beach model for beach notification and advisories/closures. (P23)
- Refine and validate other existing water quality models for freshwater and marine beach notification and advisories/closures. (P24, P25)
- Develop technical protocol for site-specific application of predictive models to be used in making beach advisory decisions. (P26)
- Develop, refine and evaluate quantitative sanitary investigation method – sanitary survey protocol for recreational waters. (P13)

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 *Enterococcus* using qPCR, *Enterococcus* using standard culture method, *E. coli* using qPCR, *Bacteroides* using qPCR (not human specific), *Bacteroides* 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 *Enterococcus* qPCR, *Bacteroides* qPCR, *Bacteroides thetaiotamicron* 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

GOALS ADDRESSED BY RESEARCH	PROJECT TITLE	RESEARCH DESCRIPTION	START DATE/ END DATE
1 — 4	Conduct epidemiologic study in fresh or marine waters impacted by urban runoff and/or conduct QMRA analysis (P5)	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 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.	2008–2010
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.	2007–2008
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, *E. coli, Cryptosporidium*, and enterovirus) (P8)	The objective of this project is to understand what happens to the *Enterococcus* qPCR signal during wastewater treatment, after release into the environment and relationship of the *Enterococcus* 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 *Enterococcus* 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	2008–2009

GOALS ADDRESSED BY RESEARCH	PROJECT TITLE	RESEARCH DESCRIPTION	START DATE/ END DATE
		enterococci, *E. coli*, and F-specific (F+) coliphage as well as specific pathogens (enterovirus and *Cryptosporidium*) through wastewater treatment. In addition, the decay of the indicators will after treatment be examined after mixing with surface water under laboratory conditions.	
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)	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.	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)	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, carbonaceous 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	2007–2009

GOALS ADDRESSED BY RESEARCH	PROJECT TITLE	RESEARCH DESCRIPTION	START DATE/ END DATE
		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 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.	
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)	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.	2008–2009
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 mutli-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.	2008–2009
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?)	2009/2009

GOALS ADDRESSED BY RESEARCH	PROJECT TITLE	RESEARCH DESCRIPTION	START DATE/ END DATE
		3) Combine results of above assessments into a nationwide protocol and set of tools.	
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 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.	2006–2008
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 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	2008–2011

GOALS ADDRESSED BY RESEARCH	PROJECT TITLE	RESEARCH DESCRIPTION	START DATE/ END DATE
		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.	
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.	2007–2008
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.	2007–2008
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 *E. coli* 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.	2008–2009
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	2008–2009

GOALS ADDRESSED BY RESEARCH	PROJECT TITLE	RESEARCH DESCRIPTION	START DATE/ END DATE
		between host populations.	
1 — 4	Re-analyze archived NEEAR samples for other indicators (depending upon the outcome of P16 and the nature of the indicator/method) (P22)	Determine quantitative relationships between absolute and/or relative levels of target DNA sequences from new water quality indicators and health data from previous epidemiologic studies based on analyses of freezer-archived samples. As many as eight new indicators, including presumptive human-specific indicators, several new *Bacteroides* species, *C. perfringens* and *E. coli* may be analyzed for in frozen archived samples from 2003, 2004, 2005 and 2007 NEEAR epidemiologic studies.	2008–2009
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 *E. coli* 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.	2007–2008
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 *E. coli*, or fecal enterococci. One beach will be used for predicting culturable *E. coli*, fecal enterococci and *Enterococcus* 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)	2007–2008

GOALS ADDRESSED BY RESEARCH	PROJECT TITLE	RESEARCH DESCRIPTION	START DATE/ END DATE
		in a small catchment that runs into beach areas along southern Lake Michigan.	
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 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 *E. coli*, fecal enterococci and one beach for predicting culturable E. coli or fecal enterococci and *Enterococcus* 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.	2008–2009
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	2008–2009

GOALS ADDRESSED BY RESEARCH	PROJECT TITLE	RESEARCH DESCRIPTION	START DATE/ END DATE
		study or QMRA application in flowing inland water.	
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 studies to characterize relative risks from different sources (P30)	Search the epidemiologic literature (international and domestic journals and government 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.	2007/2007
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 Criteria[6]

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 beprimarily 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.	
				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.			
Site Characterization	P14: Pilot Great Lakes sanitary survey		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, *E. coli*, *Cryptosporidium*, 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.		

[6] 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
			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.			
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		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)		
Modeling	Virtual Beach model and other existing models	P23: Pilot test Virtual Beach model for beach notification and advisories/closures			

<table>
<tr><th>Broad Research Category</th><th>Completed</th><th>2007</th><th>2008</th><th>2009</th><th>2010</th></tr>
<tr><td rowspan="3"></td><td rowspan="3"></td><td colspan="2">P24: Refine and validate other existing water quality models for freshwater beach notification and advisories/closures.</td><td></td><td></td></tr>
<tr><td></td><td colspan="2">P25: Refine and validate other existing water quality models for marine beach notification and advisories/closures.</td><td></td></tr>
<tr><td></td><td></td><td>P26: Develop technical protocol for site-specific application of predictive models to be used in making beach advisory decisions.</td><td></td></tr>
<tr><td rowspan="3">Appropriate Level of Public Health Protection</td><td rowspan="3">Analysis of Great Lakes NEEAR freshwater epidemiology data for general population and subgroups (e.g., children and elderly)</td><td></td><td></td><td colspan="2">P27: Compare 1986 to NEEAR data to better understand the relationship between fecal contamination and illness in these data sets.</td></tr>
<tr><td></td><td colspan="2">P28: Evaluate applicability of NEEAR Great Lakes data to inland waters.</td><td></td></tr>
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</table>

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

CHAPTER 4 FUTURE RESEARCH

4.0 SCIENCE ISSUES EPA DEFERRED FOR FUTURE RESEARCH

EPA limited the scope of the Science Plan to science and research activities that could be completed within 2 to 3 years. The completion of research by the end of 2010, which would include data collection, analysis and reporting, is critical to EPA's goal of publishing new or revised criteria by the end of 2012. EPA recognizes that a number of science issues will be deferred for future criteria efforts because the current state-of-the-science does not support their inclusion in the shorter term effort, or because preliminary research must be completed before remaining science issues can be addressed. For example, the Science Plan partially addresses the differentiation of non-human sources, and places emphasis on addressing what is expected to be the greatest sources of risk first. Additional research to potentially differentiate between non-human sources of fecal contamination (e.g., wildlife versus agricultural animals such as cows) cannot be completed in the proposed timeframe. Such longer-term research — for example, developing source identification tools that reflect avian and wildlife sources of fecal contamination — will continue on a separate track. These tools may be useful in revising the criteria in the future.

Understanding the etiology of illness arising from recreational water exposures was identified by EPA as a desired outcome of future research. This information would allow EPA to better evaluate the effectiveness of its current regulatory policies regarding waste treatment, and the relationship between discharges and beach closures. It would also improve the ability to extrapolate data from epidemiology studies to locations with different site characteristics. The tools to permit easier collection of etiology data in conjunction with illness data are not yet sufficiently developed to permit their inclusion in near term studies. They will not be available within the 2 to 3 year timeframe for the current criteria development effort.

The concern that different fecal indicators may be more appropriate for use in tropical or subtropical versus temperate environments was raised during the Experts Scientific Workshop. EPA is addressing the need for studies to develop guidance to account for the diversity of geographic conditions of marine waters by conducting epidemiology studies along diverse locations on the east, west and gulf coasts of the United States. An epidemiologic study at a tropical site is not specifically included in the Science Plan because (1) indicators of fecal contamination for temperate and subtropical waters may not be suitable for tropical waters; and (2) additional preparatory research would need to be completed prior to conducting a tropical study. The additional research activities EPA would need to complete before conducting a tropical epidemiology study include: (1) evaluating the results of marine epidemiology studies to determine if the indicators used would be suitable for tropical sites; (2) identifying and developing new potential indicators for tropical waters; (3) identifying an appropriate study site to conduct tropical epidemiology study; and (4) establishing a partnership with the municipality where the study would be conducted. These research activities are sequential and

will require more than 3 years to complete. Therefore, they are being deferred for future research.

EPA will conduct a comprehensive literature review to determine the extent to which indicators perform differently in a tropical environment compared to the temperature environment and the underlying cause if there is a difference. EPA is also open to evaluating epidemiologic and other data generated at tropical locations by other entities to determine if an alternative indicator is appropriate.

Scientific uncertainty regarding the re-growth of fecal indicators and the impact of this phenomenon on water quality as well as beach sand was also identified as having a potential impact on the utility of indicators as a measure of fecal contamination in recreational water, especially in tropical climates. EPA has not included any specific research activity in this topic in the current Science Plan but will conduct a literature review to determine: how significant is this issue, if regrowth of indicators is just an issue in tropical environments, if regrowth of indictors is due to nutrient contamination, and the impact of indicator regrowth on human health risk. EPA will evaluate the results of the literature search to identify any subsequent steps that may be helpful to address this issue. This research will not be conducted to support the current criteria development because of the short timeframe available.

CHAPTER 5 REFERENCES

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