EPA's Development of New or Revised Recreational Water Quality Criteria Stakeholder Meeting
October 6-7, 2009 - Chicago, Illinois

Meeting Summary and Highlights

EPA held a multi-stakeholder meeting on October 6–7, 2009, in Chicago, Illinois, to provide an update on the Agency's ongoing work toward the development of new/revised recreational water criteria by 2012 and to receive input on key areas.

The goals of this meeting were:

- Provide an open stakeholder forum to discuss EPA's development of new or revised recreational water quality criteria.
- Provide an update on the progress made in completing studies.
- Frame, discuss, and debate key issues and possible elements of new criteria.
- Outline a plan to keep stakeholders informed as criteria development continues.

EPA provided an overview of the timeline for developing new criteria, including research planning, criteria development, and stakeholder outreach ranging from the 2000 Beaches Environmental & Coastal Health (BEACH) Act to the 2012 deadline. EPA also shared updates on the current state of research and a summary of the elements that will form the basis of new or revised criteria.

Much of the discussion and stakeholder input surrounded three discussion topics:

1. Setting criteria to be protective of children
2. Rapid methods
3. Sources of fecal contamination and site-specific considerations

Each discussion topic was chaired by an EPA session lead and included a panel of stakeholder experts. Each session lead presented the current state of knowledge on the topic, possible approaches for use in criteria, and posed several questions to the distinguished panel. Each panelist was given the opportunity to respond to the questions. A summary of EPA presentations and each discussion session is presented below.

Tuesday, October 6, 2009

Welcome/Kickoff
Denise Keehner, USEPA

Summary of Presentation

EPA's Office of Science and Technology (OST) collaborates and partners with the Office of Research and Development (ORD) as well as external organizations (e.g., Southern California Coastal Water Project [SCCWRP], University of Miami) in research for development of new recreational water quality criteria. EPA will propose criteria for public input in early 2012 and will develop and publish final criteria by October 2012. This meeting is a follow-up to the February 2008 stakeholder meeting which reported on the progress of Critical Path Science Plan activities, solicited early input on research areas that needed focus (e.g., inland waters), desired attributes of the criteria, and options for stakeholder involvement. EPA structured this current meeting based on input received from several scoping calls with various stakeholder groups. They expressed interest in hearing EPA explain the status of research, EPA's current thinking on key issues, and the impact of the settlement agreement and pending legislation on criteria development. EPA will discuss key implementation issues during future stakeholder meetings because it is too early in the process to discuss those now. EPA will have at least two more stakeholder meetings—one in 2010 and one in 2011. EPA has also been providing information on criteria development on the EPA Recreational Water Quality Criteria web site (www.epa.gov/waterscience/criteria/recreation).

Overview of Timeline and Key Milestones
Lisa Christ, USEPA

Summary of Presentation

The BEACH Act was signed into law October 2000. The act required states to adopt water quality criteria "as protective as" the 1986 criteria by April 10, 2004. It also required EPA to conduct certain studies and publish new or revised criteria based on these studies and review the criteria every 5 years. In 2006 EPA was sued by the Natural Resources Defense Council (NRDC), the National Association of Clean Water Agencies (NACWA) the Los Angeles County, and the Los Angeles County Flood Control District for not meeting deadlines to complete studies and publish new or revised recreational water quality criteria. In March 2007, EPA conducted an Experts Scientific Workshop to inform the development of the Critical Path Science Plan (CPSP), which describes critical research and science to be conducted by EPA to establish the scientific foundation for new or revised criteria. On February 20, 2008, EPA held a stakeholder meeting to update stakeholders on the progress of the research in the CPSP. The lawsuit was settled August 2008, by a Consent Decree and Settlement Agreement that require EPA to complete the studies in the Settlement Agreement and Consent Decree by December 15, 2010 and sign for publication new or revised section 304(a)(9) water quality criteria recommendations by October 15, 2012. EPA must conduct a number of other activities as part of the Settlement Agreement, including review of other study data, avian research, and method validation. EPA will hold stakeholder meetings in

2010 and 2011, in addition to this meeting in 2009. EPA co-sponsored an Inland Waters Experts Workshop in February 18–20, 2009 with WERF. EPA also held a by invitation research forum in April 23, 2009. EPA plans to publish proposed criteria in early 2012 for public comment and sign for publication final criteria recommendations by October 15, 2012. EPA committed to keep the lines of communication open with stakeholders throughout the criteria development process.

Research Project Updates
Chuck Noss, USEPA and John Ravenscroft, USEPA

Presentation Summary
EPA has been undertaking a number of research projects related to developing the new criteria. Four epidemiological studies have been done to date in the Great Lakes and three at marine sites (Rhode Island, Alabama, and Mississippi). EPA provided technical support to SCCWRP for the Avalon and Doheny epidemiological studies. In the summer of 2009, EPA conducted epidemiological studies at Surfside Beach in South Carolina, a marine beach impacted by urban runoff, as well as at Boquerón in Puerto Rico, a tropical, marine beach impacted by POTW effluent. Eleven thousand people participated in the Surfside Beach epidemiological study, and 17,000 people were included in the study at Boquerón Beach (the largest epidemiological study site to date). EPA conducted a literature review on the persistence, ecology, fate, and behavior of indicators and pathogens in inland waters. EPA continues work to evaluate monitoring schemes specific to flowing freshwaters and has initiated other related inland water projects. EPA is evaluating how various possible options regarding the use of different indicators and the use of cultural and/or molecular methods affect CWA requirements (i.e., Total Maximum Daily Loads [TMDLs], National Pollutant Discharge Elimination System [NPDES], beach monitoring and notification) and plans to obtain input on possible implementation issues and approaches. For avian markers, EPA will determine, by July 2011, whether fecal source assays can be developed and, if feasible, will evaluate their sensitivity and specificity. For source characterization, EPA will evaluate bovine and human host specific markers as PCR assays for indicators of cattle or human fecal pollution. EPA is developing potential Quantitative Microbial Risk Assessment (QMRA) approaches for recreational waters.

EPA's Current Thinking on Development of New Criteria
Elizabeth Doyle, USEPA

Presentation Summary

Ongoing research will shape the new or revised recreational criteria. EPA is applying new technologies, determining the scope and approach as well as what tools are available, considering the limitations, and determining the goals for the next iteration. EPA OST is seeking input from other EPA offices, regions, and stakeholders. EPA is also considering studies conducted by researchers outside EPA. To scope the criteria, EPA identified criteria topic areas (e.g., water body type, fecal contamination sources, target population, human health end point, fecal indicators, analytical methods, tolerable illness level and expression of the criteria). Further, EPA has to break out issues by topic area, frame key questions, evaluate available data, identify a reasonable approach for criteria, address technical and implementation concerns, and develop a final draft for public comment. To move forward, EPA will begin to evaluate data and available information from EPA and other agencies and will integrate the developing data into the new criteria.

Discussion Topic 1: Setting Criteria to Be Protective of Children
Denise Keehner, USEPA

Three possible approaches to setting criteria to be protective of children were presented: (1) criteria value (indicator concentration) at the level that protects the general population; (2) criteria value (indicator concentration) at the level that protects children (as well as the general population); and (3) criteria value (indicator concentration) that protects an upper percentile of the general population, thereby ensuring children are also protected. The following questions were posed to the panelists:

- What are the trade-offs of the different approaches presented by EPA?
- Are criteria based on some percentile for the general population a reasonable approach to be protective for children?
- Are there other approaches you are aware of for EPA to consider?
- Are there other beach management practices that could be implemented to protect children?
    - Are there other risk management practices to protect children?

Respondent Panel: Sam Dorevitch, University of Illinois at Chicago School of Public Health; Lyman Welch, Alliance for the Great Lakes
Note: These are not EPA's opinions or definitive answers

- **Sam Dorevitch**
  It is not clear that children are more susceptible than adults. Some studies (e.g., research by Al Dufour) indicate that children are at higher risk and data do show that so far in terms of concentration/illness slopes, but there is substantial overlap of illness curves. Susceptibility of children may not be as clear cut as demonstrated.
- Scientists will need to test the interaction between age group and water quality measure.
- Children spend a lot more time in the water, but adults could be more susceptible. Data on swimmers and nonswimmers, child swimmers did not seem to be more susceptible to children who did not swim. However, there was a significant difference in adults 55 and older. There may be variation in susceptibility due to duration of recreation. However, data are not available about duration of recreation in the EPA studies.
- Immunity is derived from exposure, so the issue is more with severity of risk. The severity of illness as a child could be worse.
- One recent finding is that children spend more time in sand and are more likely to be in the sand. Sand exposure might be associated with higher illness rates. Sand exposure may be as important as water exposure since there is an increase rate of illness in children who did not swim. This relationship should be further examined.
- Any approach to protect children should use the data from children; this is not a science question it is a policy question; if there is a designated bathing beach that is heavily used by children then base it on children.
- Other issues such as beach grooming and keeping diapers and gulls off the beaches could be important.
- Promoting behavior change as a result of all this work is critical. The focus should not be on just a criteria number if the public does not follow closure recommendations.

Lyman Welch

- Children may be more susceptible, because they swallow more water and play more in the sand.
- If the data are available to set a level that will protect children it would be consistent with how EPA approaches protecting sensitive populations in other programs (e.g., pesticides, air quality).
- Beaches should be as safe and clean as possible, and that can protect both adults and children.
- Public education is crucial -
    - Storm runoff ditches/discharge points should have signage to prevent children from playing there due to the possibility of greater exposure to

higher indicator levels. Warning signs and other public education can be useful.
    - Washing hands after playing in the sand can reduce the risk of illness.
    - Public notification (signs and flags) is very important and should be improved.
- Sampling depth can influence strongly the measured levels of fecal indicator bacteria; thus, it is very important for EPA to specify, as part of implementation guidance and perhaps part of the criteria itself, the depth samples should be taken and closeness to shore for increasing health protection.

Wednesday, October 7, 2009

Discussion Topic 2: Rapid Methods
Grace Robiou, USEPA

Presentation Summary

The 2012 criteria will most likely include a rapid method (qPCR) for beach notification and monitoring. PCR and qPCR tests are genetic tests used to identify (PCR) and quantify (qPCR) DNA or RNA strands from microorganisms, plants, and animals. The advantages are that results are available sooner (hours versus day(s)) and it is easier to identify specific strains. The disadvantages are that the test does not differentiate live versus dead cells and it is technically more challenging than culture methods. One possibility is that EPA might recommend a qPCR method that would be used for beach advisories and notification purposes and qPCR and/or culture method for other CWA applications. Ideally, EPA would like to use the same indicator organism for both the qPCR and culture methods. Some of the indicators that EPA has been considering are enterococcus, *E. coli*, *Bacteroide*s, *Clostridium,* and coliphage. The pending BEACH Act legislation includes new provisions such as requirements related to publication and use of a "rapid testing method" for beach advisories/notification programs by states with EPA grants, as well as EPA promulgation of new or revised water quality standards if states do not adopt EPA recommendations within three years (i.e., by October 2015). The culture-based methods require 24–48 hours to obtain results. qPCR is a faster method to assess recreational water quality and predict swimming-related illnesses, however, beach notification decisions could not be made for 4–6 hours after a sample is collected.

The following questions were posed to the panelists:

- What are the opportunities and challenges in using rapid methods for beach programs while using rapid and/or culture methods for compliance with permitting, listing decisions, and TMDL development?
- How do you envision the use of historical data in transitioning to new criteria?
- What tools and training would be needed to ease implementation of molecular methods?

Respondent Panel: Julie Kinzelman, City of Racine Health Department; Joanna Mott, Texas A&M University–Corpus Christi; Rachel Noble, University of North Carolina at Chapel Hill

Note: These are not EPA's opinions or definitive answers

Rachel Noble

- There is ongoing work to overcoming the technical hurdles of qPCR as well as efforts to standardize and develop user-friendly methods.
- The methods can be made to be relatively cost-efficient.
- New tests may require a mindset change—qPCR is more abstract than counting colonies on a plate.
- Public perception is an issue when considering short term and long term uses. If an answer can be obtained quickly, why use different methods for different things?
- Matrix effects in different locations will be important. Sanitary surveys and source information work will be an important tool.
- EPA could provide assistance training other labs.
- Equipment sharing is also a possibility to cut costs.
  Quantitative measurements along with loads can be used for TMDLs and loading assessments.

Julie Kinzelman

- qPCR may provide better protection of public health and allow for answers in real time.
- However, there are many challenges. Possible challenges include:
  - It is necessary to have some sort of numerical match between methods for comparing CWA programs/applications.
  - Public perception. States might prefer to use new rapid methods for high use intensity beaches but might not use it for others. How can that be explained to the public?
  - Variability in data, such as replicate data, and how to handle the samples. Some places take one sample; some take three and average them. In qPCR the replicate data don't always match.

- qPCR could be considered as part of a toolbox of possible things, one of a suite of tests. IMS-ATP should be included in the discussion on rapid methods. Some of the technologies could have higher cost, but they have fewer steps involved.
- Predictive models are important, and states can encourage routine and annual sanitary surveys.
- States will need training. EPA could have a manual or guidance or an email or phone line for people to ask questions on the methods.
- It is also important to interface with the labs and the political entities—those who will have to find the resources to pay for the tests.

Joanna Mott

- qPCR is faster, but it is not real time. Time is needed to get to and from the lab, to announce results, and to post the signs. The method will not give you a same-day status on that beach.
- Are there other, faster methods, moving toward a dipstick-type method? The IMS-ATP is simpler.
- Many labs will have problems moving to qPCR. There is a big difference in the capabilities in the shift from culture to qPCR. Many beaches will continue doing culture-based methods for as long as they can because of the difficulty in switching over.
- In terms of the relationship with TMDLs, could new methods be used for tier 1 beaches but maybe tiers 2 and 3 could still use culture methods?
- There isn't always a correlation between the two methods. EPA said the Beachwatch data should be used for TMDLs, so the correlation between the methods is a real issue.
- For some states that don't have supplemental funding, training is a huge issue. If new equipment and training is needed, entities might have to sample less in order to afford to pay for it.
- As soon as the protocol is ready, let that be made available so that entities can look at it and see the needed instrumentation. We are at a standstill until we get some guidance from EPA.
- Education of the other state agencies that will be involved will be needed.

Discussion Topic 3: Sources of Fecal Contamination and Site-Specific Considerations
Shari Barash, USEPA

Presentation Summary

The 1986 ambient water quality criteria do not differentiate based on sources of fecal contamination. The criteria apply unless both a sanitary survey shows that sources of

the indicator bacteria are non-human and an epidemiological study shows that the indicator densities are not indicative of a human health risk. For the 2012 criteria, EPA plans to develop numeric criteria based on indicators of fecal contamination that will apply regardless of source. In light of stakeholder concerns and the current state of knowledge, EPA has been engaged in a number of activities, including the development of markers for human and bovine sources; data collection for agricultural animal QMRA for swine, poultry, and cattle; data collection and QMRA at a POTW-impacted site in a tropical region and an urban runoff epi study; sanitary survey/site characterization information collection for tropical POTW-impacted and urban runoff beaches for use in QMRA; and the development of a QMRA tool for use by states/stakeholders. There is also ongoing work outside of EPA, including the SCCWRP epi study of shore bird/urban-runoff/non-POTW impacted site at Doheny, California and shore bird/mixed sources site at Malibu, California, the WERF project quantifying pathogens and sources of microbial indicators for QMRA in recreational waters, and the University of Miami epi study on mixed urban sources. Researchers are still determining if there is a difference in risk between human and animal sources and if any hard science has been developed since the 2007 Experts Scientific Workshop at Arlie that informs this. It is unclear whether a difference in risk can be scientifically demonstrated and quantified, or whether tools, such as sanitary surveys and source tracking, allow for identification of sources and estimation of their relative influence.

The following questions were posed to the panelists:

- What has been your experience regarding identification of sources through sanitary investigations and/or source tracking studies? Have you found it easy or difficult to use these methods? Why?
- If EPA were to develop a QMRA tool (populated with default data) for use by states/stakeholders, what are the opportunities and challenges in using such a tool for addressing site-specific conditions? How can EPA make this tool most useful? What data is the most difficult/costly for states to obtain (e.g., infectivity, dose, fate and transport, exposure duration, fecal indicator concentration)?
- EPA has heard concerns that the 1986 criteria are over or under protective when applied to water bodies impacted by non-human sources. What has been your experience? And did you draw any conclusions about over or under protection? If so, based on what data?

Respondent Panel: John Bender, Nebraska Department of Environmental Quality; David Whiting, Florida Department of Environmental Protection; Stefan Wuertz, University of California, Davis

Note: These are not EPA's opinions or definitive answers

David Whiting

- Florida has attempted to be proactive and has used microbial source tracking tools. The state has developed an action plan to look at an entire basin. For the Hillsborough River in Tampa, we have used source tracking tools and qPCR and other PCR methods to accrue a minimum dataset, prioritized the watersheds based on the Annapolis Protocol, done contaminant source surveys to identify that prioritization, and performed suites of microbial source tracking analyses on the most highly prioritized waters.
- For Florida it is predominantly a human source issue. There has been a focus on sewage line breaks and such and we have worked upstream from there. It is costly, but it shows promise.
- In rural areas Florida is discriminating human from nonhuman sources. Regulators want the quantification to go along with presence/absence, but those types of results were not available at the time.
- In an urban setting, source tracking shows promise, but it is difficult to use in rural areas.
- When should QMRA be employed—as part of the criterion or after it is set in its application?
    - If you are allowing there to be a difference in risk associated with source, that is less likely to be a problem for the states than if there is an impaired water and states are trying to develop a site-specific criterion and explain why the highly conservative criterion used to list the water was not identifying the risk of using that water. The appearance would be that we are trying to lower the level of protection.
    - If site conditions are very different from what the default data were based on, then there is a high level of uncertainty. So there is a limited use of a default dataset and it is beyond state capacity to get site-specific data.
- For question 3, it can't be separated from how the data for the 1986 criteria were derived. Using the prospective cohort study design used in some epidemiological studies, the bathers become a source through bather-to-bather contact or bather shedding. That application would be overprotective most of the time in nonpoint source influenced waters. Those criteria are best applied under the situations from which they were derived. So, applying it to other situations is probably not appropriate.

John Bender

- In Nebraska, streams are either good or bad—there is not much in between. States need a number so they can move on with assessments.
- Most Nebraska waterbodies are impacted by nonpoint sources. Nebraska does disinfect its wastewaters.

- There is a lack of attention paid to inland flowing waters. The activities that occur are different compared to a beach. Many inland waters have a low density of use and any bather shedding is transported downstream.
- Cost is a concern. States will not be able to use new methods if they are expensive.
- Sampling in the field has been useful (e.g., being able to do Colilert).
- How do states relate a qPCR number to an effluent limit? Any new method should be accompanied with an approved method for wastewater matrices. States need something to directly apply into permits.
- If QMRA gives us another tool for capabilities that states do not already have, that is good. But if site-specific information is needed to use it, states probably will not be able to use it. It will be really difficult for many states to buy equipment for the qPCR assay.
- Nebraska is primarily concerned with the sources that can be controlled, like regulated facilities (CSOs, dischargers, etc.). Resources limit our ability to make an impact on sources we can't or don't have the authority to control.

Stefan Wuertz

- QMRA has been used in many applications, but the procedures are not yet calibrated for fecal indicators. It is unrealistic that there will be a general relationship between the fecal indicators and the QMRA.
- EPA should give up the idea of culture methods.
    - QMRA can be utilized in addition to any fecal indicator criterion to demonstrate there is still an acceptable health risk even if it appears otherwise based on the current indicator used.
    - It allows states to have a real alternative to having one standard across the nation.
    - It can be implemented by states, and things like infectivity and dose don't have to be measured specifically by each state.
    - If there is an indicator measured by qPCR, it can be correlated.
- The development of qPCR assays for Bacteroidales have been promising.
- One of the largest source-tracking studies was done in the Los Angeles River, which is highly trashed and used for recreation. The study showed there is useful information for source tracking.
- It would be nice to have an epidemiological study to address nonhuman sources. The WERF study looks at sources and discharges, and there is a need for this work because there is not much data compared to what exists for receiving waters. Once there are good data on sources and loads, models can be used to predict the potential exposure to bathers using those waters.
- There has been little emphasis on characterizing pathogen loads on sources, and this question needs to be answered.

Communication Plan for Stakeholder Engagement
Lisa Christ, USEPA

Summary of Presentation
EPA is developing a communication plan to keep stakeholders informed about progress; involve stakeholders at various stages to provide input, ideas, feedback, and review; ensure the credibility of the process; and ensure the utility of the new/revised criteria to stakeholders. EPA has held several meetings and prepared a number of documents as part of the outreach strategy to date. EPA is continuing to post relevant resources and documents to the Recreational Water Quality Web site http://www.epa.gov/waterscience/criteria/recreation, which has been redesigned to make it easier to find information. EPA is maintaining a list of email addresses of interested stakeholders, which it will use to notify interested stakeholders of workshops and document availability. EPA will continue to have stakeholder meetings in 2010 and 2011 and plans to conduct a webcast in early 2010 of some sessions from this meeting. EPA received several requests to provide a mechanism for "virtual attendance" at this meeting.

Closing Remarks
Denise Keehner, USEPA

This in an enormous undertaking—$15 million and dozens of people engaged for several years. EPA does not have all the answers but is very open to collaborating with others to resolve issues and develop the new criteria. EPA wants the stakeholders to offer ideas on managing issues, and how EPA can better engage in the stakeholder dialogue. EPA wants the new criteria to be data-driven and science-based and wants them to be easy to implement. EPA will try to offer flexibility if possible and make the criteria as receptive as they can be to emerging science. If everyone works together, by 2012 important advances will have been made, implementation issues will have been addressed in a workable way, and there will be a paradigm shift to molecular methods.

APPENDIX A
Summary of key points/issues raised during the stakeholder meeting

- EPA recognizes that when setting these criteria, they will apply for the beach monitoring and notification purposes and for all other Clean Water Act programs. As EPA considers the various criteria elements and decisions, it needs to keep in mind the implications for all Clean Water Act programs.
- The cumulative impact of a series of "conservative decisions" for various elements of the new criteria could lead to many waters being identified as not meeting criteria and could "mask" the waters that are most impaired. For example, how would you identify the waters that need immediate attention if they are all impaired?
- EPA should look for a non-East Coast venue for the next multi-stakeholder meeting to increase participation by organizations and individuals from central and western states.
- There were many instances when EPA flagged an issue as "implementation." EPA's intention was not to defer the issue altogether and shift the problem to the states. EPA intends to provide companion implementation guidance to the new criteria document. When EPA says "implementation," it just means that the Agency does not envision that issue being addressed in the actual criteria document.
- Having criteria for protecting sensitive subpopulations is consistent with other EPA policy. If data show an increased susceptibility of children (or of any other identifiable subpopulation of a meaningful size) exists, criteria should protect those subpopulations (e.g., children, over 55). However, additional analysis of epidemiological data is needed to understand whether children are more susceptible to illness. For example, review whether the duration of exposure increases the susceptibility of a population. Sand exposure might be as important as water exposure. If children are found to be more susceptible, then protecting at children's central tendency is a more direct way to ensure the protection of children.
- EPA needs to be clear about how the upper percentile number is derived. There were concerns regarding this number being arbitrary and the difficulties in communicating what it represents.
- Having a value in the criteria for children might be overprotective of adults. That could undermine our ability to protect the environment (e.g., too many waters would exceed "low" criteria).
- States want flexibility in the criteria, such as a different risk from human sources versus animal sources. Another concern is that once a water exceeds water quality standards, you must develop a Total Maximum Daily Load (TMDL). If you can't distinguish POTW sources from wildlife sources, what does the state prioritize for?
- The Highly Credible Gastrointestinal: HCG-1 dilemma is that there is an apparent increase in the number of illnesses associated with a particular level of an indicator.

If the tolerable illness rate stays the same as the 1986 criteria, that might increase the number of impaired waters, and there could be implications for the number of beach closings.

- Low-use-intensity recreational waters should not be treated the same as high-use.
- EPA needs to consider the implications for various programs (e.g., beach management, TMDL).
- There are a number of beach management practices to mitigate risk, including posting signs at discharge points, providing better education to inform parents and others of what the signs mean, developing strategies to change behavior (e.g., washing hands after playing with sand), and using models to predict water quality and posting model results. There is interest in the use of predictive models to assist in obtaining more timely assessment of water quality. EPA thinks models would not be used to derive criteria but to implement criteria; therefore, such a discussion would likely be included in implementation guidance.
- The depth of water sample collection is important, and EPA should make recommendations regarding sample depth. This would likely be included in implementation guidance.
- There are challenges with rapid methods. There is a need to define the protocol with some specificity because there are many potential sources of error in using these methods. In addition, public communication is very important, and it is more of a challenge with rapid methods.
- Source tracking has limited applications. In an urban area it can help detect specific problems (assuming human sources). It is less helpful in rural areas, where it is difficult to distinguish human from other sources. Watersheds need to be prioritized. Source identification and markers have potential in the future.
- QMRA is useful in theory; however, several issues are associated with it. A state needs the resources to use it, and there could be a public perception issue. Including it in the criteria might increase the opportunity for it to be challenged. Default data provided by EPA could be useful if applicable to a given waterbody, and it could be difficult for states to develop their own site-specific data. Providing default data is better than asking states to develop tools on their own, and states might not take advantage of QMRA unless default data are provided. QMRA could be a part of the toolbox approach. It could allow states an alternative to having one criterion number for all waters.
- There are a number of issues with the 1986 criteria. EPA needs to consider nonhuman source issues and needs to address low-use-intensity versus high-use-intensity waterbodies. The criteria are best applied to designated bathing beaches. The criteria can be overprotective in low-use-intensity recreational waterbodies and flowing waters that have different kinds of primary recreational activities with lower exposure. Short of an epidemiological study in inland waters, EPA needs

more data on sources and loads so that it can predict exposure and model fate and transport, ultimately to use with QMRA. States want approved methods for wastewater if they will be using qPCR in permits.

- There are some concerns about moving toward rapid methods. A cultural paradigm shift will occur if new criteria include a qPCR method. This shift will call for EPA to explain what this method is, how it is different from counting cells in a culture plate, and what the results mean. EPA will need to develop tools and training. Decision-making flowcharts might be appropriate. Further work is needed by EPA to lay out in detail how the method will work.
- The public will always want to have the best and most recent science used for its waterbodies. This will occur regardless of how far EPA goes to say that it is okay to have a culture method, and to demonstrate that a culture method would be protective of public health in that waterbody. Efforts are being made to develop a scientifically defensible rapid method, and it is all data-driven. Regardless of which qPCR method is recommended in the new criteria, it might not be as rapid as stakeholders would desire.
- Having linkages remains an important linchpin to establish between qPCR results and other methods that might be more appropriate for the purposes of National Pollutant Discharge Elimination System (NPDES) permitting. There is interest among stakeholders in EPA's looking further into a mechanism to allow new technologies/methods to be used as part of the criteria. It could be through a performance-based approach, in which there would be a need to "anchor" the approach on a method for which there is a health correlation in the epidemiological study results.
- EPA needs to be more precise in explaining what assays are being used so that people understand what EPA is doing and how it compares to what they are doing, such as with Bacteroidales. *E. coli* is important, and the decision on whether to include or exclude *E. coli* needs to be data-driven.
- Research suggests that there is a pattern between enumeration of indicators using culture and qPCR for both *E coli* and enterococcus in freshwater. But an issue is whether that relationship will be consistent across any waterbody. There are implications in moving to molecular methods with respect to the cost of purchasing the equipment and how the cost will be borne (e.g., BEACH Act grant money might need to be used, which would decrease the actual amount of monitoring performed).
- There could be legal vulnerabilities in states where the public argues that a waterbody may be unique and because epidemiological studies were not conducted there, the "linkages" work might not apply. EPA needs a comprehensive roll-out to develop training/tools and written materials. Workforce training will be important

as well, and a guidance manual would be helpful. EPA should consider having a hotline and Web site for questions.

- If EPA intends for different indicator-method combinations to be used for different Clean Water Act uses that needs to be spelled out in the criteria recommendation.

APPENDIX B
Select Questions & Answers

Q. Will EPA consider epidemiological data from other (non-EPA) studies?
A. EPA will consider data from epidemiological studies conducted by entities other than EPA. The Agency is evaluating how to compare study results when different study designs and different indicator/method combinations are used.

Q. What health end-points is EPA looking at in its epidemiological studies?
A. EPA's studies are investigating the relationship of fecal contamination indictor concentrations to several health end points, such as gastrointestinal illness), respiratory illness, earache and eye irritations.

Q. What fecal contamination indicators is EPA looking at in the epidemiological studies?
A. See Table Below

EPA Study	Indicator/Methods Tested in Study
Great Lakes	Enterococcus-qPCR, Enterococcus-culture, Bacteroides-qPCR
2007 Marine	Enterococcus-qPCR, Enterococcus-culture, E. coli-qPCR, Bacteroides thetaiotaomicron (human associated)-qPCR, Bacteroides (general/non-human specific)-qPCR, Male-specific Coliphage by antibody assay, Clostridium spp.-qPCR
Archived filters*	Enterococcus-qPCR, E. coli-qPCR, Bacteroides (general/non-human specific)-qPCR, Clostridium spp.-qPCR, human associated markers
Tropical	Same as 2007 marine, but no Coliphage or Fecal Bacteroides (thetaiotaomicron)
Urban Runoff	Same as 2007 marine, but no Coliphage or Fecal Bacteroides (thetaiotaomicron)

*Analysis of culture methods will not be performed on the archived frozen filters for the epidemiological studies since holding time has been exceeded.

Q. At what depth are you taking water samples for the epidemiological studies?
A. EPA is collecting water samples at multiple depths – ankle, shin and waist.

Q. Which Bacteroides method is EPA using?
A. The method EPA is using for Bacteroides is: Siefring S, Varma M, Atikovic E, Wymer L, and Haugland R. (2007) Improved real-time PCR assays for the detection of fecal indicator bacteria in surface waters with different instrument and reagent systems. J Water Heatlh, 6(2): 225-237

Q. What is the timing for laboratory validation and what methods will be tested?
A. EPA began a single lab validation study for Enterococcus qPCR (Method A) and general Bacteroides qPCR (Method B) in July 2009 and plans to complete the study in December 2009. In the spring of 2010, EPA plans to begin an inter-lab validation study in marine waters for at least Enterococcus qPCR and plans to complete the study in December of 2010. EPA plans to conduct the freshwater inter-lab validation study in the spring of 2011. EPA plans to test at least Enterococcus qPCR and may also test *E. coli* qPCR, depending on the results of the reanalysis of archived filters from the Great Lakes.

Q. Are the methods being used standardized?
A. Under the Settlement Agreement, EPA is required to validate ambient water testing methods as part of the new criteria. The validation studies will examine reproducibility and method performance and will facilitate "standardizing" methods, where that is defined as developing a final method having quality acceptance criteria developed from the inter-lab validation testing.

Q. What are EPA's plans for preparing states, laboratory technicians and others for the transition to molecular methods?
EPA acknowledges that in addition to capital costs for transition to qPCR, methods training and outreach will be needed to help states and laboratory personnel with the transition to molecular methods. The Agency will consider outreach approaches in conjunction with implementation discussions.

Q. Will *E. coli* be used in the new criteria?
A. At the time of the freshwater (Great Lakes) studies, EPA did not have an *E. coli* qPCR method ready for testing. However, *E. coli* qPCR has been used in the marine studies and will be tested in the archived filters from the freshwater studies. In addition, EPA is exploring methodologies for examining linkages between culture and qPCR datasets. Specifically, identify statistical analyses efforts to determine which indicators/methods correlate with each other or demonstrate a predictable relationship between each other and health effects from recreational water exposure.

Q. What is the purpose of the enhanced sanitary investigation and how is it being used?

A. The purpose of the sanitary investigation is to determine the predominant sources of fecal contamination at a particular site. The information gathered through the investigation can be useful for a Quantitative Microbial Risk Assessment (QMRA), to help with classification of a site by source type, and, in the future, may be useful for the development of site-specific criteria.

Q. Will EPA provide access to the data from the Great Lakes and other studies?

A Under paragraph 10(b) of the Settlement Agreement, EPA must provide access to the data from "epidemiological studies previously conducted by EPA" no later than June 15, 2009. EPA prepared a CD and codebook of the Great Lakes NEEAR studies data to meet the June 15, 2009 obligation date. EPA will not provide names and addresses (i.e., street address/apt #, city, state, zip code) of study participants. Requests for access to the data and code book from the Great Lakes sites on a CD in SAS and MS EXCEL formats should be made to:

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Q. How will new criteria address non-human sources? What tools will be available?

There are several possible options for addressing non-human sources including development of different criteria recommendations depending on the source of fecal contamination. However, for EPA to pursue such an option, EPA would need significant data to support the scientific defensibility for each of those criteria values and to allow application of such criteria recommendations nationally. At this time it seems unlikely that EPA will have enough data to support such an option for criteria in October 2012. EPA is continuing to conduct research in the areas of Quantitative Microbial Risk Assessment (QMRA), sanitary investigations, and genetic markers to inform the development of tools that can be used by states, territories and tribes for site-specific/alternative criteria development.

Q. There are several questions about the types of questions asked and which respondents are considered during epidemiological studies. Can you provide a copy of the questionnaire?

A. The survey questionnaire used for EPA's epidemiological studies is on the regulations.gov web site at: http://www.regulations.gov/search/Regs/home.html#documentDetail?R=090000648072f421

Q. How will predictive models be used in new criteria?
A. The use of modeling as a predictive tool for beach notification programs could play an important role in new criteria. However, the models will not replace monitoring. They could be a valuable tool to give advance notice of water quality.

Q. EPA is considering basing criteria on a value protective of children 10 years and younger, is there enough data for this approach? Has EPA considered the implications (i.e., more frequent beach advisories) of this approach?
A. EPA's current thinking is at a minimum to base new criteria recommendations on indicator density (concentration) protective of the general population and to the extent the science supports it, recommend criteria to be protective of children. At this time we only have data from four Great Lakes epidemiological studies, so the results from the marine epidemiological studies and also the studies conducted in the summer of 2009 at a tropical beach (Boqueron, Puerto Rico) and a beach impacted by urban runoff (Surfside Beach, South Carolina) will need to be considered. The Agency is aware that more stringent criteria may have an affect on beach closures as well as assessments of use attainment.

Q. This is the age group that is in daycare. How do you rule out the possibility that some of the children could have been sick from daycare and not from the beach? How can you be sure study participants in the general population weren't already sick before they went swimming?
A. Participants in the studies are asked detailed questions about both chronic illnesses and recent illnesses and as well as about other exposures (food, animals, etc.) which are most commonly associated with illnesses such as diarrhea. Those with illness at baseline are excluded from further analysis and many other factors which could potentially bias the relationship are accounted for in the analysis (see Wade, EHP 2006 and Wade, Epidemiological 2008 for description and discussion). In the case of specific examples such as day care, since the analysis is designed to compare differences among swimmers or between swimmers and non-swimmers such factors would be not likely to result in a systematic problem. There would be no reason that children in day care would be any more or less likely to swim or not swim than children not in day care.

Q. Is EPA considering varying risk levels (e.g., a tiered approach)?

A. It is a challenge in the 304(a) criteria because they are used for all types of purposes. We have traditionally taken the idea that a standard is a standard, for whatever purpose. There are ramifications for other programs if a waterbody exceeds a standard.

Q. Are rapid testing methods really rapid in terms of making a beach closing decision? There is more to consider besides how long the analysis takes, there is transportation time too.

A. qPCR methods generally take from 4-6 hours once samples reach the laboratory to get a result. This is time in the laboratory and does not include field sampling, transport, or communication of a decision based on the result. However, it is a great improvement over the 18-24 hours to obtain lab results for traditional culture-based methods. EPA understands that it may be difficult for some beach programs to use these qPCR methods for same day beach advisories but these methods can be an important tool in re-opening beaches faster. In addition, EPA acknowledges that many sampling locations may be in remote/inland areas and may take significant time (hours) for samples to reach the lab. We realize that given the costs for molecular method equipment multiple labs to serve remote areas is not a practical or realistic expectation. EPA recognizes that rapid methods may not be needed everywhere in all water bodies or for all CWA purposes. EPA is working to provide linkages between rapid methods and traditional culture methods to allow for continued use of culture methods for certain CWA purposes such as discharge permitting.

Q. Given how critical it is to "link" culture and qPCR methods, what approach is EPA taking?

A. EPA conducted a literature review to identify, collect and collate data from EPA and non-EPA epidemiological and/or other fecal indicator bacteria related study data to populate a matrix table. Paired datasets (culture and qPCR) are of particular interest. The completed table will be used to identify and conduct statistical analyses to determine which indicators/methods correlate with each other or demonstrate a predictable relationship between each other and health effects from recreational water exposure.

In addition, EPA is hopeful that WERF's work in this area will fill in some data gaps. Specifically WERF is initiating a study entitled "Comparative Evaluation of Molecular and Culture Methods for Fecal Indicator Bacteria for use in Inland Recreational Waters."

Q. Is EPA considering how to incorporate new technologies in the future?

A. The Alternate Test Procedure program is described in 40 CFR 136.4 and 40 CFR 136.5. The program (see http://www.epa.gov/waterscience/methods/atp) allows a method developer to ask for review (not approval) of 1) a method using a determinative

technique (e.g., a pollutant detector) different from than in an existing Part 136 method, or 2) a modification to a Part 136 method.

Q. qPCR samples for epidemiological studies have not been processed using the rapid method, but they were stored and archived for later analysis. So, how will that impact the results in terms of health risk? Has there been a baseline comparison between results from archived samples and qPCR samples?
A. EPA is addressing these questions in our stability studies.

Q. Will EPA require qPCR for new criteria?
A. EPA's current thinking for new criteria recommendations is for rapid (qPCR) methods for beach notification and monitoring; and rapid and/or culture methods for compliance with other CWA programs.

Q. Will the new criteria account for natural background conditions (pathogens)?
A. Since 1997 EPA's Office of Science and Technology has had a policy of allowing states and authorized tribes to establish site-specific aquatic life criteria equal to natural background conditions (http://www.epa.gov/waterscience/criteria/library/naturalback.pdf). However, the same policy memorandum is clear the "policy does not apply to human health uses." Specifically, it states: "For human health uses, where the natural background concentration is documented, this new information should result in, at a minimum, a re-evaluation of the human health use designation. Where the new background information documents that the natural background concentration does not support a human health use previously believed attained, it may be prudent for the State or Tribe to change the human health use to one the natural background concentration will support (e.g., from drinking water supply to drinking water supply only after treatment)." Therefore, at this time, it is unlikely that EPA will account for natural background conditions.

Q. How is QMRA being tested? How would EPA anchor, validate and confirm with high confidence that QMRA predicts the health risk that would actually be seen?
A. EPA is collecting water quality and pathogen data at the Boqueron, Puerto Rico epidemiological study site. We plan to use the epidemiological data from Boqueron to "anchor" the QMRA in Boqueron. This will help us to "fine tune" the assumptions and uncertainties in our QMRA models generally. For example, we are conducting a QMRA in waters impacted by agricultural animal runoff, where we are collecting similar data (e.g., site and source characterization, pathogen and indicator levels). We also want to revisit the original epidemiological sites, once we have anchored our

QMRA models, and conduct risk assessments there to see if we can replicate the results that came out of the NEEAR epidemiological studies.

Q. How would the use of QMRA for site-specific criteria work?
A. Under EPA's current regulation states may develop site-specific criteria as long as they are scientifically defensible. In addition, for BEACH Act states the new/revised recreational criteria have to be "as protective of human health as EPA's criteria". EPA is working to develop a QMRA tool to support the development of site-specific/alternative criteria. The benefits are that states would have a tool without expending the resources needed to develop it on their own and EPA reviewers would be able to review alternative criteria based on a consistent, EPA-supported, scientifically defensible methodology.

Q. Do the new recreational water quality criteria address naturally occurring toxins from harmful algal blooms (HAB)?
A. No, the updated recreational water quality criteria seek to evaluate and reduce risks associated with recreational water contact. These updates address only health outcomes associated with exposure to microbial contaminants emerging from human (ex: publicly owned treatment works) and animal (ex: wildlife or animal feeding operations) fecal contamination sources.

Q. Will EPA consider recommending different criteria values for different fecal contamination sources?
A. EPA is open and interested in having discussions about this approach. However, to date we have not identified data to definitively show differences in risk from different sources. If such data exists we would greatly appreciate stakeholders providing it to EPA for consideration.