Current Thinking On Development of New Criteria

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Approach To Criteria Development

- Data-centric process
- Active, ongoing research will shape the criteria
  - Application of new technologies
  - Scope and approach
  - Available tools
  - Limitations for 2012 criteria
  - Goals for next iteration

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Other Considerations

- Input from other EPA Offices and Regions
- Stakeholder input
- Studies conducted by researchers outside of EPA
- Clarity and transparency of decision-making

Scoping the Criteria

- Break out issues by topic area
- Frame key questions
- Evaluate available data to answer questions
- Identify reasonable approach for criteria
  - Technical concerns
  - Implementation concerns
- Develop final draft for public comment

Topic Areas for Discussion

- Water Body Type
- Fecal Indicators
- Analytical Methods for Fecal Indicators
- Target Population
- Human Health Endpoint
- Tolerable Illness Level
- Statistical Correlation/Data Analysis
- Expression of Criteria Value
- Sources of Fecal Contamination

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Water Body Type

- **1986 Criteria**
- A numeric AWQC value for all marine waters and a different numeric value for all fresh waters (e.g., marine, estuary, Great Lakes, other lakes, rivers, streams)

- **OST's Current Thinking**
- Develop a limited number of AWQC values for all water body types covered under the CWA (e.g., marine and fresh; coastal, lakes, reservoirs, and flowing fresh waters) at the same risk level.

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Water Body Type - Considerations

- Similar approach to 1986
- Criteria are for use in multiple Clean Water Act programs
- Will require evaluation of EPA and non-EPA epidemiology data
- Additional considerations of fate and transport
- May include a policy component

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Fecal Indicators

- **1986 Criteria and/or 2004 Rule**
- Marine: Enterococcus indicator (measured by culture method)
- Fresh water: Enterococcus or *E. coli* indicator (measured by culture method)

- **OST's Current Thinking**
- Indicator(s) measured by qPCR and/or culture methods available for criteria

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Fecal Indicators - Considerations

- New criteria will be based upon fecal indicators, not direct measurement of pathogens
- Consistent with 1986/2004
- Based on assumption that occurrence of fecal material in water is primary source of pathogens
- Correlation between indicators and illness seen in EPA fresh water data
- May add/change indicators depending upon developing data

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Analytical Methods for Fecal Indicators

- **1986 Criteria and/or 2004 Rule**
- EPA Method 1600 for enterococci
- EPA Method 1603 for *E. coli*
- Other approved vendor methods for enterococci and *E. coli*

- **OST's Current Thinking**
- Analytical methods may be developed for different CWA programs
- Rapid (qPCR) for beach notification and monitoring
- Rapid and/or culture methods for compliance with other CWA programs

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Analytical Methods for Fecal Indicators - Considerations

- BEACH Act requires EPA to include a "revised list of testing methods as appropriate" in criteria publication
- "Rapid" methods are important for beach notification and advisories
  - Currently pending BEACH Act legislation defines rapid as 6 hours after commencement of the test method in the laboratory (House bill) or 4 hours after receipt of the sample at the facility (Senate bill)
  - qPCR is the "rapid" method under consideration at this time
- Major task is to link results of culture and qPCR so different methods can be use for different CWA programs while linked to the same risk level
  - Requires synthesis of multiple data sets
  - Very important effort for providing flexibility to use a range of analytical methods to measure water quality

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Target Population

- **1986 Criteria and/or 2004 Rule**
- General population
- **OST's Current Thinking**
- Derive a criteria value protective of children, provided data allow

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Target Population - Considerations

- Epidemiology data from EPA studies has a full range of age groups
- Children are less numerous than adults
- Other epidemiology data sets focus primarily on adults
- Comparison across data from multiple data sources may warrant developing an approach to protect children while using adult data

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Human Health Endpoint

- **1986 Criteria and/or 2004 Rule**
- HCGI-1 includes any one of the following or combinations of
  - (1) vomiting
  - (2) diarrhea with fever or a disabling condition
  - (3) stomach ache or nausea accompanied by a fever
  - 8 to 10 day follow up

- **OST's Current Thinking**
- HCGI-3
  - a) Diarrhea (3 or more loose stools in a 24 hour period) or,
  - b) vomiting, nausea and stomach ache, or
  - c) nausea or stomach ache and impact on activity
  - 10 to 12 day follow up
- Include other illnesses if significant and have indicators that reflect risk

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Human Health Endpoint - Considerations

- HCGI-3 is a less severe definition of illness than HCGI-1
  - HCGI-3 definition requires only a single effect
  - HCGI-1 definition requires multiple effects including fever
- Implication: *apparent* increase in illness using HCGI-3 because easier to qualify as ill
- Use of HCGI-3 rather than HCG-1 will likely impact the criteria value and its interpretation

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Tolerable Illness Level

- **1986 Criteria and/or 2004 Rule**
- 0.8% to 1.0% HCGI-1 in freshwater
- 1.9% HCGI-1 in marine

- **OST's Current Thinking**
- Goal is to be as health protective as 1986 criteria (to be determined how this will be defined)

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Tolerable Illness Level - Considerations

- EPA has developed an approach for converting between illness definitions
- EPA will be considering this approach to develop a comparable risk level from new epidemiology studies compared to the 1986 data
- Committed to common level of public health protection in all waters of the US

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Statistical Correlation / Data Analysis

- **1986 Criteria and / or 2004 Rule**
- Correlation between HCGI-1 and indicator density
- Steady state geometric mean
- Single Sample Maximum (SSM)

- **OST's Current Thinking**
- Correlation between HCGI-3 and indicator density
- Beach notification and NPDES – a value that allows some reflection of variability for a sample (short-term measure)
- Assessment– geometric mean (longer term measure)

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Statistical Correlation / Data Analysis - Considerations

- Criteria value will be health-based
- Criteria value will draw upon the illness/indicator relationship from EPA & to the extent practicable non-EPA epidemiology studies
- Short term measure is important for "rapid" determinations in beach monitoring and advisories
- Longer term measure may make more sense for other CWA purposes such as assessment and listing

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Expression of Criteria Value

- **1986 Criteria and / or 2004 Rule**
- Bacteriological density expressed in cfu/100ml (cultural method)

- **OST's Current Thinking**
- A numeric value that is protective of public health
- Cultural methods expressed in bacteriological density (cfu/100ml)
- qPCR results (possibly expressed in CEU/100ml)

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Expression of Criteria Value -Considerations

- Currently considering single indicator density, not a range
  - Ranges have implications for implementation
  - WHO binning approach is not consistent with concept of common risk levels
- Focus will be on level of indicators associated with tolerable illness level

Sources of Fecal Contamination

- **1986 Criteria and/or 2004 Rule**
- Criteria are for all sources of fecal contamination and have same numeric AWQC
- **OST's Current Thinking**
- Develop numeric AWQC applicable to all sources of fecal contamination—that is, will not likely have different indicator levels based on source of fecal contamination

Sources of Fecal Contamination - Considerations

- Most EPA epidemiology data have evaluated illness due to POTW impacts
- 2009 study added urban runoff source
- Other non-EPA data will be considered
- To date, no data have been identified to support criteria that quantitatively takes into account whether the source of fecal contamination is animal or human

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Moving Forward

- Begin to evaluate data and available information
  - EPA data
  - Other developing data
- Integrate developing data into criteria

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