July 21, 2003

MEMORANDUM

SUBJECT: Guidance for 2004 Assessment, Listing and Reporting Requirements Pursuant to Sections 303(d) and 305(b) of the Clean Water Act; TMDL-01-03

FROM: Diane Regas, Director /s/
Office of Wetlands, Oceans, and Watersheds

TO: Water Division Directors
Regions 1 - 10

This memorandum transmits EPA's guidance for preparing the 2004 Integrated Report. The Integrated Report is intended to satisfy the listing requirements of Section 303(d) and the reporting requirements of Sections 305(b) and 314 of the Clean Water Act (CWA). This guidance replaces and supercedes the following documents:

- Guidance for 1994 Section 303(d) Lists - Geoffrey H. Grubbs, November 26, 1993;
- National Clarifying Guidance for 1998 State and Territory Section 303(d) Listing Decisions - Robert H. Wayland III, August 27, 1997;
- EPA Review of 2000 Section 303(d) Lists - Robert H. Wayland III, April 28, 2000;
- 2002 Integrated Water Quality Monitoring and Assessment Report Guidance - Robert H. Wayland III - November 19, 2001; and
- Clarification of the Use of Biological Data and Information in the 2002 Integrated Water Quality Monitoring and Assessment Report Guidance.

This guidance is intended to be used by States and Interstate Commissions (that prepare 305(b) reports) in the preparation of their 2004 Integrated Report. Building on the 2002 guidance, the 2004 guidance stresses the use of the same five reporting categories and emphasizes the need for scheduling monitoring activities to ensure that future reports build on increasingly robust data and information and continuing documentation of improved water quality. In addition, the 2004 guidance emphasizes the need for each State to develop a technically sound assessment methodology – a thorough documentation and discussion of the links between a State's water quality standards (WQS) and the rationale on which their assessment determinations are based. EPA believes that a transparent methodology, driving scientifically-based assessment decisions, fits within the Agency's goal of an information-based strategy to environmental protection.

The 2004 guidance directly addresses issues identified by the States and EPA during the 2002

Note: TMDL0103 represents a new nomenclature for AWPD guidance; TMDL represents the program, 01 represents the first in the series of AWPD guidance documents in a particular year, and 03 represents the year.

listing and reporting cycles. There were many questions during the 2002 cycle on the use of data and sample size requirements. EPA has refined, in the 2004 guidance, what should be acceptable use of minimum data requirements and sample size requirements in making assessment determinations. EPA believes that this guidance will help EPA and the States employ scientifically and statistically valid approaches in using data and information to perform assessment determinations (place waters in one of the five categories).

The 2004 guidance also addresses the use of probability-based sampling designs in the context of the State's monitoring program. It provides further detail on integrating probability-based monitoring with the more targeted monitoring needed to make decisions on proper categorization of particular waters. EPA's goal continues to be the support of the development of State monitoring programs that balance the ability to conduct broad scale analyses of water quality conditions with the monitoring necessary to make scientifically and statistically sound assessment determinations for specific waters. EPA also wants to encourage States to support the development of volunteer monitoring programs through training and technical assistance.

The 2004 guidance also emphasizes the importance of the development and consistent application by the States of a "geo-referencing" scheme, such as National Hydrography Dataset (NHD) or another compatible format. The use of a consistent segmentation or addressing scheme allows States to report the current water quality of each defined segment, document changes in that segment since the last reporting cycle, evaluate the effectiveness of management actions to attain and maintain water quality in the segment, and to obtain insights into important ecosystem processes occurring in the segment.

The 2004 guidance also provides information on how the rotating basin approach fits into the development of the Integrated Report. EPA believes that State methodologies that account for the data collection and analysis process under a rotating basin approach can fit with the regulatory requirements to consider all existing and readily available data and information in developing Section 303(d) lists. EPA continues to support the use of the rotating basin approach.

Finally, the 2004 Integrated Report guidance describes timelines for EPA review and approval actions. EPA believes that the 2004 Integrated Report guidance provides a framework for States and EPA to provide a clear, increasingly comprehensive description of the Nation's aquatic resources, assess the effectiveness of regulatory and voluntary efforts to attain and maintain WQSs and provide all stakeholders with the ability to understand how and why waters were placed in any category.

EPA recognizes that many States substantially revamped their listing process in 2002 by developing improved methodologies and moving toward adoption of the Integrated Report. States may choose to update the 2002 Integrated Report, or Section 303(d) list and 305(b) report using data and information that have become available subsequent to the approval of the 2002 Integrated Report or Section 303(d) and 305(b) report. In these cases, EPA's review will focus on changes to the 2002 list resulting from new data and information.

EPA and the States should consider the most efficient and effective ways of approving or establishing Section 303(d) lists and updating Section 305(b) reports or Integrated Reports to meet the April 1, 2004, deadline. EPA Regions and States, and where appropriate Interstate Commissions, should hold early discussions regarding how drafts and actual submissions will be reviewed and how issues can be identified and resolved as early as possible.

Regions should work closely with States in the coming months to assure the timely completion and submittal of the 2004 report. To that end, the Regions should consider obtaining report submission schedule commitments from the States through Memorandum of Agreements (MOA), annual workplans, Performance Partnership Agreements (PPA) or other appropriate vehicles. A State's

failure to adhere to these negotiated schedules may result in the establishment of the list of waters requiring TMDLs (Category 5) by EPA.

This guidance addresses the following objectives for States and Interstate Commissions (that prepare 305(b) reports):

I. A more consistent assignment of georeferenced "addresses" to each of the State's water segments,

II. A full and uniform adoption of the five-part integrated list format for reporting the status of the State's waters,

III. A thorough documentation and discussion of the linkage between the State's WQSs and the scientific and technical rationale for how the State considered data and information in placing waters into the appropriate categories.

IV. Improved coordination of listing among States with shared waters.

Finally, AWPD will work with Regions and States to assure timely submission and action on 2004 Integrated Reports. If you have any questions, please contact Mike Haire (202-566-1224).

Guidance for 2004 Assessment, Listing and Reporting Requirements Pursuant to Sections 303(d) and 305(b) of the Clean Water Act

July 21, 2003

Watershed Branch
Assessment and Watershed Protection Division
Office of Wetlands, Oceans, and Watersheds
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INTRODUCTION

The Clean Water Act (CWA) contains several sections requiring reporting on the quality of the Nation's waters. Section 305(b) requires a comprehensive biennial report and Section 303(d) requires, from time to time, a list of waters for which effluent limitations are not sufficient to meet water quality standards (WQS). In its regulations implementing Section 303(d), EPA has defined "time to time" to mean on April 1 of every even-numbered year. EPA is recommending that for the 2004 submission, States and Interstate Commissions (that prepare 305(b) reports) provide a single water quality monitoring and assessment report (the Integrated Report) that combines the comprehensive Section 305(b) report on water quality and the Section 303(d) list of waters for which TMDLs are required, while also satisfying the requirements of Section 314.

Use of the five-part Integrated Report format provides the public and other interested stakeholders a comprehensive summary of the water quality status of all of the State's waters. This integrated approach allows water quality managers to demonstrate progress of the State's efforts to identify water quality problems, develop and implement restoration actions, and to ultimately achieve WQSs in all of the State's waters. Using the results of the Integrated Report, and consistent with 40 Code of Federal Regulation (CFR) 130.8(a), States can develop water quality management (WQM) plan elements to help direct subsequent control activities. States may also use the results of the Integrated Report to describe ground water quality and to guide development of ground water plans and programs. Water quality problems identified in the Integrated Report should be emphasized and reflected in the State's WQM plan and annual work program under Sections 106, 205(j), and 319 of the CWA.

The key components of the Integrated Report are as follows: geographic referencing of all water resources; categorization of waters according to WQS attainment status; identification, prioritization and scheduling of waters needing Total Maximum Daily Loads (TMDL); identification of waters where information is not sufficient to determine a water's status; and a schedule of monitoring for the next reporting cycle.

Placement of all of a State's waters into one of the five categories is the most significant feature of the Integrated Report. The categories represent varying levels of WQS attainment, ranging from Category 1, where all of a water's designated uses are met, to Category 5, where a pollutant impairs a water and a TMDL is required. These category determinations should be based on consideration of all existing and readily available data and information consistent with the State's assessment methodology and this guidance. For the remainder of this document, the term "methodology" refers to a State's assessment methodology. Each water segment should be placed in one of the assessment categories and monitoring scheduled by year for all categories.

States must submit their 2004 Integrated Report to EPA by April 1, 2004. While EPA encourages the use of the Integrated Report format, States may choose to submit separate Section 303(d) lists and Section 305(b) reports by April 1, 2004. Submissions may be in either electronic or hardcopy format. The submissions should include revised data and information, a description of the data and information analyses performed, and certification that previously submitted data and information remain accurate. EPA recommends electronic submission. EPA does not intend to seek regulatory changes to waive or delay the April 1, 2004, submission requirement.

When States submit their 2004 Integrated Report, EPA encourages them to characterize the quality and relevance of the scientific and technical data and information they use to develop their reports. The State's 2004 Integrated Report should be supported by an assessment methodology based on sound science and technical procedures that are clear, complete and well documented.

This guidance updates previous guidance and, to the extent it is different, supercedes previous guidance. The statutory provisions in Sections 303(d) and 305(b) and EPA regulations described in this document contain legally binding requirements. This document does not substitute for those statutory provisions or regulations, nor is it a regulation itself. Thus, it does not impose legally binding requirements on EPA, States, or territories and may not apply to a particular situation based upon the circumstances. EPA, State, and territorial decision makers have the discretion to adopt approaches on a case-by-case basis that differ from this guidance where appropriate. EPA may revise this guidance in the future, as appropriate.

I. HOW SHOULD WATERS BE SEGMENTED IN THE INTEGRATED REPORT?

The Integrated Report provides for a comprehensive description of the status of all waters within a State. Fundamental to this accounting is segmentation and geo-referencing of all water resources including rivers, streams, lakes, wetlands, estuaries, and coastal waters. For instance, EPA utilizes the National Hydrography Dataset (NHD), where segments may comprise part of an NHD reach, an individual NHD reach, or a collection of NHD reaches or parts of reaches. States generally partition waters to represent homogeneity in physical, biological or chemical conditions. Initially, this segmentation reflects an *a priori* knowledge of factors such as flow, channel morphology, substrate, riparian condition, adjoining land uses, confluence with other water bodies, and potential sources of pollutant loadings (both point and nonpoint). While there can be no single *default* dimension for a water body size, States should generally consider several factors in defining the size of a segment. These factors may include the following:

- The water quality uses assigned to the segment or water body.
- The expected natural variability of the criteria associated with the assigned uses.
- The type of water (e.g., a small stream, a wide river, a tidal and stratified estuary, and coastal shoreline).
- Time of travel of a parcel of water in the water body or segment or the magnitude of any tidal excursions.
- Amount and type of data and information necessary to provide a reasonably accurate characterization of attainment of these criteria in the segment or water body.
- Any expected changes in significant influences in the watershed (land use, point or nonpoint sources of pollutants).
- Any site-specific concerns such as patchy or unique habitat distribution patterns or biological population distributions.

For the 2004 Integrated Report submission, a State should assign a discrete "address" or geo-location to each segment. States should document the process used for defining water segments in their

methodologies. Segments generally should be divided such that different WQSs for the same beneficial use and pollutant do not apply within individual segments. The individual size of a segment will vary based upon methodologies. Segments should, however, be larger than a sampling station but small enough to represent a homogenous standard attainment.

II. WHAT ARE THE COMPONENTS OF AN INTEGRATED REPORT?

This guidance stresses the use of the five assessment categories introduced in the 2002 guidance. In broad terms, the five assessment categories are as follows:

Category 1: All designated uses are met;
Category 2: Some of the designated uses are met but there is insufficient data to determine if remaining designated uses are met;
Category 3: Insufficient data to determine whether any designated uses are met;
Category 4: Water is impaired or threatened but a TMDL is not needed (see Section II E of this document);
Category 5: Water is impaired or threatened and a TMDL is needed.

All waters should be placed in one of the five assessment categories and the categories are designed so that no water is placed in more than one category. It is important to note that the State does not need to physically collect monitoring data in each water in order to assign it to an assessment category.

To properly use the five assessment categories and to satisfy Sections 303(d)(1)(A) and (B), 305(b) and 314 of the CWA, the Integrated Report should include the following components:

- A categorization of all waters in the State based on readily available data and information.
- A description of the methodology used to place waters in Categories 1 though 5.
- WQSs attainment status.
- A schedule for establishment of TMDLs.
- Monitoring schedules for waters and a statement identifying any significant changes to the State's water quality monitoring and assessment program (i.e., change in segmentation, adoption of a rotating basin approach, etc.) since the previous listing cycle.
- A description of the public participation process, summary of the comments received, the responses to the comments, and documentation that the State conferred with neighboring States concerning assessment determinations of interjurisdictional (shared) waters.
- Information to fulfill the requirements of CWA Section 305(b)(1)(C) through (E).

A. May a State use subcategories or additional categories in its Integrated Report?

Yes, in order to refine their classifications, States may choose to establish new or additional subcategories. For example, a State may decide to report waters in subcategories for Category 3 in order to distinguish between those waters where *no data and/or information* exist from those waters where *some* data and/or information exist, but the data are *insufficient* to determine that any

designated uses are met. Another example could be when a State chooses to subcategorize Category 3 waters according to high, medium, and low priority for follow-up monitoring based on information from probability-based monitoring, landscape or water quality models, or limited site-specific monitoring.

Similarly, a State may choose to report their Category 5 waters in subcategories to differentiate the causes and sources of impairment and the status of TMDL development (or other activities intended to improve water quality) for waters where more than one pollutant is causing one or more use impairments. For example, if a water is listed for pollutant A and B, and the TMDL has been completed for pollutant A, Category 5 might be subdivided to demonstrate this progress.

Another example might be when a pollutant is being addressed by other pollution control requirements and a TMDL is not necessary. Category 5A might include water-pollutant combinations still to be addressed by a TMDL, while Category 5B might include water-pollutant combinations where a TMDL has been completed and approved. However, it is important to note that a water-pollutant combination cannot be moved from Category 5 to Category 4A until TMDLs for all pollutants are completed for a given water.

As another example, a State may choose to report waters impaired by the atmospheric deposition of a pollutant in a separate subcategory of Category 5.

Finally, a State may choose to distinguish between waters that are attaining some designated uses but not others and waters that are not attaining any designated uses. A State may also use subcategories to reflect the schedule for establishing TMDLs or for conducting supplemental monitoring.

B. Which waters belong in Category 1?

Waters belong in Category 1 if they are attaining all designated uses and no use is threatened. Segments should be listed in this category if there are data and information that are consistent with the State's methodology and this guidance, and support a determination that all WQSs are attained and no designated use is threatened.

C. Which waters belong in Category 2?

Waters should be placed in Category 2 if there are data and information that meet the requirements of the State's assessment and listing methodology that support a determination that some, but not all, designated uses are attained and none are threatened. Attainment status of the remaining designated uses is unknown because data are insufficient to categorize a water consistent with the State's listing methodology.

D. Which waters belong in Category 3?

Waters belong in Category 3 if there are insufficient or no data and information to determine, consistent with the State's listing methodology, if any designated use is attained. To assess the attainment status of these waters, States should schedule monitoring on a priority basis to obtain data and should also make efforts obtain information necessary to move these waters into Categories 1, 2, 4, and 5.

When States choose to support their assessments with the collection of supplemental data, Category 3 provides States with the flexibility to monitor these waters in a manner consistent with their overall monitoring strategy and schedule.

Category 3 responds to one of the recommendations in the 2001 National Research Council's (NRC) report, *Assessing the TMDL Approach to Water Quality Management* (2001) that EPA and States identify waters where information is not sufficient to determine a water's status, and thus identify waters where additional data and information is necessary prior to making an assessment determination.

E. Which waters belong in Category 4?

Waters belong in Category 4 if one or more designated uses are impaired or threatened but establishment of a TMDL is not required. States may place an impaired or threatened water that does not require a TMDL in one of the following three subcategories: a TMDL has been completed for the water-pollutant combination (Category 4A), other required control measures are expected to result in the attainment of WQSs in a reasonable period of time (Category 4B); and the impairment or threat is not caused by a pollutant (Category 4C).

1. Which waters belong in Category 4A?

Waters should only be placed in Category 4A when all TMDLs needed to result in attainment of all applicable WQSs have been approved or established by EPA. Once the TMDLs have been approved or established, the State should implement the TMDL as soon as practicable. Additionally, EPA encourages States to provide monitoring schedules for these waters to ensure that sufficient data are obtained to document progress of the implementation actions toward the attainment of WQSs, and that progress is reasonably consistent with the projected time of attainment included in the TMDL.

2. Which waters belong in Category 4B?

Current regulations do not require TMDLs for all waters. Some waters may be excluded from Category 5, and placed into Category 4B. In order to meet the requirements to place these waters into Category 4B, the State must demonstrate that "other pollution control requirements (e.g., best management practices) required by local, State or Federal authority" (see 40 CFR 130.7(b)(1)(iii)) are expected to address all water-pollutant combinations and attain all WQSs in a reasonable period of time. EPA expects that States will provide adequate documentation that the required[1] control mechanisms will address all major pollutant sources

[1]"Although TMDLs play an important informational role in the CWA's regulatory scheme, they are not regulations, and they do not impose legal obligations or prohibitions on polluters. Rather, TMDLs identify the reductions in the overall loading of a pollutant in a designated segment of substandard water that are necessary to bring that segment into compliance with a water quality standard, thereby allowing 'the states to proceed from the identification of waters requiring additional planning to the required plans.' Pet. App. 9a, 68a-69a. 'TMDLs serve as a link in an implementation chain that includes federally-regulated point source controls, state or local plans for point and non-point source pollution reduction, and assessment of the impact of such measures on water quality.' *Id*. at 9a. When a TMDL identifies necessary reductions in pollutant loading from point sources, such reductions are achieved through restrictions set out in the NPDES permit or state permit for each point source. 33

and establish a clear link between the control mechanisms and WQSs.

3. What are EPA's expectations for including waters impaired by point sources in Category 4B?

A decision to list a water in Category 4B using §130.7 (b)(1)(i) must be supported by the issuance of technology-based effluent limitations *required* by Sections 301(b), 306, 307 or other sections of the CWA. A decision to list in Category 4B using §130.7 (b)(1)(ii) must be supported by the issuance of more stringent effluent limitations required by either Federal, State or local authority. EPA expects that the State will provide a rationale for why they believe that these effluent limits will achieve WQSs within a reasonable period of time.

4. What are EPA's expectations for including waters impaired by nonpoint sources in Category 4B?

Placement of waters in Category 4B based on §130.7 (b)(iii) must be supported by the existence of "other pollution control requirements (e.g., best management practices) required by local, State, or federal authority" that are stringent enough to implement WQSs. EPA expects that the State will demonstrate that these control requirements will achieve WQSs within a reasonable period of time. States should provide the following information to support including a water in Category 4B:

- identification of the controls to be relied upon (for example, best management practices, air emission controls, sediment dredging, etc.);
- authority (local, state, federal) under which the controls are required and will be implemented with respect to the sources contributing to the water quality impairment (for example, self-executing State or local regulations, permits, or contracts that require implementation of the necessary controls);
- document how the control measures are generally applicable to the impairment in question and can reasonably be expected to reduce pollutant loadings and ultimately attain WQSs when fully implemented. Generally, sufficient documentation will;
    - * describe the rationale for why these control mechanisms will achieve WQSs within a reasonable period of time,
    - * list the suite of controls proposed for implementation and a range of the controls' effectiveness (e.g., cover crops will reduce current sediment loadings by 50-60%),

U.S.C. 1311(a), 1362(12) and (14); 40 C.F.R. 122.44(d)(1)(vii)(B). But when a TMDL identifies necessary reductions in pollutant loadings from nonpoint sources, such reductions maybe implemented only under state law, because the CWA does not have a permit program for, or otherwise regulate pollutant loadings from, nonpoint sources. See *NRDC* v. *EPA*, 915 F.2d 1314, 1316 (9th Cir. 1990). EPA has no authority to enforce TMDL pollutant-loading reductions against nonpoint sources or to require a State to do so. EPA may, however, disburse funds to the States to assist their implementation of nonpoint source management programs, including the development of best management practices to control non-point source pollution. See 33 U.S.C. 1329(h); *NRDC*, 915 F.2d at 1318." *(Guido A. Pronsolino, et. al., vs. EPA*, 9th Circuit Court of Appeals, On Petition for a Writ of Certiorari, No. 02-1186, in the Supreme Court of the United States. (2003))

* estimate the number of acres that will be treated by the general class of controls to achieve the target load (e.g., approximately 60 acres will receive cover crops, approximately 30 acres will be subject to no-till practice, and 25 acres will be planted with riparian buffers),
* document that the water quality should be achieved as soon as practicable once full implementation occurs, or for controls required as part of an iterative or adaptive management program, provide reasonable assurance that phased implementation will continue until WQSs are achieved, and
* document the basis by which implementation of these measures is required (e.g., permits, self executing regulations, contracts, and agreements),
* provide information about the certainty of funding availability. For blended waters (waters with both point and nonpoint source pollutant loads), EPA would expect that States would provide adequate documentation that both sets of proposed controls will achieve WQS in a reasonable time frame.

Watershed plans may be used to support including a water in Category 4B if the information listed above in included in the plan for that water.

EPA also believes that management measures implemented by Federal agencies designated as management agencies, that meet one of the above criteria, might also obviate the need for establishing TMDLs.

5. What is a reasonable time for achieving WQSs?

EPA expects that waters impaired by a pollutant but not listed under Section 303(d) based on reliance on existing control requirements are expected to attain WQSs within a reasonable period of time. EPA expects that the State will consider those factors unique to the specific water and provide an estimate of the time of WQS attainment. Factors that may influence the length of this time frame may depend on the initial severity of the impairment, the cause of the impairment (e.g., point source discharges, in place sediment fluxes, atmospheric deposition, nonpoint source runoff), riparian condition, channel condition, the nature and behavior of the specific pollutant (e.g., conservative, reactive), the size and complexity of the water body (a simple first-order stream, a large thermally-stratified lake, a density-stratified estuary, and tidally-influenced coastal water), the nature of the control action, cost, public interest, etc.

For point sources, a mechanism to estimate the time frame of WQS attainment could be a schedule established under the National Pollutant Discharge Elimination System (NPDES) program demonstrating that the program requirements will be sufficient to bring about attainment of WQSs in a reasonable time. For a simple discharge (single pollutant being discharged from a single source into a free flowing river), the time frame to achieve WQSs may be by the next listing cycle or the life of the permit, whichever is greater, unless a shorter time frame is required by a compliance schedule.

For nonpoint sources, the time frame for achieving the WQS may be difficult to accurately predict; however, States have some flexibility in gauging whether the attainment will occur quickly enough to justify including a water in Category 4B. EPA suggests that the State provide a reasonable calculation that demonstrates that pollutant reductions (resulting from the implementation of the "other controls") will lead to attainment of WQS. The degree of certainty

may depend on how many sources must be controlled and the degree of specificity of control that exists with respect to each source.

6. Which waters belong in Category 4C?

Waters should be listed in this subcategory when an impairment is not caused by a pollutant. States should schedule these segments for monitoring to confirm that there continues to be no pollutant-caused impairment and to support water quality management actions necessary to address the cause(s) of the impairment.

Pollution, as defined by the CWA, is "the man-made or man-induced alteration of the chemical, physical, biological, and radiological integrity of water" (Section 502(19)). In some cases, the pollution is caused by the presence of a pollutant and a TMDL is required. In other cases, pollution does not result from a pollutant and a TMDL is not required. Elevated temperature that results from man-made thermal discharges does require a temperature TMDL based on the protection or propagation of a balanced indigenous population of shellfish, fish, and wildlife.

The following are two examples of pollution caused by pollutants. The discharge of copper from an NPDES regulated facility is the introduction of a pollutant into a water. To the extent that this pollutant alters the chemical or biological integrity of the water, it is also an example of pollution. (Copper is not likely to cause an alteration to the water's physical integrity). Similarly, actions that modify the landscape and may result in the introduction of sediment into a water constitute pollution when sediment (which is a pollutant) results in an alteration of the chemical, physical, biological or radiological integrity of the water. TMDLs would have to be established for each of these waters.

EPA does not believe that flow, or lack of flow, is a pollutant as defined by CWA Section 502(6). Low flow can be a man-induced condition of a water (i.e., a reduced volume of water) which fits the definition of pollution. Lack of flow sometimes leads to the increase of the concentration of a pollutant (e.g., sediment) in a water. In the situation where a pollutant is present a TMDL, which may consider variations in flow, is required for that pollutant.

F. Which waters belong in Category 5?

This category constitutes the Section 303(d) list that EPA will approve or disapprove under the CWA. Waters should be placed in Category 5 when it is determined, in accordance with the State's assessment and listing methodology, that a pollutant has caused, is suspected of causing, or is projected to cause an impairment or threat. If that impairment or threat is due to a pollutant, the water should be placed in Category 5 and the pollutant causing the impairment identified.

A water is considered impaired when one or more designated uses are not attained. Where more than one pollutant is causing the impairment, the water should remain in Category 5 until all pollutants are addressed in a completed/EPA-approved TMDL or by one of the delisting factors mentioned in the answer to question 2.a. below in this section.

*1. Is Category 5 of the Integrated Report for 2004 a **new** Section 303(d) list, and must the State account for all waters previously listed as needing a TMDL in the 2002 list?*

The Section 303(d) list once approved (or, if necessary, established by EPA following disapproval of a State's list) is a new list that replaces the previous list. The time frame for establishing TMDLs for individual water/ pollutant combination should be 8 to 13 years from the date of the original water/pollutant combination listing. For example, a water/pollutant combination originally included on the 1998 Section 303(d) list, and still identified on the 2004 submission as requiring a TMDL, should be addressed by 2011.

The fact that a water was previously included in Category 5 is not, by itself, positive evidence that it must remain in Category 5 until a TMDL is established. Waters should generally remain in Category 5 until a TMDL is established unless there is reason to believe that conditions that led to the initial listing have changed (WQSs are attained, actions justifying inclusion in Category 4, etc.), or that the basis for the initial listing was in error. In any of these circumstances where a water's status might change, all existing and readily available data and information should be considered, and the most current methodology applied to determine the water's most appropriate placement into one of the five categories.

EPA may request, as discussed below, that the State demonstrate "good cause" for not including previously listed segments in Category 5 (40 CFR 130.7(b)(6)(iv)). EPA may request this demonstration if the State does not develop a credible methodology (consistent with the State's WQSs, relevant sections of CALM, and this guidance), or does not apply the methodology consistently, especially where the "delisting" of an impaired water on a previous list is not supported by the application of the State's methodology.

2. What do States need to consider regarding "Good Cause" delisting?

a. What may constitute good cause for not including waters that were previously included in the current Category 5 (the Section 303(d) List)?

If EPA requests "good cause" for not including on the 2004 submission waters that had previously been identified as impaired, the State must provide the reasons why the water has not been placed in Category 5. Consistent with 40 CFR 130.7(b) "good cause" for not including waters in Category 5 may be based on:

- The assessment and interpretation of more recent or more accurate data demonstrate that the applicable WQS(s) is being met.
- The results of more sophisticated water quality modeling demonstrate that the applicable WQS(s) is being met.
- Demonstration that flaws in the original analysis of data and information led to the water being incorrectly listed.
- The development of a new listing methodology, consistent with State WQSs and federal listing requirements, and a reassessment of the data that led to the prior listing, concluding that WQSs are now attained.
- A demonstration pursuant to 40 CFR 130.7(b)(1)(ii) that there are effluent limitations required by State or local authorities that are more stringent than technology-based effluent limitations, required by the CWA, and that these

more stringent effluent limitations will result in the attainment of WQSs for the pollutant causing the impairment.

- A demonstration pursuant to 40 CFR 130.7(b)(1)(iii) that there are other pollution control requirements required by State, local, or federal authority that will result in attainment of WQSs for a specific pollutant(s) within a reasonable time (see Section II E of this document).

- Documentation that the State included on a previous Section 303(d) list an impaired water that was not required to be listed by EPA regulations, e.g., waters where there is no pollutant associated with the impairment.

- Approval or establishment by EPA of, a TMDL since the last Section 303(d) list.

- A State inappropriately listed a segment that is within Indian country, as defined in 18 U.S.C. Section 1151.

EPA has the authority to disapprove a submission if EPA identifies existing and readily available information, available at the time the State submitted the list that shows a segment should be included in Category 5 or the Section 303(d) list. In that situation, EPA will partially disapprove the State's list and identify additional waters that should be included in Category 5.

The States must apply the same methodology (including weight of evidence and minimum sample and data quality requirements) to delist waters as they apply to list waters.

b. Can previously listed segments (without new data or information) be delisted solely because they have not yet been assessed with a new methodology?

EPA does not believe it would be appropriate to delist previously listed segments (without new data or information) ***solely*** because they have not yet been assessed with a new methodology. The State must provide, at the request of the Regional Administrator, good cause for not including a previously listed segment on its new 2004 Section 303(d) list. There are some situations where a previously listed segment may be delisted without relying on data and information collected after the date of the previous list. For example, if the State evaluates the pre-existing data and information using a methodology that EPA has determined to be technically reasonable, and the results of that evaluation provide a "good cause" basis for not including the segment on the 2004 list, the segment would no longer need to be included in Category 5. However, the delisting should only occur if it is determined by EPA that the new methodology is technically sound, consistent with the State's WQSs, and is deemed statistically reasonable.

3. Should Category 5 include threatened waters?

Yes, States should include threatened waters in Category 5. Threatened waters are

waters that are currently attaining WQSs, but which are expected to exceed WQSs by the next listing cycle (every two years). Waters should be listed if the analysis demonstrates a declining trend in a specific water quality criterion (WQC), and the projected trend will result in a failure to meet a criterion by the date of the next list (i.e., 2006 for purposes of the 2004 assessment cycle). The State assessment and listing methodology should describe how the State identifies threatened waters.

4. Should Category 5 include an impaired water if the specific pollutant causing the impairment has not been identified?

States are required to identify the pollutant causing the impairment or threat for each water/pollutant combination in Category 5 (40 CFR 130.7(d)). States should include impaired and threatened waters in Category 5 when a water is shown to be impaired or threatened in relation to biological assessments used to evaluate aquatic life uses or narrative or numeric criteria adopted to protect those uses even if the specific pollutant is not known. These waters should be listed unless the State can demonstrate that non-pollutant stressors cause the impairment, or that no pollutant(s) causes or contribute to the impairment. Prior to establishing a TMDL for such waters, the pollutant causing the impairment would need to be identified. EPA has developed guidance to assist States in identifying the causes of a biological impairment. This document, "Stressor Identification Guidance," was released in December 2000 (EPA 822-B-00-025). This document is also available on the Internet at: http://www.epa.gov/ost/waterscience/biocriteria/stressors/stressorid.pdf.

5. When should Category 5 include waters covered by fish consumption advisories?

EPA generally believes that fish and shellfish consumption advisories and certain shellfish growing area classifications based on segment specific information demonstrates impairment of CWA Section 101(a) "fishable" uses. This applies to fish and shellfish consumption advisories and certain shellfish area classifications for all pollutants that constitute potential risks to human health.

For purposes of determining whether a segment is impaired by a pollutant and should be included in Category 5, EPA considers a fish consumption advisory or shellfish consumption advisory, a National Shellfish Sanitation Program (NSSP) Classification, and the supporting data to be existing and readily available data and information that demonstrate non-attainment of a Section 101(a) "fishable" use when:

- the advisory is based on fish and shellfish tissue data,
- a lower than "Approved" NSSP classification is based on water column and/or shellfish data (and this is not a precautionary "Prohibited" Classification or the State WQS does not identify lower than "Approved" as attainment of the standard),
- the data are collected from the specific segment in question, and
- the risk assessment parameters (e.g., toxicity, risk level, exposure duration and consumption rate) of the advisory or classification are cumulatively equal to, or less protective than those in the State's WQSs.

This applies to all pollutants that constitute potential risks to human health, regardless of the source of the pollutant. However, for advisories for "dioxin and dioxin-like compounds," due to unique risk characterization issues, listing decisions should be made on a case-by-case

basis.

Where a State classifies shellfish growing areas "Prohibited" as a precautionary measure due to the proximity of a wastewater treatment plant discharge, or where a required sanitary survey has not been conducted, the segment should not be included in Category 5 unless there are segment specific data (and the data were not considered during the development or review of a non-precautionary NSSP classification), showing nonattainment of Section 101(a) uses.

Finally, some fish and shellfish consumption advisories and NSSP classifications are based on Food and Drug Administration (FDA) action levels as opposed to EPA's risk-based methodology for the protection of human health. FDA action levels are established to protect consumers of interstate shipped, commercially marketed fish and shellfish rather than fish and shellfish caught and consumed within a State. FDA action levels also include non-risk-based factors (e.g., economic impacts) in their derivation, while WQC must protect the designated uses without regard to economic impacts. EPA has therefore concluded that FDA action levels do not provide a greater level of protection for consumers of fish and shellfish caught and consumed within the State than do human health criteria. In such instances, or where waterbodies have a fish or shellfish consumption advisory, they need not be listed as impaired under Section 303(d) unless there are water-specific data (and the data were not considered during the development or review of a non-precautionary NSSP classification), showing nonattainment of Section 101(a) uses.

6. Should Category 5 include impaired waters for which WQS are being revised to be less stringent?

Yes. State Section 303(d) lists and the subsequent establishment of TMDLs is linked to applicable State WQSs. For purposes of listing waters under Section 303(d), States must consider whether its waters are meeting applicable WQSs, defined in the regulations as standards under CWA Section 303(c), including numeric criteria, narrative criteria, designated uses, and antidegradation requirements (40 CFR 130.7(b)(3)).

States may revise their WQSs to address changes resulting from Use Attainability Analyses (40 CFR 131.10), development of a site-specific criterion, or updated science.

A decision not to list because a WQS is in the process of being revised would be inconsistent with the regulations cited above and the CWA, which require a State to identify "those waters within its boundaries" where controls "are not stringent enough to implement *any water quality standard applicable to such waters"* (Section 303(d)(1)(A) of the CWA, emphasis added). Therefore, States must include on their Section 303(d) lists waters that do not meet an applicable WQS at the time of listing, even if the standard is in the process of being revised to be less stringent, until such time as EPA approves the revised standard. If EPA approves a revised standard in the future, the water may be removed from the Section 303(d) list at that time provided the water does not meet the listing requirements with respect to the new standard (40 CFR 130.7(b)(3)). States have the discretion to assign a low priority for establishing a TMDL to those waters where there is probability that they may be removed from the list in the near future. States should be aware that a TMDL should be developed to meet the existing WQS, not a temporary variance that is less stringent than the existing WQS.

7. What Additional Information is needed for waters in Category 5?

a. Identification of Pollutants

Section 130.7(b)(4) requires States to identify, for each Section 303(d) list (Category 5 waters) submitted to EPA, the "pollutants causing or expected to cause violations of the applicable water quality standards." For the 2004 listing cycle, waters identified as impaired or threatened relative to biological criteria should be included in Category 5 unless it is known that a pollutant is not causing the impairment. States should identify all pollutants that are known to be causing the impairment of a water.

b. Prioritization and TMDL Schedule

Section 303(d) requires States to "establish a priority ranking" for the waters it identifies on the list, taking into account the severity of the pollution and the uses to be made of such waters, and to establish TMDLs "in accordance with the priority ranking." Federal regulations provide that "schedules for submissions of TMDLs shall be determined by the Regional Administrator and the State" (40 CFR 130.7(d)(1)). Other reasonable factors such as the State's use of a rotating basin approach or commitments specified in court orders or consent decrees may also be considered when States develop priorities and schedules. To implement this provision, EPA recommends that States develop a schedule for establishing TMDLs as expeditiously as practicable and that (1) identifies which TMDLs will be established in each year of the upcoming Integrated Reporting cycle and (2) the approximate number of TMDLs to be established for each year thereafter. EPA encourages the States to ensure that the schedule provides that all TMDLs for waters listed on previous Section 303(d) lists be established within 8 to 13 years. In addition, EPA suggests that newly identified Category 5 waters have a TMDL developed no later than 13 years after the water is first identified in Category 5. EPA will not be taking any action on either of these schedules. The schedules are intended to help the public and EPA to understand the State's priorities and assist in work planning.

In developing their schedules, States will need to decide which TMDLs are higher priority than others. States need not specifically identify each TMDL as high, medium or low priority. Instead, the schedule itself can reflect the State's priority ranking. The CWA does not prescribe a particular method of expressing a priority ranking, and EPA believes a TMDL schedule is a reasonable, efficient way to demonstrate priority ranking. In some circumstances, the order in which TMDLs are established might be subject to some modifications such as logistical efficiencies or data availability.

The State should demonstrate that it conferred with neighboring States concerning assessments of waters that cross or share State boundaries. Where neighboring States do not agree on listing decisions for these waters, the States should confer with the EPA Region(s) in advance to seek assistance in reconciling listing judgements.

G. How should States handle shared waters?

States with shared waters should make every effort to coordinate with each other in the development of their Integrated Reports. Coordination should occur early in the process. Where possible, States should work together to collect, assemble, solicit, and assess all readily available data and information relevant to the shared waters. Assessments for waters that are shared by neighboring states should be as consistent as possible. This is particularly important for waters listed in Category 5. However, differing State WQS can make consistent attainment decisions difficult. In such cases, EPA Regional offices and Interstate Commissions, where applicable, should assist in resolving inconsistencies when they arise. The Integrated Report should document the coordination that has occurred between neighboring states and Interstate Commissions.

Some Interstate Commissions are required to prepare a 305(b) report, but the responsibility of preparing Integrated Reports and 303(d) lists rests with the States. Data and information in an Interstate Commission 305(b) report should be considered by the States as one source of readily available data and information when they prepare their Integrated Report and make decisions on waters to be placed in Category 5; however, data in a 305(b) Interstate Commission Report should not be automatically entered in a State Integrated Report or 303(d) list. EPA will make the necessary modification to its ADB system to ensure that Interstate Commission data stays segregated from State data.

H. How should States use and report the results of probabilistic monitoring?

States are encouraged to use probabilistic designs for broad scale, integrated, water quality assessments, and they should report the results of these assessments as a separate component of their Integrated Report. In addition, sampling performed under probability surveys provides site-specific data about each sample location. This data should be considered along with other site-specific data used to make assessment decisions and place waters in one of the five categories.

The majority of the nation's waters remain unmonitored and unassessed, even though the CWA requires that States update the description of the quality of all navigable waters in the State every two years. It is neither necessary nor practicable for States to physically conduct site-specific monitoring of all waters in order to undertake some level of an assessment. EPA believes that States should employ a combination of monitoring tools to most efficiently address the full range of water quality management needs. These tools include probability-based monitoring surveys, landscape and water quality models, remote sensing, and targeted site-specific monitoring.

EPA believes that a probabilistic monitoring design applied over large areas, such as an entire State or large watershed, is a cost-effective approach to producing a statistical statement, of known confidence, describing the aggregate condition of water resources. Probability-based monitoring employs the basic concepts of statistical random sampling.

The results of probabilistic monitoring provide a useful benchmark for the extent that waters are likely to be healthy or degraded. Probability-based results also provide a piece of information about waters, for which little or no other data may exist. For example, a probability-based sample of all rivers and streams in a basin may find that 80% of the waters support healthy aquatic communities. In some cases, this information may be compelling enough to support site-specific decisions about water quality. For example, if a probability-based survey of fish tissue from a random sample of lakes across a State found an extremely high (e.g., 95% to 99%) probability that contaminant concentrations exceed advisory levels, decision makers *may decide* to issue statewide fish consumption advisories and consider identifying all of the State's lakes as impaired for fish consumption use.

When combined with other predictive tools, a probabilistic monitoring design can assist a State in determining monitoring priorities and in targeting site-specific monitoring activities. States are encouraged to use this information when establishing monitoring priorities for water in Categories 1 through 5. For example, waters included in Category 3 (Insufficient Data), may be sub-categorized as high, medium, or low-priority for follow-up monitoring based on results of a probability survey, landscape or water quality models, and/or limited site-specific data.

The following sections address the data requirements recommended by EPA for reporting probability-based assessments.

1. Describe the probabilistic network methodology

For each probability network or survey project, a description of the project methodology should be provided. Where there are a small number of standard project designs, a State can make reference to pertinent sections from its general monitoring design and assessment methodology materials.

The following components of all probability networks should be clearly defined:

- Probability Network Names – list of all the probability-based networks
- Reporting units (or study areas) and IDs– for each network, include reporting unit name(s), a map (see item 2) below that clearly identifies the reporting area(s) and a unique numeric identifier
- Resource Types – types of water (large streams, rivers, lakes, estuaries, confined aquifers, etc.) monitored for each reporting unit
- Designated Uses – list of all designated uses monitored for a resource type
- Indicators – list of indicators used for each type of water and designated use in each reporting unit

- Table 1 shows how this basic information on State probability survey projects should be organized.

2. Report the geographic locations of the target populations of surface water resource types including NHD referencing where relevant.

States and Territories are expected to have GIS polygon coverages related to each probability network or survey project as appropriate. Where the target population is not the same as an entire State, maps should be provided that use polygons to highlight a project's geographic area such as watershed units, eco-regions, or other geographic regions. GIS coverages should conform to Federal Geographic Data Committee (FGDC) Geospatial Data Metadata Standards. State in-house probability survey project polygons should be available with basic FGDC-compliant metadata in either a shape file format, or in a standard ESRI export file format (*.e00). Additional information can be found at: http://www.fgdc.gov/metadata/contstan.html.

Additional information to define the geographic frame (sample frame or "population") for a probability survey project should include such items as: the water resource type that is relevant to the project. Examples include the following: small order streams, large lakes, rivers, etc. Criteria should be given to distinguish each resource category. States and Territories are also expected to develop size estimates for the entire target population. States and Territories should be able to document the GIS Hydrography coverage such as the NHD or other data layer used to develop their target population sizes. States are encouraged to use segments that are linked to the NHD.

3. Report probability-based attainment results for water quality standards or other impairment criteria

For each probability survey project, probability-based water quality standards or other criteria attainment results should be summarized using the format illustrated in Table 1. Data elements in Table 1 should be considered the minimum elements reported. If states have additional elements for their reports of condition, those should be added to the table and defined. The table can be accompanied with graphics using pie charts or other business charting layouts. The presentation of the study's findings should apply a breakpoint that clearly defines the estimated percentage of the total target population meeting standards and the percentage not meeting standards or criteria as appropriate.

4. Report the precision, confidence and date of the probability-based attainment results.

The major attraction of probability designs is that statistics can be developed that show the confidence and precision levels associated with attainment results. States and Territories should provide a discussion of the statistical tests they apply to produce the confidence and precision value information illustrated in Table 1. As with reporting for AU results, the assessment data should be included for each probability survey project indicating when the State and Territory finished the technical analysis of data and made its decision on the standards/criteria attainment status. Table 1 illustrates how to display the assessment date in a YYYYMMDD format.

Table 1. Data elements and reporting format for the attainment results calculated

using a probabilistic monitoring design.

Data Element	Example
Prob. Netw. Name (name of network)	Surface water status network
Project ID (unique numeric identifier for reporting unit)	3317
Target Population (name of reporting unit)	St. Marks Basin
Resource Type (type of water)	Small lake
Designated Use (designated use of water)	Aquatic life
Indicator (indicator monitored)	Trophic State Index
Size (total population size of resource type)	75
Units (population units)	Square mile
# sites (number of sites sampled in reporting unit)	30
Percent attaining (percent of waters attaining standard or criterion for indicator	85%
Percent partial attaining (percent of waters partially attaining)	10%
Percent not attaining (percent of waters not attaining)	5%
Data (data analysis date)	021503
Precision (method precision)	90%
Confidence (method confidence)	+15

Note:

Text in parentheses is intended to further clarify what is needed for each data element.

I. How should States use community level bioassessment data?

Many states use multi-metric, community level biological assessments to report water resource condition. Biological assessments provide direct measures of the cumulative response of the biological community to all sources of stress: they measure the condition of the aquatic resource to be protected. Therefore, biocriteria set the biological endpoint, or target, to which water quality should be managed.

States using biological assessments to make assessment determinations should also consider other types of data and information (i.e., chemical and physical).

Credible assessments of biological condition can be accomplished with far fewer samples than with parameter-specific monitoring. However, attention to proper quality assurance and control is equally important in biological monitoring as it is in chemical and physical measurements. Threshold values for water impairment determinations as well as quality assurance should be addressed in the State's methodology.

J. Why should the Integrated Report include a monitoring schedule and what information should the schedule provide?

As described in numerous documents, including most recently *The Twenty Needs Report: How Research Can Improve the TMDL Program* (EPA 2002) and *The Elements of a State Monitoring and Assessment Program* (EPA 2003), effective environmental management relies upon monitoring to fulfill numerous water quality management objectives. These objectives include providing the basis for characterizing the current attainment status of a State's waters, defining trends in a water's condition, providing the data and information for establishing TMDLs, supporting the development of NPDES permits and other pollution control measures, and evaluating the water quality response to these management measures. Clearly, there is an ongoing and continuous need to routinely collect, assemble and assess data and information on the status of State water resources.

The *Elements of a State Monitoring and Assessment Program* (EPA 2003) calls for States to develop comprehensive, long term monitoring strategies that describe how and when States will implement monitoring programs that serve their water quality management needs and address all water resource types. This comprehensive monitoring strategy will likely integrate a combination of monitoring designs, assessment tools, and water quality indicators to meet the full range of decision needs for different water resource types at relevant geographic scales. EPA recommends that State monitoring program managers work with other State environmental managers and interested stakeholders (including EPA Regions, other Federal water quality and land management agencies, volunteer monitoring organizations, local government, academic institutions, etc.). This collaboration enhances opportunities to maximize the use of other data and potentially expand monitoring resources available to the State.

This Integrated Report guidance asks States to develop a schedule, as an element of the Integrated Report, that identifies the waters that will be monitored and assessed during the next two-year integrated report cycle. EPA does not expect that all waters will be scheduled for monitoring during the next two-year reporting cycle. This short-term monitoring schedule included with the Integrated Report should be consistent with monitoring priorities. For example, the short-term monitoring schedule may target borderline impairments, it may fill data gaps in specific watersheds to facilitate bundling of TMDLs, or it may focus on assessing specific designated uses. If a State has previously prepared such a schedule, it can reference the schedule in the Integrated Report.

The short-term monitoring schedule included with the Integrated Report may present upcoming monitoring activities planned under the long-term strategy, including the use of probability-based monitoring, landscape and water quality models, and targeted monitoring to predict and verify water quality conditions. For example, it might identify the use of probability-based design to provide preliminary information about the condition of some unassessed waters in Category 3. It could describe the use of landscape models to target waters with a high likelihood of degradation for follow-up monitoring.

EPA intends that the monitoring schedule will inform stakeholders and EPA of a State's upcoming monitoring activities and will help promote collaboration and coordination among monitoring organizations. This schedule, in conjunction with the integrated report, will inform stakeholders of monitoring planned for assessing additional waters, gathering sufficient information to make additional attainment decisions on Category 2 and 3 waters, and identifying water quality improvements in Category 4 and 5 waters.

K. What information should the report include regarding public participation and public comments?

Regions and States should work together to ensure that there is adequate public participation in the development of the Integrated Report. Regions should review how States provide for public participation to ensure that each State carried out it's public participation process consistent with the State's public participation requirements.

If the Region believes a State has not provided adequate public participation, the Region should ask the State to provide an additional opportunity for public involvement. If the State fails to conduct an adequate public participation process, the Region should provide such additional opportunity. If the Region receives comments during such a process, EPA recommends that the State address the comments by revising their Integrated Report or revising their response to comments. Again, if the State is unwilling or unable to do so, the Region should consider and address the comments. This process is a more appropriate way to deal with inadequate public participation in the development of the Integrated Report rather than an outright disapproval of Category 5 based on an inadequate opportunity for public participation.

EPA expects the State to provide opportunities for public participation in the development of the Integrated Report and demonstrate how it considered public comments in its final decisions. The States may respond to comments individually or through a responsiveness summary. States should submit comments or comment summaries along with responses or a responsiveness summary at the time of the Integrated Report submission. The responses should provide enough detail to clearly explain how the State considered the comment and whether and how the placement of waters in the five categories changed in response to the comment.

If the State received comments on a particular issue that opposes or questions the State's decisions, the Regions should determine whether those comments are adequately addressed in the State's comment response document. The comments and the State's responses should be included in the State's submission to EPA. If the Region agrees with the State's substantive decision, but believes that the State's comment response is inadequate, the Region can work with the State to supplement its response even after the formal submission is made (but prior to the Region's approval or disapproval action). If the State is unwilling or unable to supplement the State's responses, the Region should address the issue in its decision document or elsewhere in the administrative record. Where the recommended language indicates that the Region needs to provide a case-specific explanation or

rationale, the Region's explanation or rationale will become particularly important where public comments have been received.

While EPA recognizes that a formal approval action is made only for waters placed in Category 5, it is important that States provide the public with information about the other four categories. Without this comprehensive perspective, it may be difficult for the public and other stakeholders to adequately evaluate the appropriateness of those waters placed in Category 5. EPA also encourages States that choose to submit separate reports to provide information on the other four categories to ensure that a comprehensive review is made.

L. What information should the report include documenting that the State considered all available data and information in developing their Integrated Report?

40 CFR Section 130.7(b)(5) states that "Each State shall assemble and evaluate all existing and readily available water quality related data and information to develop the list...At a minimum, 'all existing and readily available water quality-related data and information' includes, but is not limited to all of the existing and readily available information about the following categories of waters:....(iii) Waters for which water quality problems have been reported by local, State, or federal agencies; members of the public; or academic institutions. These organizations and groups should be actively solicited for research they may be conducting or reporting. For example, university researchers, the United States Department of Agriculture, the National Oceanic and Atmospheric Administration, the United States Geological Survey, and the United States Fish and Wildlife Service are good sources of field data."

States should consider data and information from the sources listed below for the 2004 Integrated Report:

- reports prepared in 2002 to satisfy CWA Sections 305(b), 303(d) and 314 and any updates
- the most recent Section 319(a) nonpoint source assessment
- reports of ambient water quality data including State ambient water quality monitoring programs, complaint investigations, etc., from the public and other readily available data sources (e.g., STORET, USGS, research reports, etc.), and data and information provided in public comments
- reports of dilution calculations or predictive models
- water quality management plans
- Superfund Records of Decision
- SDWA source water assessments

In addition to these conventional sources of data and information EPA strongly encourages States to solicit compile and consider data and information from volunteer monitoring networks.

The State should also make reasonable efforts to obtain and consult sources of data and information referenced in public comments, but not provided by commenters. The Integrated Report submittal should also explain how the State gathered and evaluated all other forms of data and information (e.g., sediment data, tissue data, toxicity data, biological data, information on fish kills and advisories, etc.). The State should maintain a record of their decision process not to use specific data or information for a specific water in developing its list.

States may need data and information in a format that can be analyzed and interpreted by the State in a reasonable time frame. To facilitate the timely completion of a draft list that can be distributed for public review and comment, States may set a reasonable "cut-off" date after which no additional

data or information may be considered in the preparation of the Section 303(d) submission. The data that is not considered for the 2004 submission should be considered in developing the next Section 303(d) submission.

If the State intends to limit its assessment to data and information submitted or assembled prior to a certain cutoff date, the State should clearly explain that this is the only opportunity for the public to provide data and information for the current assessment cycle, and that data submitted after that cutoff date may be considered during the next listing cycle. If the State clearly describes its use of a data and information submittal cutoff, it may be reasonable for the State to limit its subsequent public comment opportunities to a review of the State's analysis of data and information assembled during the data solicitation period. EPA will generally limit its review of a State listing submission to the data and information assembled by the State prior to the data cutoff date if the State was reasonably diligent in assembling available data and information and soliciting data and information from the public.

EPA is aware that many States have turned to the rotating basin strategy as an alternative but technically sound approach for making assessment determinations of the State's waters. In this approach, the available monitoring resources are concentrated or targeted in one portion of the State for a specified period of time, thus allowing for data to be collected and assessed in a spatially and temporally "focused" manner. Over time, every portion of the state is targeted for this "higher" resolution monitoring and assessment effort (often over a five-year period).

While EPA endorses the rotating basin approach, States are expected to actively solicit data and information on a State-wide basis for all waters within their jurisdiction. Additionally, EPA expects that the State will consider all existing and readily available data and information during the development of their 2004 Integrated Report, regardless of where in the State the data and information were generated.

M. What actions will EPA take on the Integrated Report?

States are encouraged to share interim products and drafts of their Integrated Report with EPA prior to final submission. At a minimum, States should provide draft Integrated Reports and supporting documentation for EPA review at the time the State provides public notice of the draft Integrated Report. States should submit their Integrated Reports to EPA in hardcopy and electronic format. States are also encouraged to populate the Assessment Database (ADB) and submit the database file to EPA.

EPA will review and comment on the Integrated Report. Within 30 days of receipt of the final report, EPA will issue an order, approving or disapproving, in whole or in part, the waters placed in Category 5. If EPA disapproves Category 5, it will, within 30 days of disapproval, identify waters to be added to Category 5 (40 CFR 130.7(D)(2)). EPA will solicit public comment on the waters it is adding to Category 5, and may issue a subsequent order revising the list after the close of the public comment period, as appropriate. EPA will send a copy of its order(s) to the State. EPA may establish a list of impaired waters requiring a TMDL for a State if the State fails to do so by April 1, 2004.

If States follow the assessment methods recommended in this guidance and these methods are consistent with State WQS, EPA believes that in most cases the State listing decisions should be approvable by EPA. EPA may carefully review the application of the State's assessment methods to individual waters to ensure that the listing decisions are consistent with federal requirements. In particular, EPA will carefully review assessments that result in decisions not to list waters based on application of data age restrictions, minimum sample size requirements, application of percent

exceedance cutoffs and statistical methods for evaluating decision error, and interpretation of nonnumeric WQSs.

III. How Could a State Document the Scientific and Technical Rationale for Categorizing Its Waters in Its Assessment and Listing Methodology?

A. What constitutes an assessment methodology?

An assessment methodology constitutes the "decision rules" that will be employed when assessing water quality, to determine in which category, 1 through 5, a particular water belongs. EPA's regulations require States to submit a summary description of the methodology used to develop the list. EPA also requests that States provide a copy of the entire methodology. Such methodologies are essential for EPA's review of State 303(d) lists (Category 5).

EPA will not approve or disapprove the methodology. However, EPA will consider the State's methodology in its review and approval or disapproval of the Category 5 waters in a State's Integrated Report. For example, if EPA believes a methodology will not result in a credible accounting of Category 5 waters (those waters required to be on the 303(d) list), EPA may disapprove the State's submission for failure to include certain waters in Category 5. Upon a request by EPA, the State must provide any excluded data or information and a case-specific rationale for not using the data in an assessment determination. EPA may review the data and rationale, disapprove listing decisions if appropriate, and make changes in the list based on inclusion of data and information that was improperly excluded. Failure by a State to provide a defensible technical rationale for a listing methodology, or for a decision to exclude data or information from consideration, may result in partial disapproval of the list for failure to include waters in Category 5, and potential additions of waters to the list by EPA.

Methodologies for assessing and interpreting water quality data and information should be consistent with the key elements of the State's WQS - designated uses, narrative and numeric criteria, antidegradation requirements, and any implementation procedures associated with the WQS. They should also be consistent with sound science and statistics.

In order to present a scientifically credible status of all waters within a State, the State should explain to EPA and all other stakeholders how assessment determinations are made. The methodology should explain how the State identifies, considers and evaluates all existing and readily available data and information; describes data and information considered when making assessment determinations; explains what analytical approach, including statistical analyses, will be used; and describes any subcategories the State may choose to use in Categories 1 through 5.

Prior to submission of its Integrated Report, each State should provide the public with the opportunity to review and comment on the methodology, consistent with their Continuing Planing Process (CPP) and other public participation policies.

B. How should a State use non-monitored data?

Some questions have been raised about whether categorization decisions should be based only on direct observations. EPA regulations require that "reports from dilution calculations and predictive modeling" be included in the data and information that a State considers when making assessment determinations (40 CFR 130.7(b)(5)(ii)). EPA believes that a valid assessment of a water's condition should involve drawing broader conclusions than those that can be drawn from direct observations

(monitoring data, visual surveys, etc.) only. Simple dilution calculations, for example, can be used to estimate what concentration of a pollutant might be present under conditions (e.g., streamflow, pollutant loads) different from those extant at the time sampling was performed. The example below illustrates how assessment decisions might be made based on this concept.

> ***Example: Use of Dilution Calculations***. *A set of 40 valid samples collected over a 3-month period have been analyzed for pollutant X. Several of the samples are around 85 µg/L. The acute WQC for X is "1-hour average not greater than 100 µg/L." Also, the State's WQS say that excursions over the average should take place no more frequently than once in three years. Based solely on these observed data, a conclusion that the water is not impaired for the designated use to which the WQC applies might be drawn. Therefore, the water would not be placed on Category 5. But, additional information yields the following:*
>
> - *The flow in the receiving stream during the period the samples were collected remained close to the annual harmonic mean flow;*
> - *Historic discharge monitoring from the one significant source of X indicates discharge levels remain quite constant (i.e., stable) over time;*
> - *daily average flows are less than 80% of the harmonic mean flow on an average of 110 days per year.*
>
> *This additional information strongly suggests that the acute WQC for X is being exceeded[2] in this water. This conclusion can be drawn using the simple formula C = L/Q, where C = ambient concentration, L = pollutant loading rate, and Q = waterbody flow. Since in this example L remains essentially the same over time, then as streamflow declines (Q decreases), instream concentration (C) increases. Given that the concentration of 85 µg/L found in the samples collected at mean flow is only 15% lower than the criterion concentration, it follows that when streamflow drops below 85% of mean flow, instream concentration (C) will be higher than the criterion concentration of 100 µg/L. Available flow data indicates flows, lower than 80% of mean flow, occur on more than 100 days during a typical year, so it seems highly likely that excursions above the acceptable hourly average are occurring far more frequently than the maximum of one per three years specified in the WQC.*

States are not required to do such assessments on every water in the State, but the State should evaluate and consider such analyses provided to them by others.

C. What should a State consider when addressing data information quality?

[2]EPA recommends using "exceedance" in the context of assessment determinations to mean that the water's conditions are worse than conditions described in all the relevant components of a WQC. For most human health WQC, the relevant components are the magnitude (concentration) and duration. For many aquatic life WQC, there is a 3rd element – frequency. Using this definition of "exceedance", any exceedance of a WQC is grounds for determining impairment and putting a water in Category 5. (EPA discourages the use of the term "violation" to describe WQS non-attainment because WQS are not directly enforceable).

The results of a comprehensive and highly visible data and information solicitation process may often generate data and information that span a wide spectrum of quality. The many entities responding to the State's data and information solicitation may collect and compile data that follows a variety of field, laboratory and analytical protocols. Therefore, it is reasonable to expect that the State may not view all data and information in the same manner. States should include, in its assessment determinations, all relevant data that are consistent with the States' previously articulated quality assurance/quality control (QA/QC) requirements/Data Quality Objectives (DQO).

Even when working with data sets meeting the State's QA/QC guidelines, data elements are likely to vary in quality. A State's methodology should address how to deal with "good" data, as compared to "excellent" data. For example, more weight could be placed upon data of very high quality as opposed to merely "good" data. In essence, the methodology should describe how to make the best decisions possible with existing and readily available data and information while at the same time describing how to improve the quality of data.

D. What should a State consider when addressing data and information representativeness?

The representativeness of data and information should be considered by States as they attempt to characterize the temporal and spatial variability of conditions of any water. The degree of accuracy of any assessment decision increases as the amount of data and information increases. However, assessment determinations are usually made based upon a limited number of "snapshots" of information – samples, collected from a small number of locations within a water on relatively few occasions. In order to make credible assessment determinations, States should use approaches that strike a balance between the extremes of: (1) arbitrarily considering all grab samples to be representative of merely the instant in which, and the cubic foot of water from which, each was taken; and (2) arbitrarily assuming each such sample is representative of conditions over several years, and over hundreds of stream miles or thousands of lake acres.

States are encouraged to make "contextual" decisions about the meaning of data, using knowledge of variations in relevant factors over space and time. In a watershed in which the dominant land use remains largely homogenous over large areas, a State might assume that sampling results from one spot in a stream are reasonably representative of water quality at sites several miles upstream and downstream. However, if land uses vary considerably from one river mile to another, the State could conclude that sampling results from one spot are not representative of such a large segment.

In determining whether or not certain monitoring data are representative of all relevant conditions in a water, States should consider, among other factors, the type of sources of the pollutant of concern. It would generally not be appropriate to conclude that samples collected during dry weather periods showing no WQC exceedances are representative for pollutants delivered under wet weather conditions. On the other hand, if there only one source of a pollutant and it discharges at a fairly stable level over time, then failure to detect WQC exceedances during design low flow periods (e.g., 1Q3) would provide reasonable assurance that WQC are being met. State methodologies should spell out the decision rules which will be used to determine the temporal and spatial extent a grab sample can be construed to represent.

Data should not be excluded from consideration solely on the basis of age. The State's methodology should specifically discuss how the State considered age in determining relevance. A State should consider all data and information. However, in this consideration, a State may determine

that certain data are no longer representative of current conditions (e.g., land use has changed significantly, point source discharges have changed significantly, the hydrology of the water has been modified, and/or field and laboratory methods have changed), and therefore may decide not to use the data for making the assessment determination. The State may choose to place the water into Category 3, and schedule follow-up monitoring to obtain necessary data to make an assessment determination that is representative of current conditions.

States should be cautious about employing assessment methodologies that exclude data from further consideration based on a finding that it is "unrepresentative" because the data seem to represent extreme circumstances. In assessing potential adverse effects on humans or other life forms, it is just as important to be cognizant of rare circumstances as it is to reflect "average" conditions. Short term (even a matter of minutes) exposure to very high levels of pollutants (or low level of necessary elements like oxygen) can be extremely harmful, even lethal.

This point is emphasized in EPA's *Guidance for Data Quality Assessment: Practical Methods for Data Analysis (QA/G-9)* (EPA/600/R-96/084) published in July 2000, available at http://www.epa.gov/quality/qa_docs.html):

> "One should never discard an outlier based solely on a statistical test. Instead, the decision to discard an outlier should be based on some scientific or quality assurance basis. Discarding an outlier from a data set should be done with extreme caution, particularly for environmental data sets, which often contain legitimate extreme values. If an outlier is discarded from the data set, all statistical analysis of the data should be applied to both the full and truncated data set so that the effect of discarding observations may be assessed. If scientific reasoning does not explain the outlier, it should not be discarded from the data set." (EPA/600/R-96/084, pp. 4-26).

Additional guidance about "outliers" can be found in the discussion of trimmed means on page 35 of *Biological Criteria: Technical Guidance for Survey Design and Statistical Evaluation of Biosurvey Data* (EPA/822/B/97/002).

E. How should a State address data and information quantity?

All existing and readily available data and information must be considered during the assessment process. Methodologies should describe data and information quantity objectives that will be used as waters are placed in Categories 1 through 5.

EPA does not recommend the use of rigid, across the board, minimum sample size requirements in the assessment process. Target sample sizes should not be applied in an assessment methodology as absolute exclusionary rules. Assessments based on larger sample sets are, of course, more likely to yield accurate conclusions than assessments based on smaller sample sets. Smaller sample sizes are more prone to yield erroneous assessment decisions because they have a lower probability of detecting WQSs exceedances, unless the exceedances are large and pervasive (EPA, *Consolidated Assessment and Listing Methodology – Toward a Compendium of Best Practices* (CALM) July 2002, pp. 4-9).

Larger data sets are particularly desirable when dealing with WQC with a fairly long duration factor (averaging period, like 30 days, 90 days, or a year). Hence, when making an assessment determination based on comparison of ambient data and other information to a numeric WQC expressed as an "average" concentration over a substantial period of time, a statement of a target

number of samples may be appropriate. Still, the methodology should provide decision rules for concluding nonattainment even in cases where the target data quantity expectations are not met, but the available data and information indicate a reasonable likelihood of a WQC exceedance (e.g., available samples with major digressions from the criterion concentration, corroborating evidence from independent lines of evidence such as biosurveys).

However, small sample sets often provide sufficient information to support decisions to list waters because the frequency and/or magnitude of observed excursions and digressions are high enough to support a reliable impairment determination. Even a very small set of samples may be sufficient to indicate impairment, particularly when the duration/averaging periods of relevant WQC are quite short (an hour or less).

When considering small numbers of samples, it is important to consider not only the absolute number of samples, but also the percentage of total samples, with concentrations higher than those specified in relevant WQC (See Section D.6, page 47, last paragraph to page 50 of CALM for further discussion of this point).

While it is appropriate to identify target sample sizes as a methodology is developed, States should not exclude from further consideration data sets that do not meet a target sample size. A methodology may provide for an initial sample size screen, but should also provide for a further assessment of sample sets that do not meet the target sample size.

F. How should a State interpret its WQSs?

When trying to decide whether to put a water in Category 4 or 5, a State is trying to answer the question, "What is the likelihood that the WQC is being attained?" However, there may be some ambiguity in the way a WQC is expressed. For example, reference could be made to an "average" concentration. This could mean the median, the arithmetic mean, the geometric mean, or something else describing a central tendency. Also, WQS regulations and guidance sometimes don't clearly state a duration component of a WQC – particularly some types of human health criteria.

A case may also arise in which a State has failed to include, for a criterion aimed at protecting aquatic life, a "frequency" component. According to EPA guidance, "the purpose of the average frequency of allowed excursions is to provide an appropriate period of time during which the aquatic community can recover from the effect of an excursion *(from adverse combinations of concentration and duration*) and then function normally before the next excursion. The average frequency is intended to ensure that the community is not constantly recovering from effects caused by excursions of aquatic life criteria" (*Technical Support Document (TSD) for Water Quality-based Toxics Control*, Appendix D-4, EPA, 1991).

EPA guidance recommends use of a 1 in 3 year maximum allowable excursion recurrence frequency—number of times conditions in a water are worse than those specified by the concentration and duration components of a freshwater aquatic life criterion for a toxic chemical. A key basis for this recommendation was a literature survey done in 1989, looking at recovery rates of freshwater ecosystems from various kinds of natural disturbances and anthropogenic stressors. This survey indicated that components of biotic communities took between 6 months and over 20 years to recover. The 150 studies reviewed indicated that the vast majority (85% to 95%) of macroinvertebrate endpoints (death, reproductive failure, etc.) recovered in 1 to 2 years, and fish metrics reflected similar levels of recovery in 2 years or less. On the other hand, fish in large rivers and lakes might take 20 to

25 years to recover adequately. Based on this information, EPA's Office of Research and Development recommended adoption of a 1 in 3 year maximum recurrence interval.

EPA believes, therefore, that in the preponderance of situations where a State's WQC contains a specific 1 in 3 year (or some similar) frequency, the water should be listed in Category 5 if excursions occur at a rate greater than this. On the other hand, EPA recognizes that more frequent excursions might be acceptable in certain situations. For instance, biota typical of small headwater streams have often been found to usually recover more rapidly than 3 years. Segments with refugia, such as well-developed riparian zones, connected flood plains, meanders, snags, etc., foster more rapid recovery than segments without such features. (Hence, evidence of action to preserve and/or restore refugia might be grounds for adopting an excursion frequency greater than 1 in 3 years.)

If a State has articulated in its methodology a procedure for taking into consideration such site-specific factors, use of a more frequent return interval on a particular water, or type of water, could be acceptable. (Assuming, of course, that the procedure was scientifically valid, was properly applied, and is consistent with the State's WQS.)

If a State has failed, in its WQS and subsequent guidance, to specify a frequency interval for excursions with regard to aquatic life criteria, it should specify such a frequency in its assessment methodology, as with clarifying or "filling in" a duration component of a WQC, the frequency should be based on scientific rationales such as those articulated in EPA guidance, scientific literature, and other relevant information. Such rationales should be articulated in the methodology. (EPA recommends that States correct such deficiencies in their WQS program by incorporating or clarifying duration and/or frequency components in their aquatic life criteria during their next triennial review of their WQS regulations.)

G. How should statistical approaches be used in attainment determinations?

The State's methodology should provide a rationale for any statistical interpretation of data for the purpose of making an assessment determination. This can be done explicitly or by reference to State or EPA regulations, guidance, methods or analytical procedures.

The methodology should provide a clear explanation of which analytic tool the state intends to use and under which circumstances. This documentation should be especially clear in the case where the State's WQS regulations and other regulations and guidance doesn't explicitly address issues such as the selection of key sample statistics (arithmetic mean concentration, median concentration), or a percentile (e.g., 85th percentile), null and alternative hypotheses, target sample sizes, confidence intervals, and Type I and Type II error thresholds. The choice of a statistic tool also depends on the known or expected distribution of the concentration of the pollutant in the water (e.g., normal or log normal), and the manner in which the relevant WQC is expressed.

EPA recognizes that many impairment decisions will be made on the basis of data and information which do not meet defined optimum data objectives. Hence, the methodology should also describe the statistical methods to be applied when analyzing data and information sets that do not meet optimum conditions, especially when available data suggests a potential criterion exceedance.

Although the next several sections are devoted to issues in hypothesis testing, other statistical methods are available for monitoring water bodies. Other statistical analysis methods could be used by States as long as the methods are appropriate for the monitoring data at hand. EPA encourages States

to consider published methods. A good overview is *Statistical Methods for Environmental Pollution Monitoring* by Richard Gilbert, Van Nostrand (1987).

1. *What should a State consider when selecting the Null Hypothesis?*

States should also highlight policy decisions implicit in the statistical analysis employed. For example, if hypothesis testing is used, the State should explain why it chose either "meeting WQS" or "not meeting WQS" as the null hypothesis. Starting with the assumption that a water is "healthy" when employing hypothesis testing means that a water will be identified as impaired, and placed in Category 4 or 5, only if substantial amounts of credible evidence to refute the presumption that the water is not impaired are brought to light.

As EPA explained in draft Appendices C and D of CALM, which "null hypothesis" is selected may create different incentives regarding support for additional ambient monitoring. If the null hypothesis is "meeting standards," there was no previously data on the water, and no additional existing and readily available data and information are collected, then the "null hypothesis" cannot be rejected, and the water would not be placed in Category 4 or 5. In this situation, concern about possible adverse consequences of having a water declared "impaired," could lead some to have little interest in collection of additional ambient data. On the other hand, if the null hypothesis is changed to "water not meeting WQS," then those that would prefer that a particular water not be labeled "impaired" would probably want more data collected, in hopes of proving that the null hypothesis is not true.

2. *How should States balance probabilities of Type I and II errors?*

A second key policy issue in hypothesis testing is what significance level to use, in deciding whether to reject the null hypothesis. Picking a high level of significance for rejecting the null hypothesis means that great emphasis is being placed on avoiding a Type I error (rejecting the null hypothesis, when in fact, the null hypothesis is true). This means that if a 0.10 significance level is chosen, the State wants to keep the chance of making a Type I error at or below 10%. Hence, if the chosen null hypothesis is "water meeting WQS," the State is trying to keep the chance of saying a water is impaired, based on available evidence - when in reality it is not – under 10%.

Another key issue is the determination of Type II errors (not rejecting the null hypothesis, when it should have been). The probability of Type II errors depends on several factors. One key factor is which alternative hypothesis is chosen. Another key factor is the number of samples available. With a fixed number of samples, as the probability of Type I error decreases, the probability of a Type II error increases. States should ideally collect enough samples so the chances of making Type I and Type II errors are simultaneously small. (Unfortunately, resources needed to collect such numbers of samples are often not available.)

EPA recommends that, when picking the decision rules and methods to be utilized when interpreting data and information regarding a particular water, States attempt to minimize the chances of making each of the two following errors:

- Concluding the water is impaired, when in fact it is not, and
- Deciding not to declare a water impaired, when it is in fact impaired.

States should specify in their methodology what significance level and what statistical

power (statistical power is equal to 1 - the probability of Type II error) against the range of applicable statistical alternatives they are requiring, as well as explaining the consequences of the choices made. The methodology should describe in "plain English" the likelihood of not only: (1) deciding to list a water that in reality is not impaired (Type I error if the null hypothesis is "water OK"), but also (2) the probability that a water that in fact is not meeting WQS has been left off the Category 4 and 5 lists (Type II error in this case).

3. How should a State distinguish between not rejecting the null and accepting the null?

A "common mistake in hypothesis testing is the notion that null hypotheses can be 'accepted'. But failing to reject a null hypothesis does not prove it is true" (p. 9, *Data Analysis Considerations in Producing Comparable Information for Water Quality Management Purposes*, National Water Quality Monitoring Council, Technical Report 01-0, February 2001).

This means that if a null hypothesis of "water is meeting WQS" is chosen, and available evidence doesn't support rejecting the hypothesis (rejection would mean placing the water in Category 4 or Category 5), the water should not automatically be placed in Category 1 or 2. It is, however, generally appropriate to place a water in Category 1 (for a given designated use), if there is sufficient statistical power against applicable alternative hypotheses. Absent sufficient statistical power, a water should go in Category 3 (or 2) for a given designated use, if it has already been concluded that available evidence is insufficient for placing the water in Category 4 or 5, for this use. Additional monitoring should be scheduled.

Substantially greater amounts of data may be needed to conclude, based on sound statistical principles and science, that a water is quite likely fully supporting a particular designated use (i.e., belongs in Category 1 or 2 for that use), than to conclude it is not (and therefore belongs on Category 4 or 5). This is particularly true when dealing with WQC addressing acute exposures that can be harmful (see Appendix D of CALM, p. 48, last paragraph, for a discussion of this point).

Though large numbers of samples will often be needed to conclude if a water is fully supporting a designated use with chemical-specific monitoring, this may not be the case when making attainment decisions using biocriteria/bioassessment data. Biosurvey methods are generally a more reliable means of determining that, for aquatic life uses, designated uses are likely being attained, because of their ability to integrate effects of multiple stressors and reflect cumulative effects over time.

H. What specific issues arose during the 2002 listing cycle?

The following discussion provides responses to specific questions that arose during the 2002 listing cycle.

1. What Statistical methods should a State use for assessing exceedances of criteria?

The State's methodology and documentation should specifically describe its method and supporting rationale for identifying potential violations of numeric and narrative criteria. If the State applies excursion frequencies or thresholds as listing decision criteria, the submittal

should describe a reasonable rationale for the selected approach, showing they are consistent with applicable WQSs. If the State applies different decision rules for different types of pollutants (e.g., toxic, conventional, and non-conventional pollutants) and types of standards (e.g., acute and chronic standards for aquatic life or to protect human health), the State should provide a reasonable rationale supporting the choice of different approaches for different standards.

If the State uses a specific statistical analysis approach for evaluating exceedances, the submittal should provide supporting documentation explaining the analytical basis for the methods and underlying assumptions. If the method to support a listing decision is based on hypothesis testing with provisions for type I and II errors, the submittal should provide a reasonable rationale for selection of those error rates. EPA recommends selection of statistical analysis tests that balance Type I and Type II error rates.

The State should provide for listing in cases where numeric standard decision rule thresholds are not met but the data indicate a reasonable likelihood of a WQSs exceedance, - very high magnitude digressions from a criterion magnitude, corroborating evidence from independent lines of evidence to demonstrate violations of narrative standards.

2. *When is use of the "10% rule" an appropriate assessment methodology?*

Past EPA guidance (1997 305(b) and 2000 CALM) recommends making non attainment decisions for conventional pollutants where more than 10% of samples exceed applicable WQS. This guidance was intended to provide a simple "rule of thumb" in evaluating data sets of limited size for assessment purposes and is intended to account for measurement error and the potential that small data sets may not be fully representative of receiving water conditions. States should be cautious in applying the 10% rule. Use of the 10% rule when performing attainment determinations regarding effects of toxics is not appropriate unless the State's WQS regulations or WQS guidance specifically authorizes use of this rule for such pollutants. Use of this rule when addressing conventional pollutants, (TSS, pH, BOD, fecal coliform bacteria, and oil and grease) is appropriate in some additional circumstances.

It has recently come to EPA's attention that some ways of interpreting the 10% rule can lead to the incorrect conclusion that water conditions substantially worse than those described in some WQC would be supportive of the associated designated use. Such an assessment methodology would be inconsistent with the applicable WQC, and therefore, problematic as a basis for assessment determinations.

An example of a WQC for which an assessment based on the 10% rule would be appropriate is the EPA acute WQC for fecal coliform bacteria, applicable to protection of the water contact recreational use. This WQC is expressed as, "...no more than 10 percent of the samples exceeding 400 CFU per 100 ml, during a 30-day period." Here, the assessment methodology is clearly reflective of the WQC.

On the other hand, it is questionable to apply the decision rule that a water is not impaired if "criteria (are) exceeded in $\leq$ 10 percent of measurements" to WQC expressed as "the instantaneous concentration of the pollutant shall not be greater than ___ µg/L, at any time." The problem is that the 10% rule could be interpreted in such a way to allow the concentration of the pollutant in a water to be greater than the criterion concentration at some

very high frequency–perhaps even once every 10 seconds. Such a high frequency of adverse diversions from the magnitude-duration-frequency scenario spelled out in the WQC provides strong evidence that the relevant designated use is impaired. Hence, if a State intends to use the "10%" rule in conjunction with WQC expressed as "the instantaneous concentration of the pollutant shall not be greater than ___ µg/L, at any time," the State will need to provide a rationale for why such an application of the rule is a reasonable approach to evaluation of data against water quality standards.

Use of the "10% rule" in interpreting water quality data in comparison with chronic WQC will generally be more appropriate than its use when making attainment determinations where the relevant WQC is expressed "concentration never to exceed ___, at any time." Chronic WQC are always expressed as average concentrations over at least several days. (EPA's chronic WQC for toxics in freshwater environments are expressed as 4-day averages. On the other extreme, EPA's human health WQC for carcinogens are calculated based on a 70-year lifetime exposure period.) Using the "10% rule" to interpret data for comparison with chronic WQC will often be consistent with such WQC because it is unlikely to lead to the conclusion that water conditions are better than WQC when in fact, they are not. (However, use of the 10% rule in association with chronic WQC can become problematic if binomial statistics, rather than the "raw score" approach, are used to interpret the data.)

States intending to use the 10% rule in an assessment determination regarding a conventional pollutant should make clear in their assessment methodology what interpretation of the rule they plan to employ. A common interpretation of "criteria (are) exceeded in $\leq$ 10 percent of measurements" is that this really means "*concentrations worse than the criterion concentration, are found in $\leq$ 10% of individual grab samples."* But it is also possible to interpret the "10% rule" to mean "*conditions worse than those expressed by the concentration-duration scenario(s) described in WQC occur in the water no more than 10% of the time."* (The latter interpretation is more likely to be problematic than the former, given the way most WQC are expressed.)

In addition to making the intended meaning of the "10% rule" clear, States will need to explain why whatever meaning they plan to employ is a reasonable approach to evaluation of data against their water quality standards.

I. Final thoughts on the assessment methodology

The methodology is the key to improving the scientific validity of State categorizations of water quality. EPA believes that it is particularly important for the States to develop the methodology because there is not one "right way" to assess water quality against standards. The decision rules the States describe in the methodology provide all stakeholders, public and private, the opportunity to see exactly how assessment decisions are made. The methodology should include the statistical methods to be applied when target data quantity and quality requirements, consistent with the State's WQSs, are met. The methodology should also provide a description of the process the State will apply when analyzing data and information sets that do not meet optimum quantity and/or quality conditions, especially when this analysis indicates a potential criterion exceedance. EPA's comments on the methodology will focus on how decisions to place a water in a particular category fit with the State's WQSs, as well as validity of the selected analytical approaches.