Revised Draft Statements of Current Uses of Detection and Quantitation, Data Quality Objectives and Policy Issues
Thursday, November 17, 2005

The revised draft statements of uses, data quality objectives and policy issues are presented in the following order:

Category of Use: Water Quality Criteria and Local Water Quality Standards Setting
Lead Drafter: Mary Smith and Tom Mugan

Definition: State and Tribal Water Quality Standards (WQS) define the goals for a waterbody by designating its uses, setting criteria to protect those uses, and establishing provisions to protect water quality from pollutants. A water quality standard consists of four basic elements: (1) designated uses of the water body (e.g., recreation, water supply, aquatic life, agriculture), (2) ***water quality criteria*** to protect designated uses (numeric pollutant concentrations and narrative requirements), (3) an antidegradation policy to maintain and protect existing uses and high quality waters, and (4) general policies addressing implementation issues (e.g., low flows, variances, mixing zones).

Section 304(a) of the Clean Water Act requires EPA to develop criteria for water quality that accurately reflects the latest scientific knowledge. These water quality criteria (WQC) are based solely on data and scientific judgments on pollutant concentrations and environmental or human health effects. WQC are developed for the protection of aquatic life as well as for human health. To date, EPA has published aquatic life, human health, and nutrient WQC for 158 pollutants. In addition to national criteria, the Water Quality Guidance for the Great Lakes System (sometimes referred to as the Great Lakes Initiative, or GLI, and published in 1995) involved the development of separate criteria applicable to the Great Lakes states, which included the first ever criteria for protection of wildlife for four chemical classes.

In adopting their own water quality criteria, States and authorized Tribes may adopt the criteria that EPA publishes under § 304(a) of the Clean Water Act; modify the § 304(a) criteria to reflect site-specific conditions; or adopt criteria based on other scientifically-defensible methods.

Existing uses of detection and quantitation: EPA WQC are derived using the best available risk-based scientific methods and procedures, using data from studies in which various organisms are exposed in controlled environments to different concentrations of a pollutant. Many of the studies are gathered from the public literature and approaches to detection and quantitation vary. Typically, criteria are based on the most sensitive data available that is consistent with current science. In many studies, detection limits are moot because the studies rely on spiking known amounts of the pollutant into the test environment and measuring organism response. Detection of organism response (for criteria development or toxicity testing) is a different concept, typically relying on evaluation of exposed and control organisms.

Data Quality Objectives/Measurement Quality Objectives: Toxicity testing, chemical, or biological methods are generally used to evaluate whether numeric criteria for chemicals, nutrients, or pathogens are met. These methods typically specify quality control requirements and limits that should be applied when performing the method. These QC limits function as MQOs.

Policy Issues: Water quality criteria provide the basis for water quality based effluent limits, which have largely been responsible for D/Q issues. In addition, water quality criteria typically determine the targets for waters requiring total maximum daily loads (TMDLs). Because they are often lower than national criteria (and often below detection or quantitation levels obtained using EPA-approved methods), criteria resulting from the Great Lakes Initiative have helped highlight the importance of measurement and method sensitivity in EPA-approved methods.

Category of Use: EPA Method Promulgation and Validation

Lead Drafter: Mary Smith

Definition: Analytical Methods for measurement of pollutants are used for a variety of Clean Water Act purposes including the development of effluent limitations and for determining compliance with permits issued under the National Pollutant Discharge Elimination System. EPA validates methods that are developed both by EPA, voluntary consensus bodies[1] and others. Validation involves the use of six data sets from six or more laboratories, and these data sets are used to calculate the MDL and ML. The MDL and ML provide points of reference for reporting and using measurement results and vary by analyte and analytical method. EPA validated methods (with corresponding MDLs and MLs) are proposed, and, after a public comment period, are promulgated (published) in the Code of Federal Regulations at 40 CFR Part 136.

Existing uses of detection and quantitation: Analytical methods are used to acquire occurrence data for numerous Clean Water Act purposes. MDLs are calculated using 40 CFR part 136 procedures; and minimum levels (MLs) are currently calculated using a multiple of the MDL.

Generally, EPA includes MDLs and MLs in 40 CFR Part 136 procedures to characterize method performance to aid users in selection of the methods most appropriate for their particular use.

Data Quality Objectives/Measurement Quality Objectives: The method development process produces the MQOs for the MDL and ML.

Policy Issues:

- Numerous stakeholders have criticized the current procedures for calculating the MDL and ML. These criticisms have been captured by the FACADQ's Technical Workgroup.
- Should the method development process define the measurement quality objectives or should the various uses drive measurement quality objectives?
- What is an appropriate level of false positives? False negatives?
- Should quantitation be defined in terms of both precision and accuracy?
- Should precision and accuracy be established without reference to detection and quantitation?

[1] In fact, OMB Circular No. A-119 encourages Federal Agencies to use voluntary consensus standards except when inconsistent with law or otherwise impractical. The Circulars encourage the participation of federal representatives in these bodies to increase the likelihood that the standards they develop will meet both public and private sector needs. A voluntary consensus standards body is defined by the following attributes: (i) openness, (ii) balance of interest, (iii) due process, (iv) an appeals process.

- If the procedures by which EPA calculates the detection and quantitation limits change, should EPA revise detection and quantitation limits for previously promulgated methods? Which ones (there are hundreds)?
- If we change the EPA detection and quantitation limits, how can we ensure the further development of more sensitive methods?

Category of Use: EPA Development and Approval of New and Alternative Methods

Lead Drafter: Cary Jackson

Definition: Requirements for approval of alternate analytical techniques (methods) are specified at 40 CFR 136.4 and 136.5 for wastewater methods and at 40 CFR 141.27 for drinking water methods. These requirements are the basis for the Agency's alternate test procedure (ATP) program for water methods. Under the ATP program, an organization may submit an application for approval of a modified version of an approved method or for approval of a new method to be used as an alternate to an approved method.
The submitting organization is responsible for validating the new or modified method. The Agency reviews the ATP validation package and, if required, promulgates successful applications in the CFR. Rulemaking is required when a new or revised method is added to the list of approved methods in the CFR.

Existing uses of detection and quantitation:
- Method development
- Method validation
- Method comparability

Method Quality Objectives:
- Substantiate performance of a new or alternative method by method detection limit demonstration to that of the reference method

Policy Issues:
- Many of the CWA reference methods do not have published single or interlaboratory validation method detection limit performance criteria
- Lower range of quantitation stated in the method where there is no published single or interlaboratory validation method detection limit performance criteria, is often lower than what can be achieved through actual method detection limit demonstration
- Not all determinants methods are amenable to the current MDL and ML model
- States and EPA Regions don't understand the Tier method approval process, and thus are reluctant to approve Tier I method applications with method detection limit performance criteria
- Due to Agency resources (monetary and human) and agendas, method approvals are not expeditious, often taking 18 to 36 months. Thus, new or alternative methods that are superior in method detection limit performance are delayed in their use for regulatory purposes

Category of Use: Effluent Limitation Development BAT Averaging and Effluent Guideline Development Variability

Lead Drafter: Mary Smith

Definition: Effluent limitations are national guidelines for wastewater discharges to surface waters (direct dischargers) and publicly owned treatment works (municipal sewage treatment plants) (indirect dischargers). They are issued for individual industrial categories, both new and existing sources, and are based on the performance of treatment and control technologies. The effluent limitations are incorporated into individual facility permits issued under the NPDES program and represent the upper bound on the amount of pollutant that can be discharged by the facility.

In general, EPA uses data on a number of different pollutants from facilities employing the appropriate level of control technologies to establish effluent limitations. This is basically done in a two step process. First, EPA determines an average performance level ("long-term average") that a facility with well-designed and operated model technologies is capable of achieving. This long-term average is calculated from the data from the facilities using the model technologies. In the second step, EPA allows for several sources of variability (i.e., production and wastewater treatment variability; sampling and analytical variability) and incorporates these variabilities into the effluent limitations through the use of variability factors. EPA then multiplies the long-term averages by the variability factors to obtain the percentile estimates used for the effluent limitations expressed as Daily Maximum Limits and Monthly Average Limits.

Existing uses of detection and quantitation: The long term average and the variability factor are used to calculate effluent guideline numerical limits for the Daily Maximum Limit as well as the Monthly Average Limit. Generally, effluent limitations are set at or above the ML of a particular method available at the time of rulemaking. The one known exception is for the Steam Electric Power Generating Point Source Category which has a "No Discharge" effluent limitation on PCBs. This "No Discharge" limit was set based on the capability of the technology, and not via the two step process outlined above.

Data Quality Objectives/Measurement Quality Objectives: No relevant DQO/MQO.

Policy Issues: None except there is currently a concern that a more sensitive PCB method might detect PCBs that are inherent in a facility's environment.

Category of Use: Permit Applications and Permit Development

Lead Drafter: Tom Mugan

Definition/Use of data: Permit applications for reissuance of existing permits are sent to discharges with enough lead-time for dischargers to assemble the required information. Permittees may be required to supply analytical data for pollutants that the permit does not require routine monitoring for. This one-time monitoring (may be one or more samples spaced over a relatively short time period) is intended as a sort of screening for pollutants that the regulatory agency thinks could be present in an effluent but that have previously not been identified as problems. Pollutants with categorical limits are routinely monitored for in permits; so this screening requirement produces data that would normally be used to assess the need for water quality based effluent limits (WQBELs).

If monitoring data submitted for the first time with the application, or data previously collected by the permittee or the regulatory agency, identifies a pollutant as being present, the regulatory agency will determine, based on procedures in state or federal rules, what the WQBEL is and then compare the maximum expected effluent level to the potential effluent limit. If there is a "reasonable potential" that the predicted effluent level will exceed the effluent limit, the result is some sort of regulatory requirement in the reissued permit, usually an effluent limit and schedule for meeting the limit.

Data Quality Objectives: Data needs to be of high quality for determining the need for limits in permits. In addition, it is important to minimize both false positives and false negatives for this use.

Existing uses of detection and quantitation: If the WQBEL for a pollutant is lower than or close to the D/Q levels of the analytical data supplied by the permittee or collected by the regulatory agency, results of the screening may be inconclusive. Numerical data is needed for the statistics for determining reasonable potential. "Non-detects" or "less than" values are not well accommodated, particularly if most of the data points are non-numerical. To compensate, some states have developed alternative approaches for using the data based on where the effluent limit falls in relation to detection or quantitation levels. The following situations may occur:

- If the tests show pollutant concentrations above quantitation, then decisions on the need for limits are relatively straightforward.
- If tests show the pollutant to be quantifiable in some samples but not in other samples, there are statistical programs for dealing with non-quantified results as long as there are a minimum number of quantifiable values. States may differ as to whether results between quantitation and detection are used as numerical values in these statistical programs.
- If the tests show the pollutant to be not present, or present but below quantitation, the agency may require the permittee to perform repeat testing using a method with lower D/Q, if such method is available. The agency may specify what level of D/Q is acceptable. The acceptable level may be based on published values, what certain

reference labs are able to achieve or other specified criteria. Where a better method is not available or where specified levels of D/Q have been achieved, the agency may assign a value of zero to the result. The agency could then require longer term monitoring to attempt to gain addition insight into the presence or absence of the pollutant in the effluent that would be used in future reasonable potential determinations. Or, in some states, the agency may use a result that falls between detection (MDL) and quantitation, assign a limit in the permit and hope that the situation sorts itself out as a more statistically significant number of data points are generated. This approach often creates problems due to the uncertainty of what actions the permittee can take to assure it remains in compliance with the permit. Additional or alternative permit requirements, such as pollutant minimization programs or special studies to confirm or deny pollutant levels may also be imposed in addition to or in lieu of numerical permit limits.

Policy Issues: (Shaded policy issues are the highest priority for the FAC DQ)

- Should we and when should we be requiring use of methods with the lowest D/Q
- To what level should we require laboratories and permit applicants to report data? Should there be a censor point and if so, at what level (L_c, L_d, L_q, etc) or should we report the numerical data along with the L_c, L_d and L_q and then perhaps use flags to qualify data?
- At what level should the regulatory agency begin assigning numerical values (non-zero) in calculations to determine reasonable potential?
- How large of a body of data (statistical significance) should the regulatory agency require before we choose to impose an effluent limit in a permit when D/Q issues cannot be avoided because the lowest D/Q method is not enough?
- Should D/Q limits be whatever an individual laboratory determines or should the agency set acceptable D/Q limits that a lab must meet?

Category of Use: Laboratory QA/QC

Lead Drafter: Nan Thomey

Definition: Laboratory QA/QC for this purpose is the process by which a lab measures the quality of the data generated in terms of precision, accuracy, and representative ness, establishes acceptance criteria which determine when an analysis is in control so that data may be reported, and establishes criteria for communicating the quality of the result to the data user.

Existing uses of detection and quantitation: Detection is used to determine when an analyte is present or absent. A result below the detection limit is presented as ND versus a numerical value (this numerical value may be qualified as estimate if below the quantitation limit).

- Some multiple of detection is used as the basis for establishing acceptance criteria for calibration and method blanks in order to determine if the analysis is in control in order to decide if an analytical batch must be re-analyzed. A variety of criteria have been used in various programs, including detection limit, 2x detection limit, 1/2 quantitation limit and quantitation limit.
- Some multiple of the detection limit or quantitation limit (usually 3-5X) is frequently used to determine when it is appropriate to calculate relative percent difference (RPD) between duplicate samples for comparison to control limits. Below this value established by the laboratory, the RPD on a QC report may be listed as not applicable, or the lab may uses some arbitrary value such as the difference in the two results must be ± some variable of the detection limit.
- Detection may be used to assess the quality of implementation of a given instrument, method, or analyst.
- Detection and quantitation limits may (and should!) be used as a basis to determine the most appropriate method to recommend based on data user needs. Typically, people try to select methods where the detection limit is at least 5-10 times lower than the action limit. This range often correlates with the quantitation limit to improve the accuracy of the result.
- Results below the quantitation limit but above the detection limit are qualified as estimated.
- Start-up proficiency, modifications of method, annual accreditation check

Data Quality Objectives/Method Quality Objectives: I think that data quality objectives are usually determined by the data user, not the laboratory. Laboratory may calculate control limits based on historical laboratory performance and/or guidelines for precision and accuracy may be presented in the method itself. The quality objectives specified in the method will vary based on the technology used. Some tests may have RPD criteria of less than 10-20 and accuracy of 75-125% or even 90-110% recovery. Others may yield acceptance limits of as low as 10% recovery. In practice, the measured precision and accuracy will vary based upon where the concentration is in relation to the detection and quantitation limit. Laboratories usually evaluate recovery at the mid point of the quantitation range, unless specifically requested to gather information at different values.

As an aside, I would like to note that there are instances within EPA methods (I can't think of an example from the CWA) when the method specified QC objects are just not practical. (SW-846, Method 8000 comes to mind). This is significant because many clients just simply do not determine their own DQO values based on the intended use of the data; rather they rely entirely upon precision and accuracy statistics as listed in the method or the labs historical limits for control samples (which are typically obtained from interference-free matrices such as distilled water or Ottawa sand) to establish their DQO's .

Policy Issues:

- Should Lc, Ld, and Lq all three be used or would Lc and Lq suffice?
- What will the transition period be for implementation of the new procedure?
- How will communication, notification and training be accomplished for the new procedure?
- What procedures or allowances will be incorporated for matrix effects that may prohibit achieving promulgated detection limits?

Category of Use: Compliance Assurance and Enforcement

Lead Drafter: Dave Akers

Definition: Permits for the discharge of process water from municipal and industrial wastewater treatment facilities may include monitoring and/or numeric limitations for pollutants. Numeric limits may be based on protecting the water quality standard for the pollutant that has been adopted to protect beneficial uses (water quality standards-based effluent limits(WQBELs) or based on federally adopted effluent limitation guidelines (ELGs). Similarly, permits for the discharge of stormwater from regulated municipal storm sewer systems and industrial sites may include monitoring and/or numeric limitations for pollutants that are based on meeting water quality standards. All data submitted to regulatory authorities for demonstration of compliance must be certified under penalty of law that the information is true, accurate, and complete. There are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations. 40 CFR 122.22(d).

Monitoring of permitted process water and storm water discharges is necessary to establish discharge concentrations in order to assess compliance with permit WQBELs and/or ELGs. Monitoring of un-permitted discharges is necessary to determine concentrations of pollutants to establish violations. Any data gathered to assess compliance with permit limits or establish an un-permitted discharge could ultimately be used in an enforcement action. A second possible approach would be an option to use results of (routine) compliance monitoring to indicate if there is an "apparent" problem that would prompt the discharger and the agency to take a closer look. In this case, the regulatory agency might use discretion, based on the severity of the problem and certainty of the results, to decide what action, if any, to take. For example, using this type of stepped compliance assurance/enforcement process, the agency may let the discharger know that it has discovered an apparent violation (for example, effluent values between L_D and L_Q when the limit is below L_Q) but that it will continue to closely monitor the situation and only take more aggressive enforcement action after having much more certainty that a violation has actually occurred. In addition, the Great Lakes WQ Initiative regulation requires that an imposed effluent limitation that is below the quantitation level of the most sensitive test method be accompanied in the permit with a requirement for the permittee to conduct a pollutant minimization program (PMP) that has as its goal meeting the WQ based limitation even as effluent monitoring is not able to quantify levels of the pollutant.

Typically, permit limits based on ELGs are at a level that is greater than the L_Q and determinations of compliance with such limits are not affected by the method used by labs to determine L_Q.

Third parties, other than the permittee or the permit issuing authority, may also collect analytical data, which may be submitted to the regulatory agency or used to take legal action against the permittee or the agency under the citizen suit provisions of the Clean Water Act. The permittee, agency and third party could, and usually do, use different laboratories and, without a common protocol for determining L_D and L_Q, the process of proving violations could be complicated. Besides using their own laboratories, third parties may also file a legal action based on data generated by permittees, potentially using different criteria in reviewing data for compliance. For example, in the earlier description, where an agency might use discretion in taking enforcement action where results show uncertainty, a third party might aggressively seek an enforcement remedy by using the numerical results at face value (without qualifiers).

Existing uses of detection and quantation: As noted in the states' survey, the vast majority (87%) of the 31 states that responded indicated that they use 40 CFR Part 136, Appendix B to determine detection limits for use in their NPDES programs. The federal regulations do not specify a procedure for determining quantitation limits and a lesser majority of states (58%) indicated that laboratories are required to determine quantitation limits, either under a state regulation or through their laboratory accreditation program. Presumably, the remaining states are requiring, either in the permits themselves or through some other means, that a level of quantitation of pollutant concentrations in regulated discharges be established. States are divided (35% detection limit, 39% quantitation limit, 10% detection or quantitation limit, 13% "Compliance Limit", 3% "Other") as to the level they require for reporting with respect to compliance determinations. As with the discussion on permit applications, there is uncertainty when analytical results fall below the detection limit or quantitation limit as appropriate. It is in this area that clear guidance as to how compliance will be determined is very important since such determinations will define what the regulated entity must do to comply and may be the basis for legal action that the state or EPA would have to defend if challenged by the permittee/discharger. A number of states do allow for the determination of a discharge/matrix-specific detection limit and/or quantitation limit.

Data Quality Objectives/Method Quality Objectives: Due to the need for a high level of assurance as to the accuracy of the data, by both the regulatory agency and the discharger, the level of confidence that the methods for determining L_D and L_Q should be high. Perhaps the level of confidence would be somewhat higher for enforcement than for compliance but this might be limited to situations where compliance data are not used for enforcement.

Policy Issues: (The most important issues are shaded)

- What is the appropriate level of confidence for both type 1 and type 2 errors that should be used to establish L_Q, L_D, and L_C for determining compliance? For enforcement?
- Where the calculated limit is less than L_Q, L_D, or L_C should the limit be set at the calculated value or at L_Q, L_D or L_C, respectively. (Really three questions)
- Where the calculated limit is less than L_Q, L_D, or L_C should L_Q, L_D or L_C, be used to determine compliance? (Again, three questions)
- Should L_Q, L_D, and L_C be determined at the individual laboratory level or based on inter-laboratory studies?

- If L_Q, L_D or L_C are used to determine compliance, how would that be accomplished where averages (weekly or monthly) would have to be calculated?
- With respect to determining compliance and taking enforcement, should there be any distinction between the types of discharge (permitted process water, permitted stormwater, or un-permitted)?

Category of Use: Pretreatment (enforcement of pretreatment standards)

Lead Drafter: Chris Hornback

Definition: The general pretreatment regulations (40 CFR Part 403) establish requirements for the implementation of pretreatment standards to control pollutants from industrial users which may pass through or interfere with publicly owned wastewater utility treatment processes or which may contaminate sewage sludge. These ‘pretreatment standards’ include the federally-promulgated categorical pretreatment standards in 40 CFR Parts 405 – 424 as well as any locally developed standards or local limits developed by the wastewater utility.

Existing uses of detection and quantitation: All publicly owned wastewater utilities operating approved pretreatment programs use detection and/or quantitation levels in some manner to determine industrial user compliance with applicable pretreatment standards. Data may be generated by the utility itself or through industrial user self-monitoring. Wastewater utilities may also use detection and/or quantitation levels in the context of non-regulatory operation monitoring (for local limits studies, residential flow calculations).

Based on a brief survey of pretreatment programs, there is a wide range of approaches for determining what value is reported and for how compliance determinations are made. Some agencies use detection levels for determining compliance and others used a quantitation level. There was also a wide range in how agencies require reporting when the measured value falls between the DL and QL or below the DL.

Most survey respondents indicated that there are very few instances where the local pretreatment limit has been set below the level of detection. In fact, in most cases the discharge limits are well above the current level of quantitation. With the exception of the matrix effects issues noted below, the uses of DL/QL in the pretreatment program generally do not appear to be different from the NPDES program for most agencies.

Data Quality Objectives/Method Quality Objectives: Given the similarities between this program and the NPDES program, the DQOs and MQOs for these two uses will likely be identical. However, the biggest issues for pretreatment and data quality are the possible matrix effects in the industrial discharges. For this use there should be a well-defined process for showing where expected detection and quantitation limits cannot be met and how to determine the lowest limit where MQOs can be met. These wastes are often not pretreated and the opportunity for analytical interference is great. There may be compromises between the sensitivity of methods needed to protect the environment (effluent) and the sensitivities available for industrial and raw influent matrices. Additionally, where TMDLs may be expected, pretreatment programs may decide to regulate at detection when the effluent program uses quantitation, further complicating the impact of matrix on detection and quantitation uses.

Policy Issues: Policy issues closely track those for Permit Applications and Compliance Assurance and Enforcement. In addition, how will the possibility for matrix effects unique to indirect dischargers be addressed? Though there are few instances now where categorical pretreatment standards or local limits have been set at or below the level of detection or even quantitation, there are cases where TMDLs may drive pretreatment programs to regulate at detection (mercury limits for some POTWs can also be a driver). Compounded by the possibility for large matrix effects, additional guidance will be needed for determining where expected detection and quantitation limits cannot be met.

Category of Use: Water Quality Monitoring

Lead Drafter: Mike Murray (revised by Barry Sulkin to blend issues)

Definition: Ambient monitoring is used to assess the existing quality of surface waters and may be done for a variety of purposes, including:

- To determine water quality trends over time
- To assess a water body's ability to support its designated uses
- To assist in decisions on reporting/listing of water bodies as per Sections 305(b) and 303(d) requirements
- To evaluate the impacts and/or ability to assimilate both point source and nonpoint source pollution
- To support development of water quality-based effluent limitations for point source dischargers

Existing uses of detection and quantitation: Surface waters far removed from pollution sources (particularly those designated as high quality waters) will often contain low concentrations of pollutants, such that D/Q issues frequently limit the generation of numerical concentration data or point to the need to use methods with lower D/Q. When available (and in particular approved) methods are not capable of quantifying ambient concentrations for a given pollutant, the regulatory agency must specify how data will be reported based on the objectives for the monitoring. (In addition to chemical assessments, biological indicators are sometimes used to assess water quality, and in some cases may be able to provide information on the health of the water body relevant to chemical parameters which may not be measurable.).

In cases where ambient water quality criteria are below detection and/or quantitation levels attained with approved methods, or where sampling conditions are such that pollutants are diluted to low levels (such as at flows well above critical conditions upon which criteria are based) there is a need to identify new methods (or modifications to existing methods) in order to assure that water quality limited, threatened, and non-support waters are identified, and that pollutant reduction measures for point sources and nonpoint sources are adequately developed in order for designated uses to be attained.

Data Quality Objectives/Method Quality Objectives: Current federal law and rules on water quality monitoring, reporting, and listing include no specific reference to detection or quantitation issues (40 CFR Part 130.4, 40 CFR Part 130.7, and 40 CFR Part 130.8, respectively). There are several general EPA guidance documents on measurement procedures that reference detection and quantitation in general terms. For example, in the context of decision-making, the EPA Guidance for the Data Quality Objectives Process report states that, once an action level is identified, the planning team needs to "select the measurement and analysis methods capable of performing over the expected range of values and verify that the Action Level is greater than the detection limit of the measurement method that will be used." In cases, where the Action Level is lower than the detection limit for a particular method, the guidance states that "a more sensitive method should be specified or a different approach should be used.” (See p. 5-2, 5-4, EPA, Guidance for the Data Quality Objectives Process, EPA/600/R-96/055, Aug. 2000, http://www.epa.gov/quality/qs-docs/g4-final.pdf)

Another EPA guidance document includes approaches for analyzing datasets with values below detection limits (EPA’s *Guidance for Data Quality Assessment: Practical Methods for Data Analysis (QA/G-9),* EPA/600/R-96/084, July 2000, http://www.epa.gov/quality/qs-docs/g9-final.pdf)

Some general detection issues are addressed in EPA’s guidance for listing and reporting requirements. (See EPA’s Consolidated Listing and Methodology [CALM] guidance and pp. 23-25 of Guidance for Assessment, Listing and Reporting Requirements Pursuant to Sections 303(d) and 305(b) of the Clean Water Act, EPA July 21, 2003. http://www.epa.gov/owow/tmdl/tmdl0103/2004rpt_guidance.pdf) However, these guidance documents do not include or refer to any methodology for determining or using detection limits, but do discuss dilution calculations, hypothesis testing, Type I and II errors, and addresses issues surrounding attainment decisions (e.g., a sample distribution in the range of a particular criterion), using the t-statistic.

The most recent integrated reporting guidance from EPA also has no discussion concerning determination or use of detection or quantitation limits (EPA, Guidance for 2006 Assessment, Listing and Reporting Requirements Pursuant to Sections 303(d), 305(b) and 314 of the Clean Water Act, Memorandum from Diane Rigas to EPA Water Division Directors, July 29, 2005.)

(Concerning uses by individual states, currently in process of hearing back from several.)

Policy Issues:

- As with the establishment or modification of water quality standards (in particular water quality criteria), detection and quantitation issues may drive the need for development of more sensitive test methods that allow for detection and quantitation at levels low enough in order to make more informed use support decisions for surface waters.
- What detection and quantitation criteria should be used as part of decisions to identify waters not meeting standards [per 305(b)] or water quality limited segments needing more than mandated minimum technology-based controls [per 303(d)]?

Category of Use: Non-Regulatory Operational Monitoring

Lead Drafter: Larry LaFleur

Definition: Industry often uses 40 CFR Part 136 methods in internal process optimization studies. Optimization or operational monitoring activities are triggered by changes in the manufacturing process. Examples would include production of a new or special grade, non-steady-state conditions at unit startup or shutdown; compositional changes due to maintenance problems or equipment wear; alteration of manufacturing conditions to change product specifications; variability in process feedstocks or additives; etc. In these instances, short term trials may be run while appropriate samples are collected for analysis. In addition, both industry and municipalities may utilize 40 CFR Part136 method is studies undertaken to optimize performance of wastewater treatment systems

Existing uses of detection and quantitation: Promulgated DLs and QLs are used to help the facility operators select analytical procedures appropriate to their needs. The QLs will also provide the data users important information about where they can consider the analytical results reliable. Generally speaking, these trials and/or optimization studies involve measurement of analytes above the QL.

However, in cases where the target parameter is being regulated based on a water quality standard, the data user may have to draw inferences from data reported below the QL. Under no circumstance are important process design or operation made based on a single measurement due to the given the greater uncertainty in measurements below the QL. When the study involves or requires the use of data below the QL, it would be helpful to know L_d so the data user knows the level where they can be assured that if the analyte were present above that level, it has a very high probability of being detected. At the same time, knowing L_c provides information that provides protection against making expensive process modifications based on a false positive.

Data Quality Objectives/Method Quality Objectives: Known L_c and L_d with false positive and false negative rates of less than 1%. If analytical method performance (e.g. accuracy and precision) were known as a function of concentration, the study designers could explore the most cost effective combination sampling frequency to provide a given level of confidence in making the correct process optimization decision.

Generally, dischargers wish to design plants that comply with CWA requirements. To demonstrate this, most plant designers and dischargers wish to use laboratory techniques, including QL and DL procedures, which are "industry standards" and thus have a very strong tendency to use DQOs / MQOs found in 40 CFR 136 or other published sources for relevant regulatory agencies.

Policy Issues: Permitees are required to report all analytical results generated on a permitted outfall in the DMR if a 40 CFR Part 136 procedure is used. This makes all such measurement subject to the same certification requirements as for routine compliance monitoring.

Category of Use: Other Studies - 2001 National Sewage Sludge Survey

Lead Drafter: Mary Smith

Definition: The objective of the 2001 National Sewage Sludge Survey conducted by EPA was to obtain unbiased national estimates of dioxin and dioxin-like compounds in sewage sludge. Specific analytes of interest were the seven 2, 3, 7, 8-substituted polychlorinated dibenzo-p-dioxin congeners, the ten 2, 3, 7, 8-substituted polychlorinated dibenzofuran congeners, and the full set of 209 polychlorinated biphenyls (PCBs) congeners. This information was used in the multi-pathway exposure analysis/risk assessment that will form the technical basis of the numerical standard for land application of sewage sludge. This information also was used in the revised risk assessments for the surface disposal and incineration of sewage sludges.

Existing Uses of detection and quantitation: The MDL and ML for the specified analyte were identified and results were reported at or above the ML.

Data Quality Objectives/Measurement Quality Objectives: MQOs taken from Method 1613B and 1668A. No formal development of DQOs (e.g., the 7-step process was not performed

Policy Issues: None

Category of Use: Other Studies - National Study of Chemical Residues in Lake Fish Tissue

Lead Drafter: Mary Smith

Definition: The objective of this EPA four-year screening-level study is to estimate the national distribution of selected, persistent, bioaccumulative and toxic (PBT) chemicals in fish tissue from lakes and reservoirs of the contiguous U.S. It will generate data on the largest set of PBT chemicals ever studied in fish. EPA will use the study results to define the first national mean concentrations for the 268 chemicals in lake fish, to provide a national fish contamination baseline to track progress of pollution control activities, and to identify areas where contaminant levels are high enough to warrant further investigation. Data was collected in 2000-2003 and sampling teams applied consistent methods nationwide to collect composites of one predator species and one bottom-dwelling species at each lake. Composites consist of 5 adult fish of similar size that are large enough to provide 560 grams (20 ounces) of tissue for analysis of fillets for predators and whole bodies for bottom dwellers. EPA is currently analyzing the fish tissue for: 2 metals (mercury and 5 forms of arsenic), 17 dioxins and furans, 159 PCB congener measurements, 46 pesticides, 40 other semi-volatile organics (e.g., phenols), and 49 PBDE congener measurements (fourth year samples only).

Existing Uses of detection and quantitation: Data that is less than the MDL is recorded as “nondetect.” Data that is between the MDL and ML is qualified in the dataset with a “j”-flag, indicating that the value is an estimate (still clarifying whether this data is used in statistical calculations).

Data Quality Objectives/Measurement Quality Objectives: DQOs: To allow EPA to report on the extent of PBTs in fish tissue in lakes with known confidence. Study results should allow statements such as: “35% of the lakes PBT levels in fish that exceed the criteria of concern. The estimate of uncertainty iṣ 5%, suggesting the proportion of lakes of concern might be as low as 30% or as high as 40%.” MQOs: Numerical MQOs were specified in the analytical QAPP for precision, bias, and completeness.

Policy Issues: None