DRAFT
Prescriptive and Descriptive Approaches for Detection and Quantitation in Clean Water Act Programs

Approach	Description of Approach	Examples	Advantages	Disadvantages
Prescriptive	This approach says "This is what a laboratory must do." An approach where Lq, Ld, and / or Lc is set in regulation and is the same for a given regulated analyte for all laboratories. This is the approach used by the USEPA for CWA compliance for Methods 1613, 1624, 1625, and 1634e, for Information Collection and the Unregulated Chemical Monitoring Rules, and the California SDWA and CWA primacy programs (Lq). The laboratory would on an a batch by batch analyze a validation sample to demonstrate compliance. That sample will require a range of limits. Using a prescriptive approach would probably favor a multi-laboratory pilot study design as the USEPA would require data from many laboratories to sufficiently define and prescribe reporting limits for the laboratories.	1634e 12.5 Lq = 0.5 ng/L Lc = 0.2 ng/L Unspiked Blanks <Lc (1634e 9.4) (also see 1613, 1624, and 1625) EPA 814-B-96-02 DBP / ICR Analytical Methods Manual Spiked Blanks at Lq +/- 25% or 40% Table 9.2 Unspiked Blanks <Lc Table 9.6	1) These values would not change over time or between laboratories. . 2) Laboratories would not need to do separate MDL like studies. 3) If Lq, Ld, and/or Lc are used as a Compliance Evaluation Threshold (CET), the CET is the same for all permit holders irrespective which laboratory or instrumentation they use. 4) Verification of Lq and Lc occurs with each batch so for every individual compliance sample result there is a matching Lq and Lc quality control result. 5) It is consistent with many elements of existing CWA practices. 6) It will eliminate unrealistically low Detection Limits 7) Does not require statistical or theoretical assumptions about the distribution of data that are often not met in real data.	1) Without a built-in mechanism for lowering Lq and Lc, these values become locked in and cannot be changed without a change in regulation. 2) If new Lq and Lc are set for all 40 CFR 136 analytes, it will require considerable regulatory change. 3) For laboratories that are not familiar with the QC in the 1600 series methods or ICR procedures, verification Lc and Lq will be a dramatic change.

Descriptive	This approach asks "What can a laboratory achieve?" One uses a prescriptive process, such as the MDL to develop a description of what a lab can achieve with a specific analytical method. Analyses with the analytical method are used to estimate (i.e. describe) a lab's detection and quantitation limit for a pollutant. An authority, vendor or developer determines whether these descriptive estimates meet intended uses (DQOs). If the descriptive values are used to set mandatory limits, they become prescriptive values (or limits) that are expected to meet intended uses of these limits, e.g. NPDES, lab accred., instrument comparisons, etc.	40 CFR appendix B MDL procedure is used to estimate a detection limit. MLs are a multiple (~3) of the MDL in some cases; in others ML may be lowest calibration point observed in the method development study.	1) Descriptive approach allows characterization of individual laboratory performance. This information may be pooled to develop a realistic expectation of future performance by qualified laboratories. 2) A range of descriptive laboratory performance is used to develop prescriptive requirements for various uses (regulatory, monitoring, laboratory accreditation, method equivalency studies, etc.).	1) Descriptive estimates of detection and quantitation limits vary with time, laboratory, analyst, instrument, etc.. Thus, using them as mandatory (prescriptive) benchmarks requires that a representative set of estimates that address laboratory, temporal and other sources of variability be obtained to prescribe acceptable future performance. 2) For some types of methods (e.g., censored), spiking experiments to describe a laboratory's performance may differ depending on whether (a) acceptable performance at a specific (i.e., prescriptive) detection or quantitation limit is required, or (b) laboratory simply describes its best performance.

Use of Both	It is possible to combine both approaches. For example, the California CWA primacy program has a mixture of these two approaches. The Lq is set prescriptively and the Lc is set descriptively. Other permutations are also possible.	California – Lq is set in Regulation (SIP)* however Lc is determined by each laboratory.	1) Opportunity to choose advantages of both approaches	1) Mixing different approaches

*** SIP = State Implementation Plan (2005)for the California Toxics Rule (FR Vol. 65, No. 97 31682)**