

METHOD DETECTION/QUANTITATION: PROGRAM USE/NEEDS

FINAL

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The following is a summary of program uses and needs for method detection and/or quantitation as integral background information to establish greater consistency across the Agency.

OAR – Indoor Air – Their main concerns are as follows: teaching the concepts clearly so that labs, project planners, and data users do not misuse and abuse those concepts; allowing labs the flexibility to use evaluation methods and equations that make sense for their measurement processes, consistent with the conceptual definitions; encouraging the radiation world to use quantitation limits where appropriate instead of trying to adapt and apply detection limits to questions of quantitation; and encouraging/requiring labs to perform reality checks on their estimated detection and quantitation limits, which can be unrealistic if they are based on too many false assumptions about the statistics of the measurement process.

OAR – Stationary Source/Ambient Air – The OAR Stationary Source program uses MDLs to define method performance, but it does not use quantitation limits. Instead it uses an approach that is similar to that of OSW where the lower reporting limit is determined by the lowest calibration standard.

The OAR Ambient Monitoring program also uses MDLs to define method performance. All measured data are reported, but those below the detection limit are flagged so that the end data user may make their own decision about whether the data are of sufficient quality for their intended purpose.

OCEM – Homeland Security – Too much information is scattered across the Agency without even knowing all that is available for use. Putting it in one place or creating a road map would be a vast improvement.

OECA – National Enforcement Investigation Center – Uncertainty estimates in analysis to comply with ISO 17025 accreditation is a primary concern for NEIC to get a better grip on the validity of the analysis. Defining the quantitation range and particularly what is the uncertainty associated with the results throughout the range given the nature of NEIC's samples is a challenge. Having a procedure(s) to determine the LOD and LOQ that takes into consideration the complexities of the variety of sample matrices that are encountered and the uncertainty associated with these values is of the greatest need.

OPPTS – Office of Pesticide Programs – Information and data are received from many different sources using a wide array of different methods. A variety of approaches

are used to satisfy different needs and purposes. Best for these programs to retain the flexibility of not dictating any one approach, but open to possibilities of new approaches.

ORD – Office of Research and Development Programs – Need something with flexibility for both method detection and quantitation limits that considers both precision and accuracy. Guidance versus a specified procedure would be more useful.

OSWER – Contract Laboratory Program – In the FACA Report on detection and quantitation limits, the Limits of Detection approach that was developed by the Consensus Group Committee I was reviewed with past CLP data. Our program found that for inorganics that the approach was straight forward and gave data that was more defensible than the current approach, so we were hopeful it would be retained in the final package. Unfortunately for us, it was removed, so we are still looking for another alternative.

OSWER – Solid Waste Program – *What are ORCR Methods Program Needs....* Since the SW-846 methods are being used by various programs, including RCRA, Superfund, TSCA, and Homeland Security for waste and materials characterization, compliance testing, risk assessment for human health and the environment, better management and use of wastes and materials...etc.; our methods program needs flexibility for both method selection and modification. For this reason, ORCR strongly supports the performance-based approach and promotes this approach in the RCRA testing program whenever feasible.

Why there are differences..... ORCR develops separate sample preparation methods (for extraction, clean-up, and concentration) and determinative procedures that are specific for a variety of sample matrices. To better handle a waste or material, analysts need to select the best combination of the aforementioned methods and procedures that are appropriate for the specific matrix and desired target analytes. This selection process is also based on achieving the appropriate compound sensitivity while meeting the data quality objectives for a given project application.

How LLOQs are established..... ORCR has removed the need for a MDL determination from the Update IV and draft new methods and has instead recommended establishing the lower level of quantitation (LLOQ). This LLOQ is typically established as the lowest point of quantitation which, in most cases, is the lowest concentration in the calibration curve. LLOQ verification is recommended for each project application to validate quantitation capability at low analyte concentration levels. This verification may be accomplished either with clean control material (e.g., reagent water, solvent blank, Ottawa sand, diatomaceous earth, etc.) or a representative sample matrix (free of target compounds). Optimally, the LLOQ should be less than or equal to the desired regulatory action levels (or risk levels) based on the stated project-specific requirements.

How LLOQs are used... ORCR deals with complex wastes and materials that are managed or used in numerous scenarios such as: land filling, land application, incineration, and recycling. Therefore, the thresholds for remediation or concentration levels derived from a risk model for data users (e.g., engineers or risk assessors) to make their decisions, may vary widely. Method users will need to properly plan their analytical strategy to ensure the LLOQs for targeted analytes are lower than the thresholds so that data would be useful for engineers and risk assessors to determine how waste or materials can be properly managed or used.

OW – Office of Ground Water/Drinking Water Program – Detection and quantitation limits are both used by the GWDW program, but an effort is being made to reduce the use of the detection limit, which is not the most important to the program. The program is working to establish a national Method Reporting Level (MRL) for regulated analytes that laboratories can demonstrate performance to. This value would be established by using individual Lowest Concentration Minimum Reporting Levels (LCMRLs) which are generated using an algorithm that accounts for both precision and bias simultaneously. For more information see:
http://www.epa.gov/safewater/methods/analyticalmethods_ogwdw.html#four

OW – Office of Science and Technology – Ways to improve the use and calculation of detection and quantitation limits in CWA programs are being re-evaluated in light of the deliberations of a federal advisory committee.

Current CWA detection and quantitation limit uses include: Method Development and Promulgation, Verification of Laboratory Performance, Occurrence Studies, the National Pollutant Discharge Elimination System (NPDES). Specific NPDES uses include: Development and Implementation of Technology-based Controls (Effluent Guidelines), Development and Implementation of Water Quality-based Controls, and Permit Compliance Monitoring. (If you want more information, there is an attachment provided from CWA Regulatory Issues Chapter from the 2004 Revised Assessment of Detection and Quantitation Approaches or you can goto <http://www.epa.gov/waterscience/methods/det/rad.pdf> .)