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**Office of Water Quality Technical Memorandum 2014.01**

**Subject: Updated Policy for the Evaluation and Approval of Analytical Laboratory Performance for Water Mission Area Projects and Programs**

## Introduction

The purpose of this memorandum is to update the previous Office of Water Quality (OWQ) policy and guidance regarding the evaluation of performance of analytical laboratories providing results to Water Mission Area (WMA) supported projects. This memorandum recommends flexible and relatively simple guidelines for assessing laboratory capability that relies, in most cases, on performance data and information rather than laboratory inspections. This guidance can be applied in combination with a user's knowledge about a service laboratory and method performance to produce confidence in results.

Survey Manual SM 502.2 requires the documentation of data quality and is the basis for this memorandum. This memorandum describes how Fundamental Science Practices are met for laboratory results and reiterates the need for review and approval of results obtained from service laboratories as a policy of the WMA. This policy applies to results provided to WMA supported projects by USGS laboratories and other laboratories. The term "project" for purposes of this memorandum is defined in Survey Manual (SM) 502.2.3.B.

## Policy

Results obtained from water, air, sediment, and tissue environmental samples analyzed at USGS and other analytical laboratories and published in USGS information products must meet the documentation standards required in SM 502.2.3A. The National Water Quality Laboratory (NWQL), NWQL contract laboratories, laboratories accredited to relevant national or international standards (introduced in OWQ Technical Memorandum 2002.05) , and USGS sediment laboratories are classified as Level 1 for methods that subscribe to either the Branch of Quality Systems (BQS) Blind Sample Projects or other independent proficiency test (PT) sample studies for the analytes of interest. Additionally, laboratories that provide project analytical results with directly corresponding set- or run-specific internal quality-control data and information may be considered Level 1 when the targeted analytes, quality controls, and analytical performance meet project objectives.

All other laboratories are classified as Level 2 unless equivalence with the objectives of the BQS Blind Sample Projects or adequate laboratory performance is demonstrated.

**Guidelines**

Guidelines for documentation of the quality of laboratories that provide results to WMA supported projects are fully described on the BQS website. The guidelines begin with the assignment of a laboratory to a simple two tiered classification based upon the laboratory's level and availability of performance information to assess reliability of results produced from environmental analyses. The first step of determining whether the laboratory is capable of providing the necessary data quality to the project is to assure that an appropriate analytical method is selected and results obtained by use of this method have a reasonable expectation of meeting project objectives. This step is done at the beginning of a project. The second step is to assure, on an ongoing basis that the analytical method continues to provide reliable results of acceptable quality through the period of performance. Recommendations for documenting the results of a method assessment for Level 2, and seeking review and approval of the data-quality documentation are described on the BQS website.

Regardless of the laboratory providing the results, performance data and information are needed to evaluate a laboratory and a method's ability to meet the project objectives for each measurement or set of measurements. Analyses of samples with known composition (typically referred to as standard reference materials, certified reference materials, or performance test (PT) samples) are an excellent source of performance data. When available, PT sample results serve as the basis for the laboratory evaluation for water, air, sediment, and tissue analyses. PT sample results are reviewed at the beginning of a project, when possible, as a test of acceptance of initial method performance, and subsequently over the life of a project to provide information needed, in part, to interpret results from the environmental samples.

PT samples should contain the constituents to be analyzed at one or more levels within the expected environmental range and in the corresponding matrix. PT samples effectively evaluate the laboratory treatment of the sample and the method performance of the test method. Some laboratories will be able to provide sufficient PT sample data and information to meet the needs of a project initially and on an ongoing basis while other laboratories will be able to provide little or no relevant PT sample data. Guidelines provided herein and on the BQS website distinguish between these laboratories with sufficient PT information about their methods and those that do not. Guidelines also provide advice on using internal laboratory data when including set- and run-specific quality-control data with environmental sample results.

The following terms are introduced in this memo to simplify further discussions related to the available PT sample data:

Level 1 – The laboratory participates in an ongoing quality-assurance program which demonstrates initial and ongoing reliability of results (precision, accuracy, specific methods of

laboratory quality assurance). Sufficient PT sample or external performance data and information are available from the laboratory, or an external third-party source, to evaluate performance before and during the project's data-collection phase, as well including all of the constituents needed by the project and within expected environmental concentration ranges.

Level 2 – Insufficient or no PT sample or external performance data or information are available from the laboratory, or a third-party external program, to evaluate performance before and during the data-collection phase of the project for some or all of the constituents needed by the project and their expected environmental ranges. Projects must assess the capabilities and on-going performance of Level 2 laboratories through performance data appropriate to the project objectives.

Level 1 or Level 2 classification is dependent on the availability of relevant PT sample performance data or equivalent information. The same analyses may be assigned Level 1 for one project and Level 2 for another project having different environmental concentration ranges for which relevant PT data are not available. It is the responsibility of the Water Science Center (WSC) to assess the performance of each laboratory analysis for its projects and to formally evaluate laboratories in a Level 2 situation with a laboratory evaluation package.

Investigators intending to use a laboratory providing analyses that are deemed Level 2 must find project relevant PT samples to produce the data needed to evaluate performance. When PT samples are not available for a particular analyte or analysis, alternate performance data must be collected that addresses the quality of analysis by the laboratory and meets the objectives of the project. Examples of alternate performance data could be project replicate samples, blanks, matrix spikes, reference laboratory duplicate analysis, and information gathered from published peer-reviewed reports. The BQS is available to assist investigators in obtaining PT samples but is not a source for any and all PT samples that a project might need. A number of other resources and vendors of PT samples are listed on the BQS web page.

Examples of laboratories that typically will meet the criteria for Level 1 classification are those that have performance data and information that support project objectives, such as PT sample data, participation in external audits or reviews, sample level estimates of variability, accreditation, or complete internal quality controls. When supported by these data, the following are considered Level 1: results from methods used by the NWQL when it participates in the BQS Blind Sample Project or for the analytes for which it is accredited, NWQL contract laboratory data when supported by third-party PT sample testing program or the contract data are quality-assured by the NWQL, and USGS sediment laboratories that routinely participate in the BQS Sediment Laboratory Quality Assurance testing and are evaluated by the Office of Surface Water. Although this memorandum supersedes OWQ Technical Memorandum 2002.05, the intent of 2002.05 remains relevant: Accredited laboratories incur outside oversight and review, and participate in PT sample analyses where available. These attributes enable accredited

laboratories to be considered Level 1 when the accreditation covers the analytes, analytical methods, and environmental ranges of interest.

Any laboratory using analytical methods supported by relevant PT data or sufficient performance information are Level 1. All other laboratories are considered Level 2 until they can demonstrate equivalency with Level 1.

It is recommended that information on all laboratory and method performance (either Level 1 or Level 2) be documented within project or program produced formal USGS reports, or peer–reviewed literature containing the results of the project or program.

**Exemptions**

Field measurements and analyses that follow USGS published measurement and quality-assurance guidelines in the National Field Manual (http://water.usgs.gov/owq/FieldManual/) such as pH, specific conductance (field), alkalinity, and indicator bacteria do not require an evaluation package for review and approval.

Evaluation of the performance of analytical methods that are still under development and for which there are no established measurement performance criteria (e.g., control limits, reporting levels, variability, spike recoveries, calibration rules) is not required. Results generated during analytical method development are considered to be preliminary and may not be provided to the public without explanatory comment or interpretation in a peer reviewed and published information product. Projects using data produced by analytical methods under development may require extensive laboratory data evaluation for valid interpretation of results.

**Documentation, Review and Approval**

Knowledge about the data quality from analytical laboratories providing services to USGS WMA projects is crucial to the appropriate assessment of the environmental data. All analytical work needs to be evaluated against project specific needs and documented in project reports. Use of laboratory data classified as Level 2 requires the production of a separate laboratory evaluation package to assess and document specific laboratory performance; one that must be additionally reviewed and approved.

The Water-Quality Specialist (or designee) in the WSC and a Water-Quality Specialist on the Water Science Field Team (WSFT) will review Level 2 laboratory evaluation packages to verify that the laboratory has proven the capability of providing results appropriate for the objectives of the project. Reviewer comments should be addressed and resolved before the package is submitted to the appropriate WSC Director or National Program Manager for approval to use the laboratory.

Completed Level 2 evaluation packages with appropriate signatures should be maintained in the WSC files; copies should be provided to the appropriate WSFT Water-Quality Specialist and the Chief of Laboratory Evaluations, BQS, for their records.

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This memorandum supersedes OWQ Technical Memoranda 2007.01, 2002.05, and 98.03R.

Distribution: All WMA Employees

References

Office of Water Quality Technical Memorandum, 2007.01, Policy for the Evaluation and Approval of Analytical Laboratories.

Office of Water Quality Technical Memorandum, 2002.05, Approval of Laboratories with existing National Environmental Laboratory Accreditation Conference (NELAC) accreditation.

Office of Water Quality Technical Memorandum, 98.03R, Policy for the Evaluation and Approval of Production Analytical Laboratories.

Fundamental Science Practices: Planning and Conducting Data Collection and Research, 12/16/2011, FSP 502.2.