

PERFORMANCE-BASED EVALUATION OF LABORATORY QUALITY SYSTEMS
An Objective Tool to Identify QA Program Elements that Actually Impact Data Quality

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ABSTRACT

On-site laboratory evaluations, a key element of the laboratory approval process, encourage the proper implementation of analytical methods and provide supporting documentation to demonstrate method performance. These evaluations, regardless of their complexity, usually do not focus on identifying the key, explicit QA program activities that may *in fact* adversely affect the production of acceptable level data quality. They emphasize secondary elements of a QA system or program, such as, the organization, facilities, equipment, good laboratory practices, record keeping habits, and performance in the external intercomparison studies.

This paper proposes a non-conventional, performance-based evaluation to *effectively* assess the technical ability of an analytical laboratory to perform acceptably over the lifetime of an extended project. It focuses on the assessment of (1) current, valid method proficiency data in terms of empirical method detection limits, (2) related quantitative measures of precision and accuracy, and (3) on-going demonstration of precision and accuracy through the analysis of laboratory control samples using statistical techniques. Effective, comprehensive laboratory QA programs comprise of, but are not limited to, internal audit and non-conformance/corrective action reports, training and analytical proficiency files, properly maintained instrument logbooks and laboratory bench sheets, etc. The evaluator's review of these documents can detect trends and systematic deficiencies, thus providing a more sweeping technical evaluation of the laboratory's potential to perform.

INTRODUCTION

Selecting the analytical laboratory that will provide the best complement of services for an environmental project is of utmost importance. Each year, analytical laboratories are subjected to numerous on-site systems audits by various regulatory authorities and by prime contractors as part of pre-award and post-award evaluations. These, a key element of the laboratory selection and approval process, encourage the proper implementation of analytical methods and provide supporting documentation to demonstrate method performance. The objective is to select laboratories that are capable, technically qualified, and credible so that a laboratory performs adequately during a data collection process. Systems evaluations typically range from one-day surveillances to five-day or more intensive compliance audits conducted by a team of two or more auditors. Although sometimes seemingly complex, these evaluations do not necessarily focus on identifying the key, explicit QA program activities that may *in fact* adversely affect the production of acceptable level data quality.

SCOPE OF AUDITS

On-site audits are typically associated with large Federal programs, namely Department of Defense (DoD), Department of Energy (DOE), U.S. Environmental Protection Agency (EPA), etc. There are no universally recognized guidelines or unified checklists for laboratory audits.^{1,2,3} Different segments of the same Federal entity may conduct the evaluations based on historical precedence, experience (or lack thereof) of the evaluators, and requirements of special Quality Assurance Project Plans (QAPP) and data quality objectives (DQOs). Unless it is a health risk assessment investigation, most commercial clients are notably less demanding, hence their audits are usually less rigorous.

The vast majority of the audits annually experienced by a laboratory fall in the category of CLP-like evidentiary or "paper-trail" audits, or those focusing on the identification of common deficiencies, such as:

- inconsistencies in laboratory support equipment monitoring, such as:
 - temperature excursions
 - reagent water
 - balance calibrations
 - pipette calibrations
- determination of precision and accuracy of containers
- incomplete training files (e.g., resumes);
- adequacy of bench space, facilities, or instrumentation;
- whether or not the laboratory has a procedure for cleaning glassware;
- improper error corrections;
- labeling of reagent containers;
- inadequacy of logbook reviews, etc.;
- and whether or not logbooks are permanently bound.

Most self-respecting laboratories have a system ensuring that these types of quality control (QC) checks are implemented routinely. Identification of occasional incidents of inefficiencies in the laboratory's QA system does not necessarily constitute a major breakdown of the system that would result in the production of unacceptable quality data. In parallel, a laboratory that may seem to have in place an adequate system of minimizing these common deficiencies mentioned above does not guarantee the generation of high-quality data. All phases of laboratory operations should be designed with the objective of preventing problems and improving quality on a continuous bases.

The US Air Force for Environmental Excellence (AFCEE)⁴ and the US Army Corps of Engineers⁵ provide a more useful type of guidance for "validation of analytical chemistry laboratories." Here the emphasis is more on actual day-to-day compliance with the QAPPs and the analytical methods.

USING KEY ELEMENTS OF THE LABORATORY'S OWN QA SYSTEM

There are specific, key elements of a QA system that must be assessed to determine whether the laboratory's quality system is capable of meeting the DQOs needed to generate analytical data of sufficient quality. Assurance of data quality can only be achieved through understanding the client's needs and expectations and developing effective means to communicate these requirements to all personnel involved in a data collection project.

An effective QA system is one that emphasizes prevention rather than detection. To accomplish this, laboratories conduct routine internal surveillances to determine the extent of conformance to established, internal procedures and policies covering all critical functions affecting data quality.

Attention to quality begins by ensuring that all technical staff are thoroughly trained in their assigned responsibilities. An auditor, through observation and interviews, can determine the evidence of deviations from laboratory's own internal procedures and project-specific requirements and poor documentation which may indicate a lack of understanding of the procedures, a lack of training, and a lack of QA oversight of staff and procedures.

An evaluator with a working knowledge of laboratory operations and specific analytical procedures can determine the presence and effectiveness of an internal QA system by reviewing:

1. Documents that indicate that the QAPPs, *Request for Proposals (RFPs)/Request for Qualifications (RFQs)*, or other pertinent contractual documents are routinely reviewed by key operational and project management and QA personnel;
2. The laboratory's manual or electronic mechanism that enables the effective and timely dissemination of project-specific requirements,
3. The laboratory's internal technical systems audit and data validation reports: these provide a more realistic, candid illustration of on-going nonconformities and the management's commitment to resolving them.
4. A full set of method SOPs, followed by analyst interviews; and
5. Method performance data generated by the analysts using internal and/or external blind performance evaluation (PE) samples, e.g. method detection limits (MDLs), laboratory control samples (LCSs), EPA Water Pollution/Water Supply PE samples, etc.

ELEMENTS OF PERFORMANCE-BASED EVALUATIONS

The performance-based evaluation must focus on the assessment of on-going method performance in terms of:

1. Current, valid method proficiency data in terms of empirical MDLs;
2. Related quantitative measures of precision and accuracy; and
3. On-going demonstration of precision and accuracy through the analysis of LCSs using statistical techniques.

The sample receiving area is generally the starting point for most audits, when tracing the route of a sample. A laboratory must have a well-documented system of ensuring the traceability of environmental samples from receipt to disposal via maintaining unique identification throughout the life of a sample. An evaluator must be able to determine that sample integrity is maintained through adequate custody of samples from the time samples are collected until disposal or until they may be introduced as evidence in legal proceedings.⁶

Reviewing the results of the laboratory's *internal system audit* reports usually provides the auditor with a plethora of quality issues to help focus his/her attention on the critically deficient areas of operation. Similarly, reports delineating *independent validation* of data reports performed by QA personnel provide a wealth of information about the systematic nonconformities in the data production system.

Coupled with external PE sample data, *internal blind PE samples* can establish the analysts' proficiency in preparing and analyzing multi-media samples and prove acceptable method performance.

The review of *instrument logbooks and laboratory bench sheets* yields information on the prescribed analytical sequence of the correct number, types, and frequencies of method-required QC samples.

The system in place for *technical data review* at various steps during the data production process can illustrate the level of commitment to the early detection and correction of those anomalies that adversely affect data quality. An observation related to reporting of out-of-control data may be an indication of poor review procedures as well as poor techniques in the laboratory.

Nonconformance/corrective action documentation should be reviewed to assess the degree of the systematic deficiencies, and whether adequate corrective measures were implemented in time to eliminate the root cause of such deficiencies. This review can also confirm management's commitment to addressing such nonconformities that lead to insufficient data quality.

Follow-up reviews of nonconformance/corrective action reports indicate the effectiveness of the corrective action program in identifying and correcting *systematic* deficiencies before data quality is further impacted.

Regardless of the advancements in the analytical technologies, competence and expertise of the technical staff are essential to quality measurements. Reviews of *training files* should then emphasize documentation demonstrating analysts' proficiency in performing the assigned tasks. These files should also document the required procedures for training as appropriate for each laboratory staff member.

Reviews of *software validation* documentation can help determine whether a laboratory has a policy and a procedure in place to ensure that Laboratory Information Management System (LIMS), internally developed or modified software configurations (e.g., spreadsheets), and instrument software provided by instrument manufacturers produce accurate and precise data.⁷ It is also critical for laboratories to thoroughly document procedures for control of software configuration and process for controlling the release and change of configuration items through the system life cycle and data security. In recent years, software QA has become a central issue for many of the projects governed by DoD, DOE, and EPA organizations. Lack of software QA system has resulted in the generation of questionable data which has cost the government multimillion dollars in resampling and reanalysis costs. For example, an instrument data system not adequately verified can easily process quantitative results that are biased high or low resulting in false positives or false negative. This would result in the generation of erroneous data leading to costly, incorrect clean-up decisions.

Chemical measurements almost always involve the comparison of an unknown with a standard. Laboratories without exception must use standards with documented uncertainties.⁸ For reference materials, integrity and traceability to a known, certified source are prerequisites to accurate and precise chemical measurements. Standard labeling with dates of preparation and expiration will aid in avoiding use of reference materials past their normal shelf life. Routine purity verification on a lot-by-lot basis can establish the quality of the material. Unique identifiers for standards must be documented on bench sheets and in the standard preparation logs to document traceability. Integrity of the standard materials must be ensured through proper storage facilities. A review of traceability documentation can reveal information regarding a laboratory's process in ensuring all of the required elements mentioned above.

Another key element of the QA system is to assess the degree of deficiencies and the corrective actions so that similar deficiencies will not recur. Too often the symptoms of individual deficiencies get corrected, not the fundamental cause, and, when the evaluator performs a follow-up evaluation, he generally uncovers the same type of deficiencies.⁸ A detailed review of nonconformance/corrective action reports provides a tool to evaluate a laboratory's ability in correcting data deficiencies early in the process before they impact data quality. It is vital that

key laboratory personnel (analyst, supervisor, and QA) take part in the problem solving and identifying the most effective measures that will correct the root cause of the nonconformity.

An active, effective QA Program is vital to the success of a laboratory in the environmental arena. However, to conform to any given requirements demands that an organization has the desire and direction from top management to perform and enforce the discipline necessary to maintain a quality system.⁹ Without this, no Quality system can be effective.

CONCLUSION

The effectiveness of the QA Program is measured by the quality of data generated by the laboratory. The analytical laboratory already functions with an effective, comprehensive QA program that implements the critical QA/QC elements discussed above. The performance-related documentation of the laboratory itself provides the evaluator with a vast array of critical issues to focus on. The initial as well as the on-going qualifications of an environmental laboratory should be undertaken using primarily these tools. Technical systems evaluations are most effective when they are tailored to examining the critical methods of interest for a specific environmental project. To accomplish this, a good procedure is to trace the path of a group of project samples through all vital areas of the laboratory operations. Another focus of laboratory evaluations should be to identify noteworthy practices or procedures that help maximize data quality. The on-site laboratory audits should not be intended as a policing function. Rather, these audits should serve as a basis to nurture a successful partnership between the laboratory community, prime contractors, and the regulators. These tools can ultimately be used to select competent laboratories and ensure successful and sustained performance of an environmental project.

REFERENCES

1. U.S. Environmental Protection Agency, "2185 - Good Automated Laboratory Practices - Principles and Guidance to Regulations for Ensuring Data Integrity in Automated Laboratory Operations with Implementation Guidance," 1995, Edition, 10 August 1995, USEPA, Research Triangle Park, North Carolina 27771.
2. U.S. Environmental Protection Agency, "Good Laboratory Practice Standards Inspection Manual," EPA 723-B-93-001, September 1993, USEPA, Washington, DC.
3. International Organization for Standardization, "ISO Guide 25 - General Requirements for the Competence of Calibration and Testing Laboratories," 1990, ISO, Genève, Switzerland.
4. HQ Air Force Center for Environmental Excellence, "Technical Services Quality Assurance Program," Chapter 3.0 Laboratory Evaluation, Version 1.0, August 1996, AFCEE, Brooks Air Force Base, San Antonio, Texas.
5. US Army Corps of Engineers, "Validation of Analytical Chemistry Laboratories," Engineer Manual EM 200-1-1, 1 July 1994, U.S. Army Corps of Engineers, Department of the Army, Washington, DC.
6. US Environmental Protection Agency, "Guidelines for Conducting On-Site Laboratory Evaluations," Edition 5.0, 1994, Environmental Systems Monitoring Laboratory, Las Vegas, Nevada.
7. US Naval Facilities Engineering Service Center, "Naval Installation Restoration Laboratory Quality Assurance Guide," 1996, Port Hueneme, California.
8. John K. Taylor "Quality Assurance of Chemical Measurements," Chapters 17, 18, and 19, 1987, Lewis Publishers, Inc., Chelsea, Michigan.
9. L. Marvin Johnson, Lead Auditor Training, "Quality Assurance Program Evaluation," Page 37, 1990, L. Marvin Johnson and Associates, Inc., West Covina, California.