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QA/QC IN THE LABORATORY

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ABSTRACT

Session F

Presentation Title: QA/QC IN THE LABORATORY

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Quality assurance and quality control (QA/QC) of analytical chemistry laboratory activities are essential to the validity and usefulness of resultant data. However, in themselves, conventional QA/QC measures will not always ensure that fraudulent data are not generated. Conventional QA/QC measures are based on the assumption that work will be done in good faith; to assure against fraudulent practices, QA/QC measures must be tailored to specific analyses protocols in anticipation of intentional misapplication of those protocols.

Application of specific QA/QC measures to ensure against fraudulent practices result in an increased administrative burden being placed on the analytical process; accordingly, in keeping with graded QA philosophy, data quality objectives must be used to identify specific points of concern for special control to minimize the administrative impact.

INTRODUCTION

Analytical Lab Processes and Products

The data produced by contract laboratories to support U.S. Department of Energy (DOE) waste site characterization and remediation activities are the bases for scoping remediation programs. These data are also the bases for communication and agreement between the DOE and the Environmental Protection Agency (EPA), and state and local agencies on the appropriateness of planned and actual characterization and remediation activities.

Contemporary Issues

"Allegations of fraud in certain environmental analytical laboratories 'cast a shadow of doubt on EPA, DoD, and DOE cleanups of hazardous waste sites....Data alterations to meet method/contract quality control criteria have caused the authenticity to be questioned, and unethical laboratory practices have compromised the data quality required to support cleanup decisions,' the agencies say."[1]

Accordingly, measures must be established to assure the desired levels of quality of the analytical processes and products (i.e., data) are achieved.

QA/QC of Lab Activities

Quality assurance (QA) program coverage must be established, to the satisfaction of the customer and before work starts, to provide the customer with confidence that essential management controls exist to achieve performance objectives. Quality assurance measures must exist for contractual requirements flowdown, data quality objectives, documentation of lab procedures, sample and standards management, process configuration management, waste management, qualification of procedures and staff, documentation of analyses results, records management, and data reporting.

Quality control (QC) measures must be established prior to the start of work to ensure analytical process validity through in-process verifications, and data validity through sample testing (e.g., blind and spiked samples, "round-robin" testing).

PLANNING FOR SUCCESS

Regulatory Requirements

Several documents are used as environmental analytical requirement sources; some of them were not initially intended for that purpose, but were pressed into service in the absence of suitable requirements documents. The ambiguous and sometimes conflicting elements of some these environmental documents are subject to interpretation by the laboratories, customers, and regulators -

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[1]Superfund Report; Agencies Join Forces to Combat Contract Laboratory Fraud, November 20, 1991

often varying with the individual involved in quality achievement or verification activities. These documents also tend to have a QC orientation.

Source requirement documents used by the DOE and its prime contractors generally have a QA (or process management) orientation. Those responsible for DOE quality achievement and verification often have a nuclear power plant experience base. Some documents used as DOE source requirement documents were also originally intended as guidance documents, but were pressed into "requirements" service in the absence of suitable source documents.

The two sets of requirements documents use sometimes inconsistent terminology that requires interpretation sometime prior to starting work, if there is to be an opportunity to achieve the desired level of product quality without controversy.

Customer Expectations

Customer expectations must be clearly specified and flowed down to analytical labs contractually. The customer must award a contract based on criteria that are consistent with the desired product, e.g., valid data. Unfortunately, many analytical contracts are awarded based on "production rate" criteria which are weighted more heavily in terms of the cost of numbers of samples analyzed per unit time than in terms of the level of desired quality.

Also, as noted above, the available environmental analytical source documents can be ambiguous and conflicting unless care is taken to specify performance expectations in the contract rather than imposing the set of requirements documents by reference, without attempting to tailor them to the needs of application.

Contract Requirements

The terms and requirements of a contract with an analytical lab (or anyone, for that matter) should be consistent with the desired product, e.g., data quality/validity. Data quality requirements must be specified in clear terms that can be implemented, achieved, and verified without controversy. Unqualified imposition of the environmental source documents currently available will probably result in interpretive implementation and verification that will lead to data credibility challenges.

Industry practice appears to assign the highest weight during award of an analytical lab contract on cost per sample versus the quality of the deliverable. This practice has been classically demonstrated in other industries to encourage achievement of production rates to maximize profit at the expense of product quality.

Quality Objectives

The need for development of product and performance quality objectives prior to the start of work is essential for success. For quality objectives to be effective, the customer must document the requirements for them in the contract in terms that support their development, i.e., what the data will be

used for, accuracy tolerances, etc. The lab should translate contractual requirements into quality objectives and document how to achieve them in anayticaland administrative procedures. Accurate records of performance and product quality are needed to demonstrate that quality objectives were met and requirements complied with.

The labs need to conduct on-going self-assessments of performance to assure the quality objectives are being or can be met. Although most labs have self-assessment methods, they must document their results to strengthen the credibility of their analytical processes.

People and the QA Program

The best QA program will be ineffectual unless people implement it properly. To do so, staff must be qualified to do their assigned work through job-specific training that emphasizes the importance of developing and following appropriate analytical procedures, rigorous record-keeping, disciplined operations - and an understanding of the civil and criminal consequences of real or perceived fraudulent actions.

A conventional QA program is based on the premise that people inherently want to do good work. Quality verification actions, such as audits, will typically not detect fraud because they are after-the-fact actions largely based on review of documentation and interviews, both of which can be falsified if the intent to do so exists. Surveillance is a performance-based verification activity more likely to detect intentional anomalies, but only if the observer is technically astute about the process being observed - and if the worker is inattentive to the presence of the observer.

Emphasis on production rates and regulatory compliance rather than data quality can lead to application of "accepted" management practices which can result in questionable data quality. Such practices can include back-dating receiving samples and inappropriate use of signatures on chain-of-custody forms to "meet" compliance requirements. From a QA standpoint, overt data manipulation is much less of a problem and harder to detect than falsification of records.

Operational Conflicts

Conflict between lab staff and customers (and regulators) about lab procedures and data quality exists largely because of the lack of, or poorly defined quality objectives and associated programmatic controls.

Proper planning will eliminate the source of conflict by specifying performance expectations and the methodologies to be used to achieve them, as well as communication interfaces and role expectations for lab staff, the customer, and the regulators. This planning will be best accomplished if based on clearly defined contractual requirements.

MANAGE FOR SUCCESS

Instead of the current emphasis of concentrating on trying to discover fraudulent practices, it seems prudent to weight data quality expectations higher than cost/sample production considerations in the contracts awarded to analytical laboratories. The contracts should specify the expected QA programmatic as well as applicable QC controls needed to achieve the desired level of data quality; requirements should be specified, not imposed through references.

Site evaluations, on-site lab inspections and data reviews, and methods for reassessment of questionable data to establish its validity, will still be needed to verify product quality. However, questions about fraudulent practices resulting from these after-the-fact verification activities should be diminished as a result of programmatic credibility and process quality borne of a solid definition of customer expectations in the contract - and approval of the lab QA and QC programs prior to starting work.

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