HISTORICAL PERSPECTIVE OF PERFORMANCE-BASED MEASUREMENT SYSTEMS (PBMS) AT ROCKY MOUNTAIN ARSENAL (RMA)

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ABSTRACT

Compliance monitoring under a performance-based measurement systems (PBMS) is an on-going process at the Rocky Mountain Arsenal (RMA) in Commerce City, CO. RMA is a Superfund site where disposal of industrial and military chemical wastes in unlined basins over a period of approximately 10 years during and following World War II resulted in widespread contamination of soil and both surface and ground waters. The United States Army, along with Shell Oil Company and the U.S. Fish and Wildlife Service, are in the process of remediating RMA. The remediation effort involves the analysis of various matrices for a wide variety of analytes, some of which are unique to RMA, and standard analytical methodologies are either not available or are not adequate to fulfill regulatory requirements in certain instances. Hence the requirement to develop methods which are specific to the RMA and are performance-based.

In response to these site specific requirements and utilizing the Army Environmental Agency Guidelines, RMA developed the RMA Chemical Quality Assurance Plan (CQAP), which addresses all activities from planning to data verification related to the remediation of RMA. Compliance with the CQAP ensures that data produced are legally defensible, cost effective, and scientifically sound. A strict proficiency demonstration process for methods is prescribed by the CQAP to validate both standard and new or unproven methods.

Recently the Environmental Laboratory Advisory Board (ELAB) defined five critical elements for PBMS implementation. As recommended by ELAB, the data produced by laboratories should be legally defensible, cost effective, scientifically sound, demonstrate good performance criteria, and achieve regulatory compliance monitoring requirements. Historically, analogous criteria have been applied to the analytical work performed by laboratories supporting the RMA remediation effort. ELAB has also recommended essential elements for PBMS implementation. This presentation discusses the analytical program at RMA, under the Comprehensive Analytical Laboratory Services (CALS) contract (CALS contractor URS Greiner Woodward Clyde), in the context of these elements. Utilizing the performance criteria, regulatory development, and analytical methods specific to RMA, the remediation of RMA has progressed at an accelerated rate.

INTRODUCTION

RMA was established in 1942 during World War II. It is located ten miles northeast of downtown Denver and occupies 27 square miles. The U.S. Army manufactured military chemical weapons at the Arsenal until the 1960's. Also, during that time and through the early 1980's chemical weapons were destroyed. Following World War II, in an effort to increase economic growth in the area, offset costs, and maintain the facilities for national security, private industry leased the facilities at RMA. One of the manufacturers operating under the lease program was Julius Hyman and Company which produced pesticides. In 1952, Shell Chemical Company acquired Julius Hyman and Company and continued to produce pesticides until 1982. Most of RMA was placed on the National Priorities List (NPL) in 1987. As such, RMA is subject to compliance with CERCLA (Comprehensive Environmental Response, Compensation, and Liability Act, also know as Superfund).

The Remediation Venture Office (RVO), formed in October 1996 to expedite the implementation of the remediation, is an innovative triparty arrangement consisting of personnel from the Army, Shell Chemical, and the Fish and Wildlife Service. Members of the RVO work together to coordinate and provide oversight of the remediation management based on best value concepts, including but not limited to, quality assurance (QA), health and safety, regulatory compliance, fiscal monitoring, and community involvement. Today there is no manufacturing, weapons production, or storage at RMA. As a Superfund site, RMA's only mission is environmental cleanup.

DISCUSSION

The production of the military chemical weapons, pesticides, insecticides, and herbicides generated many waste streams. These wastes were disposed of using widely accepted practices of the time. Efforts to contain liquid wastes began soon after the discovery that contaminated groundwater was causing damage to crops north of RMA in the mid1950s. The Army and Shell Chemical began a systematic investigation into the contamination problems at RMA. Beginning in 1974, Interim Response Actions (IRA) were implemented to protect offsite human health and the environment from RMA pollution.

The United States Environmental Protection Agency (USEPA) has defined PBMS as "a set of processes wherein the data quality needs, mandates or limitations of a program or project are specified, and serve as criteria for selecting appropriate methods to meet those needs in a cost-effect manner."[1] The unusual matrices and analytes routinely found at RMA pose unique problems for the regulators and the analytical laboratories. Analyses for analytes in matrices for which no standard method exists have been required. This has necessitated the modification of existing approved standard methods, thus the formation of a PBMS at RMA.

The RMA Chemical Quality Assurance Plan (CQAP) was developed from the Army Environmental Agency Guidelines and provides the written guidance for operating the RMA QA program. The purpose of the RMA CQAP is to provide for consistent generation of analytical data, establish standard practices which permit interlaboratory comparisons of data, establish procedures for demonstrating that analytical systems are in control, and ensure that the data produced by the laboratories is not only of highest quality, but scientifically and legally defensible.

The remediation efforts at RMA pose unique problems for project site evaluations as they are being defined. The unusual matrices, along with analytes of raw chemicals, by-products, and break-down products cause unique problems for project site specifications. The regulatory agencies, along with the RVO, meet and determine the goals for the remediation effort, the critical health care risks, the analytes of interest, and the reporting limits for those analytes.

The data quality objectives (DQO) are written detailing a clear objective of the project site evaluation, defining the most appropriate type of data to collect and the most appropriate conditions from which to collect data, and specifying acceptable levels of decision errors that will be used to establish the quantity and quality of data needed to support the decision.

The DQOs may include analytes or matrices that may or may not have specific methods available to produce the required analytical results. The laboratories, after reviewing the project site specified requirements select the appropriate method, or, if needed, modify an existing method to analyze the samples. The specifications within the CQAP allow the laboratories the flexibility to use their expertise to modify existing methods to achieve regulatory compliance.

Laboratory standard operating procedures (SOP) provide specific instructions for the performance-based method analysis. The SOPs include a summary of the performance-based method with information about the matrix, analytes, and a short description of the procedure. The application of the method is stated along with tested concentration range, instrument response, detection/reporting limits, interferences, and analysis rate. Other aspects that are covered in SOPs are safety considerations, apparatus and reagents. Detailed and specific procedures are stated for the preparation of standards including initial and daily calibration standards, instrument mass tuning criteria and performance, and the analysis of calibration data. Acceptance criteria for all standards along with corrective actions if criteria are not met are specified. A description of sample collection and storage conditions is given. Also stated is a detailed procedure of the analytical process, including acceptance criteria for sample analysis, calculations, and the preparation and analysis of quality control samples. The function of quality control charts and acceptance criteria for controlling the method is outlined. Finally, references are given on which the performance-based methods are based. The performance-based method SOPs prescribe strict quality control (QC) and analytical requirements, ensuring that data generated are legally defensible, scientifically sound, and meets good performance criteria based on historical laboratory performance.

A capacity/capabilities visit (CCV) is performed by the CALS contractor to determine whether the laboratory will be able to support RVO with the analyses that are needed. Personnel from URS Greiner Woodward Clyde will visit the laboratories to inspect the laboratory statement of qualifications, training files, facilities and equipment, data management systems, analytical capabilities, and SOPs. The program and contract requirements of RMA are discussed in detail during the visit. These requirements include performance audits, performance-based method proficiency demonstration for analytical methods, participation in the Analytical Laboratory Performance Evaluation System (ALPES), development of performance-based method SOPs, laboratory QA plan, laboratory QC plan, a data management plan, quality systems audits, and attendance at QA meetings as required .

Contract laboratories before performing analytical work, in support of the CALS contract, must demonstrate their competence in meeting RVO specific QA/QC requirements through a performance-based method proficiency demonstration. The purpose of performance-based method proficiency demonstration is to: a) establish the lowest concentration at which a result may be reliably reported, b) define the working range of the analytical process, and c) provide initial performance-based quality control acceptance criteria which will be used to control the analytical process during sample analysis. Performance-based method proficiency demonstration provides evidence that a laboratory is able to meet RVO DQOs.

CALS provides to the contract laboratories a reference method (if available), target analyte lists, and the target reporting limits (TRLs). The TRLs are the reporting limits needed by RVO to support remediation goals. The TRL information is used by the laboratories during the performance-based method proficiency demonstration to determine the dynamic concentration range of the method. The performance-based method proficiency demonstration consists of three parts:

- Instrument calibration
- Preparation and analysis of proficiency samples
- Calculation of method reporting limits (MRL)

INSTRUMENT CALIBRATION

The performance-based method requires an initial calibration, prior to the analysis of samples. The initial calibration sequence includes, at a minimum, five calibration standards and a zero standard. The standards will bracket the working range of the measurement system. The acceptability of the initial calibration will be reviewed using appropriate QC criteria. Upon completion of an acceptable initial calibration, the laboratory proceeds with the analysis of the proficiency samples.

PREPARATION AND ANALYSIS OF PROFICIENCY SAMPLES

RMA standard matrix, which includes RMA standard soil, standard water (ASTM Type II water, plus 100 milligrams per liter of sulfate and chloride), or other matrices specific to RMA, must be used during the performance-based method proficiency demonstration. Spiking solutions are prepared that are independent of the calibration stock solutions. A minimum of five concentrations of the target analytes is prepared in the RMA standard matrix plus a preparation blank sample. The concentrations of the target analytes are evenly distributed throughout the dynamic concentration range. Two sets of performance-based method proficiency samples are prepared and analyzed according to the specified performance-based method SOP. The proficiency samples are prepared and analyzed on two separate days to introduce day-to-day laboratory variability.

CALCULATION OF MRLS

After the analysis of the performance-based method proficiency samples, the results of the analysis is evaluated for the determination of the MRLs. The found concentrations of the target analytes for each spiking concentration, including the blank sample, is entered into the MRL computer program. The MRL is extracted using confidence bands as described by Habaux and Vos using 2-tail 90% confidence bands. The software program: a) plots the found versus target concentration data, b) determines the confidence band about the resultant linear regression curve, and c) calculates the MRL.

MRLs are the lowest reportable target analyte concentration in a sample using a specific analytical method. Reporting MRL concentrations as performance-based method target concentrations considers both the measurement precision and the method accuracy. Analyte concentrations in field samples are corrected for method recovery efficiencies determined during the performance-based method proficiency demonstration.

Upon completion of the performance-based method proficiency demonstration, the laboratories will submit the data to RVO for review. Method proficiency data includes the calibration data, sample preparation, sample analysis, MRL calculations, and certificates of analysis for all reference materials assuring the purity and identification of all analytes.

Upon method approval, the RVO will provide the laboratory with the a unique method number to be used when reporting data. The pre-award performance evaluation (PE) sample is shipped to the laboratory ensuring method performance criteria are met. The laboratory will analyze the pre-award PE sample and submit the data to RVO as a RVO-required data package. The data package is reviewed and comments submitted to the laboratory. Corrective action, if necessary, is implemented by the laboratory before the laboratory is awarded a contract by the CALS contractor to perform work for RMA. If necessary, a second pre-award PE sample may be submitted to the laboratory to demonstrate that the corrective actions have been implemented. If the laboratory fails two pre-award PE samples a contract will not be awarded.

While performing analysis of samples, the laboratories analyze QC checks. These include, at a minimum method blanks, laboratory control samples (LCSs), matrix spikes, surrogates, and duplicates (when applicable). The results obtained from the QC samples must be evaluated against acceptance criteria per the laboratory performance-based method SOP and historical laboratory QC performance. The results of the QC checks are included in the electronic data file which is sent to PMRMA with the results of the field sample analysis.

A requirement of each laboratory is to control chart the LCS to demonstrate that the laboratory's process for sample preparation and analysis is in control. The LCS matrix should be comparable to the sample matrix. RVO identifies specific controlling analytes (RMA target analytes) contained in the LCS solution that are control charted for each method. The recoveries of the analytes should be in a state of statistical control. The control charts are used to monitor the variation of the analytical method and provide a mechanism for the laboratories to detect out-of-control situations and to improve the analytical method. When an out-of-control situation is observed the laboratories must investigate the method, determine a cause, and implement corrective action.

The laboratories generating data for RVO prepare data packages that are stand-alone compilations of all data related to the analysis of a single analytical lot. An analytical lot is defined as the number of samples, including QC, that can be processed through the rate limiting step of an analytical method. The data packages contain all information necessary to verify the reported results and to completely document the quality control procedures utilized during the analysis. Any deviations from the performance-based method SOP must be clearly noted in the data package. This ensures that the data generated are accurate, defensible, and meets the project site-specific DQOs.

Information contained in the data packages includes:

- reported sample results and associated MRLs;
- reported QC sample results;
- case narrative that explains deviations during the preparation and analysis of the samples, corrective actions, manual integrations, and other observations identified and noted during the preparation or analysis of the samples;
- standards preparation, including certificates of analyses of the standards;
- sample preparation and extraction;
- initial and continuing calibration information;
- copies of the chain-of -custodies; and
- quantitation reports and chromatograms of the calibration and sample analysis.

As part of the CALS contract, laboratories submit monthly quality assurance status reports (QASR). These reports include: QA/QC changes, method changes, personnel changes, facility changes, data quality indicators (including accuracy, precision, and completeness), revisions of MRLs, and non-conformance occurrences. Each of these areas discuss, acceptance criteria, out-of-control situations, or modifications performed that relate to RMA samples. The QASRs are reviewed by the CALS contractor. During the review the CALS contractor, determines if any out-of-control situations have occurred and if the laboratories have addressed the situations. What caused the situation and the types of corrective actions taken by the laboratories should be noted in the QASRs by the laboratories. The CALS contractor may request additional information concerning the laboratories' corrective actions to more fully understand and evaluate the situation. If the severity of the situation is warranted. The CALS contractor may conduct an unannounced audit or may issue a stop work order until all out-of-control issues have been adequately addressed. This is an on-going performance-based assessment of the laboratories method proficiency, accuracy, and data deliverables.

Audits are an essential part of the PBMS at RMA. The two types of audits performed by the CALS contractor are quality systems audits and performance audits. Quality systems audits are audits of the operational functions of the contract laboratories including the QA program. The performance audits monitor the laboratories' ability to produce accurate analytical measurements of the specific RMA analytes through analysis of PE samples.

Quality systems audits provide RVO a performance-based assessment of the contact laboratories. Quality system audits are either external or internal (self-assessment). The external quality systems audits, through on-site visits, verify that the laboratories are complying with the CQAP's QA/QC requirements and determine if the QA/QC procedures were implemented effectively and suitably to achieve technically sound and defensible analytical data. During the life of the laboratories' contract with the CALS contractor, a minimum of one quality systems audit is conducted every six months. Additional quality system audits may be performed if there are QA/QC concerns, large sample volumes, PE sample results, changes in laboratory management and/or QA program, and/or results of previous quality systems audits.

During the quality systems audit the CALS audit team will review QA plans and performance-based method SOPs and verify that previous audit findings have been implemented. Specific data packages, both routine and PE samples, will be inspected to verify reported results and verify conformance with QA and program requirements. Interviews will be conducted, if necessary, to clarify concerns, substantiate auditor concerns, or verify the implementation of corrective actions. A walk-through of the laboratory is performed to evaluate the various areas of the laboratory. This may include sample receipt, organic preparation and analysis, inorganic preparation and analysis, data management and review, quality assurance, and training.

A quality systems audit report is prepared by the CALS audit team and submitted to the laboratory detailing the findings and observations of the audit. The laboratory addresses the findings and observations presented in the audit report and submits the response to the CALS contractor. RVO reviews the response and determines whether the laboratory has addressed and implemented corrective actions appropriately.

Internal quality systems audits will be performed by the contract laboratories annually, at a minimum. These audits are conducted by the QA department in order to assess the PBMS used by the laboratories. Any deficiencies observed during the internal audits are documented and corrective actions implemented. Documentation of the quality systems internal audits is retained by the laboratories and is reviewed by the CALS audit team during the external quality systems audit. The corrective actions of the internal quality systems audit must have been satisfactorily implemented or the associated deficiencies will become findings during the external quality systems audit.

ALPES, as an independent QA oversight, administers the performance audits for RVO performance-based methods. These performance audits are conducted semiannually or whenever problems occur. The PE samples may be prepared for special projects or in batches for distribution to multiple laboratories. The batch is submitted in the form of samples ready for analysis. Double-blind PE samples may also be submitted to the laboratories to further monitor the PBMS of the laboratories.

RMA analytes of interest are added to the required matrix to achieve the desired concentration. Matrices used are RMA standard water, soil, quartz filters or passivated summa canisters, or other special matrices such as concrete, waste material, or biota. The laboratories are notified of single-blind PE sample shipment and the expected arrival date. Double-blind PE samples are included in the shipments of field samples. The PE samples are analyzed in accordance with the laboratories' approved performance-based method SOP. A RVO stand-alone data package is generated and submitted for review. The data are reviewed for accuracy and completeness.

Contract laboratories may participate in performance audits conducted and evaluated by outside organizations such as the National Institute of Occupational Safety and Health (NIOSH) Proficiency Testing Program or by state certifications. The laboratories submit to the CALS contractor copies of the PE sample results, the acceptance criteria, and any corrective action taken to address deficiencies. RVO may, after reviewing the corrective actions, perform a quality systems audit.

SUMMARY

Compliance monitoring under the PBMS is an integral part of the analytical program at RMA. The PBMS's flexibility supports RVO's analytical program with methodologies that are scientifically sound, legally defensible, demonstrate good performance criteria and meet regulatory compliance monitoring requirements.

The remediation effort will transform the former military chemical weapons and pesticides manufacturing facility into one of the largest urban wildlife refuges in the country.

FOOTNOTES

1. Federal Register, Vol. 62, No. 193, October 6, 1997, Page 52098

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