THE ROLE OF A COMPLIANCE PROGRAM AND DATA QUALITY REVIEW PROCEDURE UNDER PBMS

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INTRODUCTION

The trend away from sole reliance on method specified quality control (QC) to a performance based measurements system (PBMS) creates the need for a broader based oversight program to ensure that environmental project and regulatory program requirements are met. A strict QC program based on method compliance will not be sufficient to ensure compliance with PBMS guidelines. Further, strict QC programs have not always been effective in ensuring method and project compliance and in preventing ethics violations.

Under PBMS, a comprehensive compliance program is warranted to help ensure compliance of all activities and ethical performance of work, regardless of the method or project requirements. New approaches to data review are needed to ensure that performance standards can be met. This paper provides guidance on key elements that should be included in an effective compliance program and presents a data quality review procedure to use for determining if data of acceptable quality can be generated.

IMPLEMENTING A COMPLIANCE PROGRAM

Ethics Policy or Statement

A compliance program must have an ethics policy or statement. This policy or statement should define the company or organization's position on ethics and state what is expected of its employees or members with regards to ethical behavior.

For example, a company's ethics policy may be the following:

> "All employees at all times shall conduct themselves and the business of the Company in an honest and ethical manner. Compliance with this policy shall be strictly enforced."

The ethics policy should be documented and posted for all employees to view. Companies may wish to further affirm and document employee commitment to compliance with the ethics policy through an Employee Ethics Agreement that each employee must sign as a condition of their employment.

Compliance Program Management

The compliance program should be managed by a senior management employee with the authority, skills and availability to perform such an assignment. The compliance program manager should report to upper management on a regular basis on the status of ethics activities within the organization. Companies may also elect to form an Ethics Committee with members from their upper management staff or Board of Directors that meets on a regular basis to set ethics policy and discuss ethics related matters.

Ethics Procedures

Policies and procedures for ethical conduct and for reporting and investigating suspected ethics violations should be developed and included in the company's policy and procedures manual. An ethics procedure should define ethical conduct and what constitutes unethical behavior and how it is handled. Disciplinary action for ethics violations, up to and including termination, should be stated in the ethics procedure. Fair procedures for reporting and investigating alleged unethical behavior should be included in an ethics reporting and investigation procedure. These procedures as well as other company procedures should be accessible to all employees.

Zero Tolerance Policy

Companies should have a zero tolerance policy on unethical activities and non-compliance with required procedures. Unethical behavior or fraud may be defined as intentional falsification of data or records, such as sampling or sample handling records, laboratory worksheets or logbooks, instrument settings or data, sample results or data, and laboratory analysis reports. Unacceptable behavior may be defined as deliberate lack of adherence to company and method requirements, such as procedures for instrument calibration, quality control, standards and reagents preparation, sample handling, and sample preparation and analysis.

Laboratories may wish to go one step further and issue a policy that defines specific unacceptable and fraudulent activities. Since most laboratory procedures define what employees are required to do, this policy ensures that employees are educated as to what they are not allowed to do. Such a policy may include the following unacceptable and fraudulent activities: 1) making up data (dry labbing) or other sampling and analysis information; 2) misrepresentation of QC samples and spikes as being extracted or digested when in fact they were not extracted or digested; 3) improper clock setting (time traveling) or improper date/time recording; 4) improper peak integration (peak shaving or enhancing); 5) improper GC/MS tuning; 6) improper calibration/QC analysis; 7) file substitution; 8) deletion of non-compliant data; 9) improper alteration of analytical conditions; 10) unwarranted manipulation of computer software; and 11) lack of notification to management on identified sample or data errors.

Laboratories that are proactive in informing employees of what constitutes unacceptable and fraudulent behavior have a better chance of preventing fraud than laboratories that do not.

Ethics Assistance and Reporting Mechanism

Companies should a have a single point of contact for assisting employees with questions on ethics related matters and for reporting observations of suspected unethical behavior or business conduct. A Helpline or Hotline is such a mechanism where phone calls, faxes or other correspondence on ethics concerns, questions or reports of suspected unethical behavior can be directed and then addressed appropriately. The phone numbers and addresses for the Helpline or Hotline should be documented and readily available to all employees. The Helpline or Hotline can be manned by a senior management employee, such as the compliance program manager, or by an outside service.

Compliance Plan

A compliance plan should include or refer to all of the procedures used by an organization for ensuring compliance with company, client and government requirements. The compliance plan should include or refer to company policies and procedures on business conduct, especially ethics. Also include or refer to technical and quality assurance procedures used by the laboratory and required by client, method or regulatory agencies to ensure that data are accurate and traceable. The compliance plan should further include or refer to environmental management activities and procedures used for chemical and waste handling to comply with federal, state and local regulations. A compliance plan may also include a quality management program such as ISO 9002.

Compliance Training

Compliance training should be provided to all employees and include, at a minimum, training on the ethics policy and procedures. Ethics training should be documented on training forms and included in the employee training or personnel files. Training on laboratory procedures should be ongoing and based on each individual and their work assignments.

Compliance Audits

Adherence to the compliance plan and associated procedures/requirements should be checked on a regular basis via on-site audits. The compliance officer, quality assurance staff or outside consultants may conduct compliance audits. Any findings of non-compliance with company, client or government requirements should be documented and provided to management. Prompt and effective corrective action should be taken on any findings and reported back to the auditing body for review and approval.

DATA QUALITY REVIEW

Despite the number of laboratory audits that are conducted at environmental testing laboratories, many of these audits do not address data quality and thus do not identify data quality problems. Traditional audits tend to focus on laboratory procedures and QC criteria rather than data quality. Probably the most important area that affects the usability of sample data is not receiving the critical attention it should have.

A data quality review should be performed to determine if data of acceptable quality can be and are being generated by a given laboratory. This review does not replace on-site assessments that evaluate method compliance or tape audits that evaluate the accuracy of reported data. The following items should be included in a data quality review of organic analysis data, whether for PBMS methods or traditional methods. Similar principles apply to inorganic analysis data.

Initial Demonstration of Competency Data

An initial demonstration of competency (IDC) study (also referred to as initial demonstration of capability or proficiency study) demonstrates the ability of each analyst and instrument to achieve acceptable accuracy and precision for each analyte in each test method performed. It should be performed prior to performing sample analyses and whenever there is a new analyst or major change in the instrumentation. An IDC study involves the preparation and analysis of a minimum of four spiked samples at concentrations of 20 µg/L for volatiles, 100 µg/L for semivolatiles and 2-50 µg/L for pesticides and PCBs.

First determine if IDC studies have been performed for each analyst and instrument. If not performed, note which studies are needed for immediate action. If performed, review the data from each study and determine if each target analyte was included. For each analyte, evaluate the spike value, found values, average percent recovery and standard deviation (SD). Compare the average percent recovery and SD for each analyte to the method or project specified acceptance range or values. If the average percent recovery is within the acceptance range, then acceptable accuracy can be achieved. If the SD is less than the maximum allowable value, then acceptable precision can be achieved. If either criteria were not met, then note the analytes that require immediate action (repeat of study.)

Method Detection Limits

A method detection limit (MDL) determination or study establishes the lowest concentration that the laboratory can measure an analyte with 99% confidence. Using the procedure in 40 CFR Part 136 Appendix B, a MDL study involves the preparation and analysis of a minimum of seven spiked samples at a concentration 1-5 times the estimated MDL. The MDL is calculated by multiplying the standard deviation obtained for the seven measurements by 3.14.

First determine if MDL studies have been performed for each method and analyte. If not performed, note which studies are needed for immediate action. If performed, evaluate each study to determine if each target analyte was included. For each analyte, evaluate the spike value, found values, average percent recovery, standard deviation (SD) and calculated MDL. Compare the calculated MDL and the spike value. If the calculated MDL is greater than the spike concentration, then the study should be repeated at a higher spike concentration. If the spike concentration is greater than 10 times the calculated MDL, then the study should be repeated at a lower spike concentration.

Laboratory Reporting Limits

Laboratory reporting limits (RLs) are the minimum values used by the laboratory to report sample data. Laboratories typically use quantitation limits or values that are generally 5 to 10 times the MDLs for their RLs. For samples that are diluted, the RLs must be multiplied by the sample dilution factor. Target analytes found in samples at concentrations greater than the RLs are reported as numerical values. Target analytes not detected above the corresponding RLs are reported as “not detected” or at a qualified value greater than the MDL.

First obtain and review the laboratory's RLs for each method, matrix and analyte. Then evaluate the RLs in water for each method and analyte to determine if the laboratory RLs are greater than the MDLs (data for other matrices may also be reviewed.) If any RLs are less than the associated MDLs, then note which analytes require immediate action (Note: an error here means that the laboratory may be reporting data lower than it can actually measure.) If the RLs are greater than or equal to the associated MDLs, then it can be expected that the laboratory's reports will provide values that can be detected or backed up by laboratory measurements. Alternately, if MDLs are not available for certain analytes, the lowest calibration standard may be evaluated and compared to the laboratory RLs. If any RLs are less than the lowest concentration calibration standard, then note the analytes that require immediate action. If the RLs are greater than or equal to the lowest concentration calibration standard, then it can be expected that the laboratory's reports will provide values that can be detected by calibration standards.

Initial Calibration Data

Initial calibration is performed to establish the calibration curve and range for each analyte.

Analyte Presence and Standard Concentration. First review recent initial calibration data for each method and analyte. Also review the source and concentration for each initial calibration standard. Determine if all target analytes were included in the calibration standards. If not, note any missing analytes for immediate action. Next determine if the concentration values used for each analyte in the calibration table or curve match the actual concentrations provided with the calibration standards. If the concentrations do not match, then note any analytes that require immediate action (Note: this error could result in incorrect concentrations in samples.) If the values do match, then the calibration table or curve can be considered accurate with regards to assigned standard concentration. Also evaluate if surrogates were analyzed at multiple concentrations. Previous EPA SW-846 methods allowed single concentrations but recent updates to SW-846, i.e., Update III and Method 8000B, require multi-point concentration for surrogates as well as target analytes. If surrogates were not analyzed at multiple concentrations, then note which analyses are affected for immediate action.

Analyte Identification. Evaluate the data for the lowest concentration standard analysis to determine if the identification data for each target analyte is representative of that analyte, such as GC/MS mass spectrum or characteristic ions, GC/MS "Q" value, GC retention time, elution order, etc. If not, note which analytes are questionable and require immediate action (Note: this error could result in incorrect analyte identification in samples.) If all analytes are included and the data are representative, then the laboratory should be able to correctly identify target analytes in samples.

Analyte Response. Evaluate the analyte response in each calibration standard to determine if the responses are acceptable and proportionate to concentration. For GC/MS analyses, determine if the relative response factors (RRFs) for each analyte are above the minimum required value. For each target analyte, evaluate if the responses increase with concentration (e.g., the area for benzene in a 100 ppb standard should have twice the area as a 50 ppb standard.) If RRFs are below the minimum value or if responses are not proportionate to concentration, then note the analytes that require immediate action. If the analyte responses are acceptable, then it can be expected that the laboratory can acceptably measure responses for target analytes in samples.

Calibration Accuracy. Evaluate the calibration table or curve to determine if all data were used and that no points in the middle of the calibration table or curve were deleted to force the calibration to meet certain criteria. Also evaluate if manual integrations appear to be acceptable. The only points (concentrations) that should be deleted from the calibration are low or high points that are outside the calibration range or points with a known error. If any analytes were deleted from the middle of the calibration or if manual integration appears to be improper, then note the analytes that require immediate action.

Next evaluate the %RSD for average RFs or RRFs for each analyte in the initial calibration and determine the method used for sample quantitation. If the %RSD value for each analyte is less than or equal to 15%, it is acceptable by EPA SW-846 methods to use RRF or RF for quantitation. If the %RSD is greater than 15% for any analyte, evaluate if a linear or higher order calibration curve was used for quantitation and if the minimum number of standards (5 for 1st order, 6 for 2nd order and 7 for 3rd order) were included in the calibration. If not, note the analytes that require immediate action. If the correct number of standards were analyzed and the appropriate technique is used for quantitation, then the initial calibration can be considered acceptable for sample quantitation.

Analytical Conditions. Also evaluate the conditions used for initial calibration to determine if the same conditions were used for sample analysis (such as purging temperature for volatiles). If not, note the analyses that are affected for immediate action.

Calibration Verification

Calibration verification is performed at a regular frequency (every 12 hours for GC/MS analysis and at the beginning, end, and 5 to 10% of the runs for GC analysis) to verify that the current instrument performance is still acceptable in comparison to performance during the initial calibration.

First review recent calibration verification data for each analysis. Also review the source and concentration for the calibration verification analysis. Determine if the concentration values used in the calibration verification matches the actual concentration provided with the calibration standard. If the concentrations do not match, then note any analytes that require immediate action. If the values do match, then the calibration can be considered accurate with regards to assigned standard concentration. Next evaluate the data for the calibration verification standard analysis to determine if all of the target analytes were included and detected in the standard. If any target analytes were not included or not detected, then note the analytes that require immediate action.

Evaluate the % difference (%D) from the expected value or the % recovery compared to the known value for each target analyte in the calibration verification. Determine if the %D or % recovery for each analyte was within the method or project specified acceptance values, generally +/- 15 to 20%. If not, note the analytes that require immediate action. (Note: Action may not be necessary if the analyte(s) in question was not detected in any associated samples and the standard indicates that the analyte could be detected if it was present in a sample.) If the %D or % recovery for each analyte was within the allowable values, then the calibration verification can be considered valid with regard to the initial calibration.

Laboratory Control Sample

A laboratory control sample (LCS) is a purchased or prepared sample with a known concentration of target analytes taken through the entire sample preparation and analysis procedure and used to measure recovery.

First evaluate the analytes that were included in the LCS and their concentration values. Determine if the method or project required analytes were included in the LCS and if the concentration was at the required value(s). Review the source data for the LCS to determine if the LCS was from a different source or lot than the calibration standards and if the concentration values assigned by the laboratory match the values from the source. If any analytes or concentrations are incorrect, note the analytes that require immediate action. For each spiked analyte, evaluate the spike value, found values and percent recovery. Compare the percent recovery for each analyte to the method or project specified acceptance values. If the percent recovery is within the acceptance range, then acceptable accuracy can be achieved. If not, note the analytes that require immediate action.

Laboratory Blanks

Laboratory blanks are analyzed to measure any background contamination introduced by the laboratory during the sample preparation or analysis procedures. Laboratory blanks include method blanks, reagent blanks, calibration blanks and holding or storage blanks.

Review blank data to determine if any analytes are present and at what concentrations. If target analytes are present in the blank, review associated sample data to determine if the background in the blank could have a significant affect on the sample values. If there are no detects for the affected analyte(s) in the sample or if the analyte concentration is the sample is high, then low level background contamination will not have a significant affect. If there are low level concentrations in the sample slightly above or near the blank level, then the sample may be affected. Also review surrogate data in the blank to establish a baseline level with which to compare the sample data. If surrogate recovery is acceptable in the blank, then unacceptable recovery in samples is probably due to the sample and not laboratory performance. Note any unacceptable recovery of surrogates in blanks for immediate action.

Sample Data

Last but not least are the sample data. Review sample data for surrogate recovery, internal standard response (if internal standards are used), and analyte identification and quantitation. Determine if surrogates and internal standards (if applicable) were added to each sample and if the surrogate recovery and internal standard responses were within method or project specifications. If not, determine if corrective action was taken or if additional analyses were performed. If reanalysis data still are not acceptable, then note the impact (low or high bias) on sample results. Evaluate reported analytes in samples to determine if identification characteristics and criteria were satisfied, such as GC/MS mass spectrum, GC/MS "Q" value, GC retention time and elution order. If not, the analyte identification and presence may be suspect and sample results should be handled accordingly (i.e., reprocessed or rejected.) Next determine if concentrations for found analytes were calculated and reported correctly. If not, the analyte concentration may be incorrect and sample results should be handled appropriately (i.e., recalculated or rejected.) Also review matrix spike and duplicate data if available for the same sample to determine if the results for found analytes correlate between each analysis. Determine if non-spiked analytes found in the original sample are also found in the matrix spike and duplicate at similar concentrations. If not, there may be a lack of precision or an error in one or more of the analyses; sample results should be handled appropriately (i.e., qualified or rejected.) Also review all sample documentation to determine if complete and consistent. If not, note what is needed for immediate action.

For any of the items that require action, consult with the laboratory manager for correction and resolution. Data of acceptable quality can be achieved when all of the above criteria are satisfied.

CONCLUSION

With PBMS on the horizon, environmental professionals may wonder what will happen to control of laboratory data quality if adherence to strict method requirements is no longer mandatory. Data quality has not been guaranteed by the traditional focus on method QC limits, and in fact many unethical practices have occurred in environmental laboratories in order to meet QC limits. Change is disconcerting but necessary for improvement. By implementing an effective compliance program and by conducting data quality review with the guidance provided in this paper, ethics awareness and environmental data quality can be improved.