EMSL

ANALYTICAL, INC.

Outline of the
LABORATORY
QUALITY ASSURANCE
PROGRAM

Based on Revision 9 of the Quality Assurance Manual

The Quality program at EMSL is built on a commitment to quality and continued improvement. This program is a primary part of our every day work; developed, utilized, and maintained by all the dedicated staff at EMSL.

Introduction

This program outline presents a comprehensive overview of the Quality Assurance Program. It provides the reader with a summary of EMSL Laboratory policies and procedures as they relate to the technical aspects of the corporate quality objectives.

This program follows quality guidelines as documented by ISO/IEC 17025, the American Industrial Hygiene Association (AIHA), the EPA's National Voluntary Laboratory Approval Program (NVLAP), National Environmental Laboratory Accreditation Program (NELAP) and other applicable state and federal regulatory agencies.

This QA program is designed to ensure that the highest level of quality professional services and technical excellence is provided to our clients. This is accomplished by the implementation of program policies including:

- Development of company standard quality control programs
- Standardization of reporting formats
- Review of regional laboratory QC performance
- Providing technical training for all staff levels
- Achieving traceability of data
- Performance of quality audits
- Participation in applicable Accreditation Programs
- Participation in third party proficiency testing programs

The objectives of these program policies ensure the quality, accuracy and integrity of our analytical data.

The Quality Assurance objectives, policies and procedures are formally documented in the Quality Assurance Manual. A summary of this manual is presented on the following pages.

Quality Assurance Program

The goals of the QA program are to ensure the following:

- Conformance with all analytical methodologies
- Conformance with corporate mandated QA/QC requirements.
- Delivery of the highest quality of professional services and technical excellence to our clients.
- Fulfill the requirements of the American Industrial Hygiene Association, the National Voluntary Laboratory Approval Program, and/or the National Environmental Laboratory Accreditation Committee.

The QA Manual, which documents the policies of the EMSL QA program, is kept accessible to all employees, and all employees are responsible for being familiar with and adhering to its contents.

The Quality Assurance Program is reviewed at least annually by the QA Manager. It is also reviewed any time a problem arises that indicates a possible program flaw. In such an instance, the QA Manager will discuss the problem with National, Regional and Laboratory Management, Quality Control personnel and Analysts to ensure needed input from all levels within the laboratory.

Program Objectives

Implementation of the Quality Assurance Program

The program is designed to plan and institute company policies and quality objectives throughout the branch laboratories. It is intended to provide support and issue policies including:

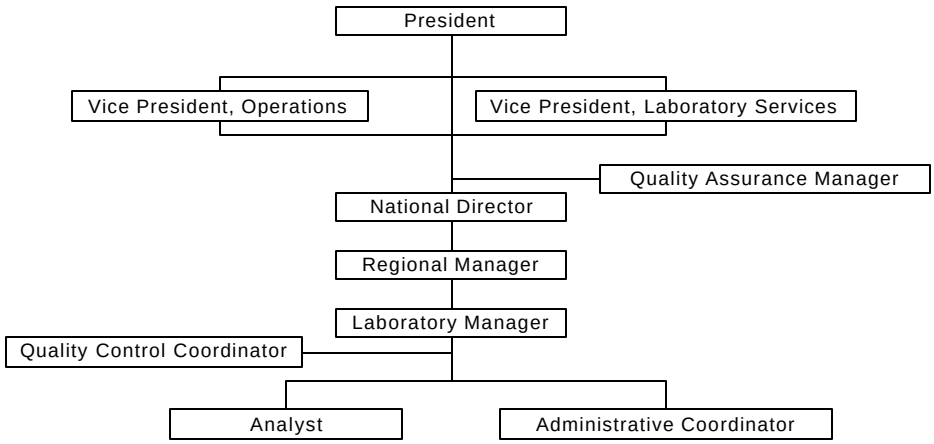
- Clear job descriptions delineating responsibilities of each employee involved at all steps of laboratory procedures, data analysis and report generation.
- Completion and evaluation of Quality Control (QC) samples.
- Proper documentation of analytical data.
- Good laboratory technique that ensures a contamination-free environment.
- Use of appropriate analytical technology including review of current literature to capture recent applicable developments.
- Review of reports to Clients.
- Understanding and compliance with procedures which insure Client confidentiality

The program is managed and maintained by the corporate Quality Assurance Manager.

It is our intention to ensure that all goals and objectives of our Quality Program are met and maintained. Quality policies and procedures are integrated into our daily work, and are constantly reviewed by Management.

Organization and Responsibility

EMSL Laboratory Organizational Chart



The corporate headquarters of EMSL Analytical operates out of the Westmont N.J. office location. The corporate headquarters oversee the laboratory operations located there, as well as the branch laboratory locations. Corporate headquarters are responsible for the management of all company activities.

Branch laboratories (as well as the laboratory located in Westmont) perform the company's analytical services. They report to the corporate headquarters on quality control, productivity, staffing and market issues

Training

All analysts must complete an EMSL training program in order to perform such analysis independently. EMSL provides in-house training pertinent to all areas of analysis. Laboratory Managers are responsible for insuring that appropriate training is provided to every analyst and that they are completely qualified to perform analysis.

Ethics

One of the objectives of the Quality Assurance Program is to insure the staff of EMSL is provided information in the aspects of ethics as they pertain to corporate policy. The goals of this program are:

- For each staff member to understand the responsibility to provide true and accurate information
- The understanding of the consequences of unethical conduct
- Provide direction to employees
- Define right and wrong (as it is job related)
- Ensuring that all employees are free of undue pressures
- The understanding of the impact of our actions

Standard Operating Procedures

Instructions or procedures for the activities affecting the quality of our analytical services are developed by management for their respective critical functions. The Quality Assurance Program is used as a

guideline for their development, use and revision.

Technically specific Standard Operating Procedures are documented in the SOP manuals, located at each laboratory facility. These SOPs include step by step procedures for the preparation, analysis, and reporting of data.

Acceptance of Work

Our services are generally offered as line item tests which reference documented methodologies. Laboratory services are typically requested by the client as "open order" request. Samples may be delivered to the laboratory at any given time, without a firm documented arrangement. Analytical services are often performed on verbal contract. In these situations, our general terms and conditions apply. The Management review procedures are established in the Quality Assurance program for these open orders, verbal contracts and also for the cases where a written contract is utilized.

Sample Tracking

Chain of Custody

In order to ensure the integrity of any sample, records of its custody must be maintained throughout the sample collection in the field, acknowledgement of receipt, acceptance by the laboratory and analysis.

Since the client collects samples for analysis, the laboratory cannot be responsible for issuing a chain of custody at the time of sampling. However, the laboratory will advise all clients regarding sampling requirements (sampling materials, recommended sampling volumes, packaging, instructions for shipping, etc.) and chain-of-custody, and recommend that they use our form if they do not have their own.

Once the sample is accepted for analysis by the laboratory, the EMSL "Internal Chain of Custody" is used to document the handling of the samples throughout the analytical process.

Sample Acceptance Criteria

In addition to acknowledgement of the receipt of samples, samples must also be accepted for analysis. Prior to accepting samples, the person preparing the samples for analysis inspects them to determine if they conform to laboratory acceptance criteria. If they do not, or if this person has any question as to the validity of the sample, the Laboratory Manager or an analyst trained to analyze such samples will determine whether the questionable circumstance is sufficient to cause rejection. Rejections of samples are to be followed up by immediate notification to the client with an explanation.

Log In

Log in of samples is normally done by the Administrative Coordinator, but may be done by any other employee familiar with the process. Information is entered for samples received into the Laboratory Information Management system (LIMS). LIMS is a computer laboratory management system which serves to track all samples from receipt through the analysis, reporting, and billing processes.

Archival and Disposal of Samples

Once the analysis is complete and the analysis worksheet is signed, the analyst stores the sample in the appropriate storage box, as indicated in the SOP. All storage boxes are to be stored in a safe manner for the period indicated for that category of waste and in accordance with regulatory requirements for sample retention.

Samples are disposed of by a licensed contractor, where required and a copy of the waste manifest is obtained and kept on file. If requested, samples will be returned to the client.

Subcontracting

EMSL laboratories do not generally subcontract technical services. However, in the event such services are required, the Laboratory Manager will ensure all procedures are performed by laboratories that comply with the quality systems as addressed in this document and the policies of the accreditation program(s) currently held by the laboratory. Laboratories must subcontract to outside laboratories that maintain accreditation's appropriate for that analysis.

Data Processing and Validation

EMSL utilizes an automated Laboratory Information Management System (LIMS) to record, document and assimilate pertinent field, laboratory, and administrative data. The validation of the software, including final report templates are performed by the corporate MIS Department and the Quality Assurance Department.

Data validation is also a continuing process that takes place every time samples arrive at the laboratory and is carried through during log in, analysis and final reporting. This process is performed by the Laboratory Manager each time a final report goes through the procedures of review and signature.

Exported Data

Exported data is provided in a variety of formats, depending on the specific needs of our clients. Export formats for data deliverables are implemented and controlled by the corporate MIS staff, which has the flexibility; to implement new export formats as required. Electronically delivered data is not intended to replace hard copy results. Final, signed client reports are to be submitted in addition to delivery by email or diskette. In this way, exported data can be verified. Electronically transmitted results meet the requirements of the QA policies.

Record Retention Policies

It is EMSL policy to store records for 5 years (if not otherwise contractually established or regulated as for drinking water). The following records shall be maintained:

- Copy of Chain of Custody documents
- Original analytical data recording worksheets
- Quality control data
- All other records relating to the preparation of the client report

Quality of Materials

The high quality of materials used in the laboratories shall be assured through specific purchasing and verification procedures and/or proper preparation techniques.

Selection of the appropriate grade of reagent(s) is designated in the reagent section of each analysis SOP and in addition may be specified by the Laboratory Manager in unusual circumstances. As a general practice, reagents will be of at least ACS reagent quality.

Reagents inclusive of SRM shall be purchased in accordance with the analytical needs of the laboratories as determined by the Laboratory Manager. When received by the laboratory, these item's labels are dated and initialed with date received and expiration dates (if appropriate) as indicated and/or suggested by the manufacturer. Labels are also dated and initialed when opened and/or when reagent mixtures are prepared.

Verification will consist of confirming that the priority grade recorded on the reagent label conforms to the requirements of the SOP unless analysis difficulties indicate a possible problem or regulatory agency requirements specify otherwise. In the latter case, the appropriate analytical SOP will indicate the proper

verification procedure.

Equipment/instrument maintenance

The quality and maintenance of equipment plays a critical role in providing quality analytical services. Maintenance schedules for equipment will be established by the Laboratory Manager. The Laboratory Manager shall also determine whether each instrument is maintained and repaired in-house or by an outside agency following EMSL administrative procedures. Servicing will also be performed when a need had been identified by calibration or other QC checks.

A maintenance file will be maintained for all equipment. In addition to a schedule of normal preventive maintenance, this file will contain a record of servicing.

Contamination Management

Proper observance of laboratory procedures is necessary to guarantee accuracy of results and the safety of laboratory staff members.

Contamination of samples and of the environment (including reagents used in analysis) must be avoided to provide the highest quality, legally defensible data to our clients. In order to achieve this goal, laboratory staff must adhere to various preventative measures and use the testing procedures for contamination detection as established by the QA Manager.

If analysis of the blank samples indicate the possibility of contamination, the area and tools are cleaned and another sample is prepared and analyzed. If analysis of the third sample shows contamination, a complete investigation is conducted to determine the contamination source. If contamination is detected in any situation, the source of contamination must be traced and the problem resolved to prevent reoccurrence. All procedures taken to resolve a contamination circumstance shall be documented properly and completely in the laboratory files.

Document preparation and control

In order to prepare and distribute documents in an organized fashion, procedures for initiation, preparation, review, approval and issuance of controlled copies will be followed. This program is a coordinated effort involving both technical review and custodial control. Analysts are to use only controlled, i.e., approved documents for all calibrations, analyses, final reports, and other activities performed in this laboratory.

Reporting results

The client report is ultimately, our “final product”. The quality of our report reflects on our standard of quality. Final client reports are released only after data has been approved by the Laboratory Manager. This review includes evaluation of quality control results, calibration measurements, etc.

Procedures for dealing with deficiencies

Any complaint by a client will be treated as a non-conformance, and treated with the same corrective action follow-up as a discrepancy seen in following internal Quality Control procedures.

If a client makes a complaint about a test result, the sample in question will be reanalyzed where possible. If the second result agrees with the original the Laboratory Manager shall advise the client in writing that a quality control check has confirmed the original analysis.

In all cases where a deficiency is discovered, the QA Manager will initiate a corrective action review to determine the root cause of the problem and action to take to prevent reoccurrence. A report will be issued to the Laboratory Manager, who is responsible for the corrective action implementation.

The corrective action will consist of a review of all steps leading up to the non-conformance including root cause. This will include a review of QC data, sample tracking, data transcription, instrument calibration, training documentation and discussion with personnel.

Following the review, the QA Manager will prepare a report detailing the cause of the error and corrective action to take to prevent re-occurrence. The QA Manager will also follow up on the corrective action to ensure its implementation.

Analytical Performance Monitoring

The monitoring of laboratory performance is determined by:

1) Results from intra/inter analysts, intra/inter-lab and round robin testing plotted against control/acceptance limits.
2) Results from calibration measurements plotted against control/acceptance limits.
3) Lab performance in proficiency testing programs.
4) Achievement of internal and external on-site Quality audits. These audits will verify compliance with all QA and QC policies as documented in this manual.

Quality Control

The Quality Control program is established and managed by the QA Manager and insures our laboratories are producing quality data. This process validates, at a minimum, that our data is legally defensible and that all personnel perform their responsibilities properly.

Quality control is performed continuously throughout the course of laboratory sample analysis regardless of laboratory productivity and is made part of the normal course of laboratory sample analysis.

Our laboratories internal QC program includes at a minimum, 10% quality control on all samples received for analysis. These are summarized below in each analytical section and include:

- Analysis of standard reference materials
- Intra analyst QC
- Inter analyst QC
- Analysis of blank samples
- Participation in inter laboratory programs
- Participation in proficiency testing programs

This QC data is graphed on control charts designed specifically for each analysis type. Quality control reports are reviewed by the corporate Quality Assurance Department on a monthly basis.

Quality control is performed according to the scope of the laboratories accreditation status and quality control requirements for each type of analysis. Performance criteria will be maintained for both individual analysts and for the entire laboratory. The standards for acceptance criteria are documented in the EMSL Standard Operating Procedure Manuals and the QA Manual.

Demonstration of Traceablilty

The Quality Assurance program is designed to provide a method which achieves traceability of data to national standards. This is accomplished by setting requirements, which include:

- Use of Standard Reference Materials as certified and traceable to the National Institute of Standards and Technology. SRMs are used for QC analysis and training for achieving performance evaluations of analysts and overall laboratory accuracy.
- Calibration of instrumentation against NIST traceable standards
- Laboratory participation in independent (non EMSL) proficiency testing programs
- Analysis of consensus standards

Client Communications

Clear, continuous and open communication between the laboratory and the client is one of the keys to maintaining a successful, quality operation. Communication should be established prior to the start of any work. Information should be clearly understood between Laboratory Management and the client. EMSL provides Quality Assurance information and technical support to the client to assure continued quality service. The support and information provided in relation to the work performed includes:

- Field sampling guides
- Availability of pertinent QC records
- Access to the Quality Assurance Department for technical assistance
- Security of data (confidentiality)
- Reasonable access to the relevant areas of the laboratory for the witnessing of analysis

Confidentiality

It is understood that confidentiality and proprietary rights must be respected throughout the performance of services for any client or for those that may include national security concerns. Information will not be given to those for whom it is not intended and the proprietary rights of our client will be protected.

Notice of Performance

The Laboratory Manager should provide the client with information as it relates to the performance of the analysis and turnaround time. The laboratory must notify the client if:

- Analysis cannot be performed on time
- Integrity of the sample has been jeopardized (either by the laboratory or the client)
- A discrepancy in the analysis has been found during QC analysis.

Statement of Uncertainty

EMSL laboratories have completed an evaluation aimed at characterizing the range within which the true value of a test result exists. This measure of uncertainty is specific for each service area and may be found in the EMSL QA Manual and is available upon request.

This precision-based measures of uncertainty (for random error) have been determined by the evaluation of the reanalysis of samples. QC performance, calculated as relative percent is averaged over a sufficient sample population size. Qualitative determinations are not included in the evaluation.