EMSL Analytical, Inc.

LABORATORY
QUALITY ASSURANCE
MANUAL

REVISION 10 – December 2008

Note: This is an uncontrolled copy and has been printed for client distribution purposes only. Only the title page differs from the laboratory copy. This manual's title page does not include:

- *Laboratory Location*
- *Signature of Lab Manager*
- *Signature of QA Manager*
- *President Name*
- *Internal audit schedule*
- *List of Modules included*

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General and Administrative

1.0 QUALITY ASSURANCE PROGRAM

1.1 Scope

EMSL Analytical, Inc.'s commitment to providing quality services to our customers is embodied in EMSL's corporate policy on quality assurance (QA). The objectives of the EMSL quality assurance program are to ensure the following:

- Quality, accuracy and integrity of analytical results.
- 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 customers.
- Fulfillment of the requirements of the American Industrial Hygiene Association (AIHA), the National Voluntary Laboratory Accreditation Program (NVLAP), The NELAC Institute (TNI) and/or state and local accrediting authorities.

To achieve these goals, this Quality Assurance Manual (QAM) directs the implementation and maintenance of the quality assurance program, describes responsibilities and duties of personnel, and addresses the elements of the quality assurance system. This QAM covers analytical services offered in the EMSL laboratories, which include asbestos, lead, environmental microbiology, industrial hygiene organics, inorganics and radon. The specific policies, procedures and requirements for each of these service areas are addressed in individual modules. These modules are organized as follows:

Module	Program Description
A	Asbestos
B	Environmental Lead
C	Environmental Microbiology
D	IH Organics
E	IH Inorganics
F	Radon

This manual is administered by the corporate Quality Assurance Department. Only those modules that apply to a specific laboratory are provided to that laboratory. Laboratories shall comply with the requirements detailed in this manual and the additional program requirements specified in Modules A - F. This manual is to be kept accessible to all employees. Employees are responsible for being familiar with, and adhering to its contents.

This manual is the property of EMSL and may not be used for any other purposes other than those related to EMSL work. Under no circumstances, will this manual be removed from the laboratory facility nor will any of its contents be disclosed to any outside entity unless prior approval has been granted by EMSL corporate management. Requests for copies of this manual must be made to the EMSL quality assurance manager.

1.1.1 Manual Revision History

The QAM will be reviewed annually for continued suitability. The revisions made to the QAM are recorded in a Revision History which follows each section of the QAM. A 'Notice from the

Quality Assurance Department' may also be provided with the QAM at distribution summarizing the additions and changes to the QAM.

1.2 Quality Policy Statement

EMSL is committed to providing a high standard of service and producing dependable, accurate and technically defensible test results in order to best serve our customers. Our experienced and qualified technical personnel are committed to providing data of the highest quality achievable.

The senior management of EMSL Analytical, Inc. is committed to adopting the quality standards utilized by the various accrediting authorities – namely, NVLAP, AIHA, state authorities and The NELAC Institute. The major goal (and focus) of the laboratory and its personnel will be toward constant improvement in the quality management system which has been designed with the purpose of ensuring consistent operations leading to quality data.

The senior management staff of EMSL acknowledges and accepts the responsibility for the overall quality of the data produced by the laboratory and makes a commitment toward constant improvement of the final product. In doing so, management provides the laboratory manager and the Quality Assurance Department with full authority to accomplish this end. Management is committed to providing all of the resources necessary to provide high quality analytical data.

All personnel concerned with testing within the laboratory must familiarize themselves with the quality documentation and implement the policies and procedures addressed in this manual.

This statement is issued under the authority of company President, Peter Frasca, Ph.D.

1.3 Program Objectives

The program described in this manual is designed to help plan and institute company policies and quality objectives throughout the laboratory facilities. This program is intended to provide procedures and policies, which provide:

- Development of company quality control programs
- Good laboratory technique that ensures a contamination-free environment
- Constant oversight of laboratory quality performance
- Establishment of training requirements
- Job descriptions of each employee delineating responsibilities
- Development and maintenance of internal quality audit program
- Use of appropriate analytical technology including review of current literature to capture recent applicable developments
- Proper documentation and quality review of analytical data
- A comfortable work atmosphere away from undue productivity pressures
- Maintenance of accreditation programs
- Assurance that national coherency is maintained through standardization of policies and procedures
- Control and maintenance of round robin programs
- Control of documents
- Respect for customer confidentiality

Quality policies and procedures are integrated into our daily work, and are constantly reviewed by national, regional and laboratory management and by the Quality Assurance (QA) Department.

The program is managed and maintained by the corporate QA Department.

1.3.1 Commitment to ISO Standards

Starting with corporate management and extending to regional and local laboratory management, EMSL is committed to ensuring that the standards documented in the ISO 17025 are upheld in all aspects of the company affairs. These standards cover:

- Organization of management system
- Management system - definition, establishment and maintenance
- Document control
- Review of requests for work (contracts, etc.)
- Subcontracting services/interlaboratory exchange of samples
- Purchasing supplies
- Service to the customer
- Complaints
- Control of non-conforming work
- Corrective and preventative action
- Control of records
- Internal audits
- Management reviews
- Personnel qualifications
- Method validation
- Traceability
- Assuring quality
- Reporting results

By way of authority, it is corporate management whom implements, maintains and monitors compliance.

1.4 Changes to the Quality Management System

The quality management system is designed to ensure the integrity of the system is maintained in the event any changes take place. Procedures include:

- Contingency plans
- Assignment of the same responsibility by multiple personnel (back ups)
- Assignment of deputies or designated second person

1.5 Departures from Quality Assurance Policies

Any departure from the procedures and policies as stated in this document must under go a review by the Quality Assurance Department and corporate management prior to approval and effect. This will include, at a minimum:

- Reason for deviation from policy and/or procedure
- Applicability of alternative policy and/or procedure
- Availability of resources
- For deviations of analytical procedures, assurance that data is reported with appropriate references and disclaimer on final reports affected by a policy and/or procedure change (if applicable).

A record of the review of the alternative procedure or policy is maintained as part of the project files.

No departures from the policies and procedures, as written in this document, are permitted without

acceptance by the QA manager or corporate management.

1.6 Quality Management System Review

The QA manager will review the quality management system at least annually. It will also be reviewed any time a problem arises that indicates a possible program flaw. In such an instance, the QA manager will discuss the problem with corporate regional and laboratory management and analytical staff to ensure needed input from all levels within the laboratory.

1.7 Normative References

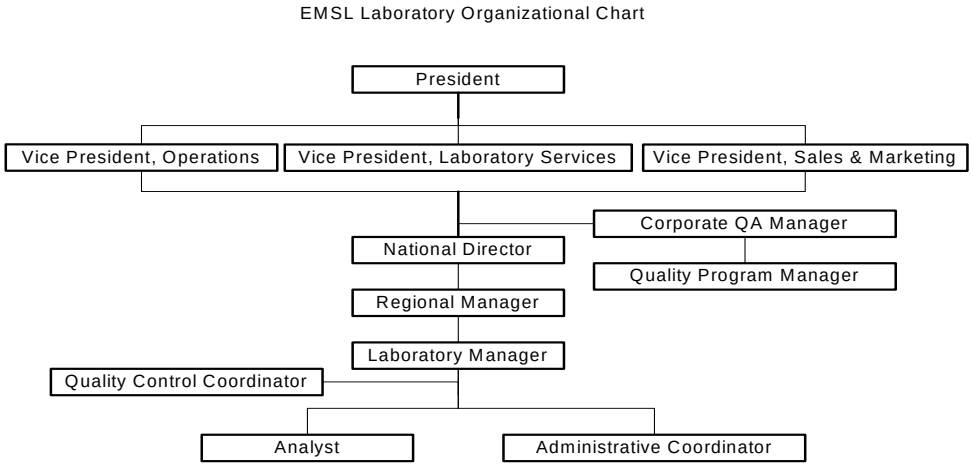
The EMSL Analytical management system complies with the requirements of the following references as well as those of several other State and local accrediting agencies:

- ISO/IEC 17025:2005
- 2003 NELAC Standards
- AIHA Accreditation Policies (May 2008)
- NIST Handbook 150, 150-3 and 150-13 (2006 Edition)
- NYS Department of Health ELAP Certification Manual (March 2008)

Revision History below begins with Revision 10 of all modules. All prior revision history is available through the corporate QA department

Revision	Date	Changes
10	12/19/08	Minor editorial changes throughout. Added Revision History. Divided QAM into separately controlled sections for simplified revision. References to "NELAC" were replaced with "The NELAC Institute" or "TNI" throughout. Added requirement that QAM is to be reviewed annually. The "Notice" referenced in 1.1.1 has been made optional. Quality Policy Statement updated by adding more stress on service to the customer, defining purpose of quality system and incorporating the previous amendment in last paragraph. Updated program objective regarding coherency to clarify that this is accomplished through standardization of policy and procedure. Added Section 1.7.

2.0 ORGANIZATION, RESPONSIBILITY AND TRAINING



2.1 Scope

The following section describes the company organization and the responsibilities of laboratory personnel. Technical training requirements for personnel are also covered here. Specialized training for each analytical service is found in the modules. This section also discusses EMSL's ethics and data integrity policies.

2.2 Corporate Organization

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. Organizational charts for each laboratory are maintained by the corporate QA department. Copies of these charts are stored at each EMSL laboratory. Corporate headquarters are responsible for the management of the company activities. These include:

- Fiscal management
- Personnel management
- Human resources
- Information technology (IT)
- Credit and collections
- Accounting (including billings)
- Sales
- Customer service
- Contracts review
- Business development
- Quality assurance/quality control management systems
- Legal counsel
- Purchasing

The corporate laboratory and the branch laboratories perform the company's analytical services. They report to the corporate headquarters on quality control, productivity, staffing and marketing issues.

2.2.1 EMSL Analytical and LA Testing

Pursuant to the terms of an out-of-court settlement, EMSL Analytical, Inc. operates as "LA Testing," a duly registered Fictitious Business Name, within a 5 county area in southern California. For simplicity, this manual refers to the EMSL name only. The policies and procedures documented in this manual apply to all facilities including those doing business as LA Testing.

2.2.2 Products Division

EMSL Analytical, Inc. also operates a Products Division which supplies environmental sampling equipment. No key personnel in this division have involvement or influence on the testing activities of our laboratories and, therefore, present no conflict of interest.

2.3 Laboratory Job Responsibilities/Descriptions

2.3.1 Scope

This section describes the positions and responsibilities of the technical personnel in a basic laboratory operation of EMSL. It does not include specialized assignments or positions that may have been instituted for specific projects or special laboratory needs. It is possible that more than one of these job responsibilities is shared among one person. For example, an analyst may also be assigned administrative support duties.

Minimum education and experience requirements are listed for each position. Specific requirements for education, training and skills for method specific requirements are listed in each of the individual program modules.

2.3.2 Administrative Coordinator

The administrative coordinator reports to the laboratory manager.

The minimum education and experience requirement is on the job training.

The position is a support position to the entire laboratory including the analysts. The responsibilities include but are not limited to those listed below:

2.3.2.1 Sample Receipt Responsibilities*:*

- Reviews paperwork for all incoming samples to ensure completeness and correctness.
- Inspects samples to ensure sample integrity is retained and that packaging is not compromised.
- Logs in all samples in a timely manner based on turn around time.
- Ensures all samples are placed in the proper storage area to await analysis.
- Delivers incoming samples to the laboratory.
- Informs the laboratory manager or analyst of any special priorities regarding the samples and informs them if there are any concerns noted regarding sample integrity.

The administrative coordinator shall also be aware of sample origin as it impacts regulatory requirements. The administrative coordinator follows all sample tracking protocols in handling samples, in particular, completing and verifying chain-of-custody forms.

Ensures that proper numbering is used and transcribed correctly into the Laboratory Information Management System (LIMS) and onto all applicable forms. The administrative coordinator also ensures compliance with all relevant quality standards (e.g., ISO 17025, NELAC, NIST) as

related to job responsibilities.

2.3.2.2 Data Entry Responsibilities:

- Generates analytical reports.
- Enters data produced by the analysts into the computer system for production of the final, customer ready report.
- Generates reports in the priority in which the laboratory manager assigns them.
- Ensures that the final report is prepared within the required time frames and that the results are reported to the customer in a timely matter.
- Reviews the information in the report and check the data for any obvious errors.
- Checks both technical and non-technical information, such as sample location, volume and sample I.D. numbers for possible transcription errors.
- Reports any observations of erroneous or unusual data or apparent errors to the laboratory manager.
- Ensures compliance with all relevant quality standards (e.g., ISO 17025, NELAC) as related to job responsibilities

The administrative coordinator contributes to the EMSL quality objectives by ensuring that they act as a professional interface with laboratory customers. Administrative coordinators ensure that samples are received with the appropriate paperwork and that data is transcribed accurately and in a manner which prevents questions about the integrity of laboratory data. They also ensure that they record all non-conforming work, non-conformities, opportunities for improvement and customer complaints and report these to the attention of those personnel authorized to handle these situations.

2.3.3 Analyst

All analysts report directly to the laboratory manager.

Minimum education and experience requirements:

- In house training documented by the EMSL qualifications checklist.
- Participation in ongoing training programs (in-house workshops, laboratory meetings, etc.)

The analyst is responsible for performing calibrations of equipment, assigned analysis, and recording of all analytical data according to established procedures. The analyst must use good analytical technique and he/she must provide analytical results suitable for issuing a customer report.

The analyst manages all work assigned. He/she completes all paperwork in accordance with established laboratory procedures. The analyst reviews all paperwork for correctness and completeness and ensures that work progresses in a timely and productive manner.

The analyst is responsible for performing all required analysis on QC samples as directed by the QC coordinator or laboratory manager. The analyst is required to notify the laboratory manager or QC coordinator of any occurrence that could affect the validity of an analytical result.

He/she must ensure compliance with all relevant quality standards (e.g., ISO 17025, NELAC) as related to job responsibilities.

The analyst contributes to the EMSL quality objectives by ensuring that they have read and understood all EMSL policies and procedures relevant to their job tasks and follows all SOPs in order to ensure consistent and accurate analyses. The analyst ensures that all required QC functions of their job are performed in a timely manner including calibration of equipment and analysis of QC samples at the required frequency. Analysts also ensure that they record all non-conforming work, non-conformities, possible opportunities for improvement and customer complaints and report these to the attention to those personnel authorized to handle these situations. Analysts contribute to the overall quality of the EMSL final results by ensuring they avoid any actions which may call into question the integrity of their work.

2.3.4 Quality Manager (QM)

The QM works under the direction of the laboratory manager (or regional manager /national director if the QM is the laboratory manager) with periodic interaction with the quality assurance manager.

Minimum education and experience requirements:

- Knowledge of analytical methodologies
- Basic understanding of EMSL QA/QC program (including statistical analysis)
- Participation in ongoing training programs (in-house workshops, laboratory meetings, etc.)

The QM is responsible for ensuring that all QA/QC procedures are performed at the required frequencies. He/she collects and maintains all QC data for reporting to the laboratory manager.

He/she oversees the QA/QC program and is responsible for the laboratory's compliance with all standard policies as guided by the corporate quality assurance manager. An analyst or laboratory manager may also function as the QM.

The QM ensures that all QA/QC is being performed by the analyst and is responsible for reporting any non-compliance issues to the laboratory manager or, if necessary, directly to the corporate QA manager. The QM performs periodic reviews of final data reports. These reviews are documented and placed in the project file. Any errors or discrepancies are corrected and documented on a corrective action form.

The QM ensures that the laboratory maintains compliance with the policies and procedures documented in this manual and the requirements documented in all relevant quality (e.g., ISO 17025, NELAC) standards.

The laboratory quality manager contributes to the EMSL quality objectives by ensuring that all quality system requirements are being followed in the laboratory. The laboratory quality manager oversees the implementation of the system in their laboratory, and ensures it is consistently followed by those employed in the laboratory in such a manner that the laboratory remains a coherent part of EMSL and is not operating on its own set of policies and procedures. They oversee the quality reports being submitted to ensure that they are generated on-time and that any problems reported have been handled and resolved maintaining the accuracy of laboratory data.

2.3.5 Laboratory Manager

The laboratory manager reports to the regional manager. In the circumstance where no regional manager is assigned to the laboratory, the laboratory manager reports to the national director.

Minimum education and experience requirement is 1 year of related analytical experience.

The laboratory manager makes technical decisions for the laboratory such as:

- Assuring all requirements for laboratory equipment and supplies are met
- Resolution of analytical problems
- Development and implementation of training programs for analysts

The laboratory manager is responsible for overall administration of laboratory operations. He/she ensures that company policies are understood by all personnel, that adequate supervision is provided to the staff, ensures that work-scheduling procedures adequately address customer needs, and is responsible for ensuring all customer complaints are resolved. He/she also approves all employee reviews and promotions and provides regional or corporate management with information regarding laboratory budgeting issues (e.g., purchase of equipment and supplies, expenses for out-of-house training, staffing requirements). The laboratory manager is responsible for designating qualified personnel (deputy) to assume specific, temporary management responsibilities in the event of absence. The deputy is identified on the laboratory organization chart. The laboratory manager is also responsible for ensuring a comfortable working atmosphere, free from excessive pressures (including unreasonable productivity rates), for all their laboratory employees. The laboratory manager must ensure that the policies and procedures of this quality management system are communicated to the laboratory staff.

The laboratory manager is responsible for the data reported by the laboratory. The laboratory manager reviews and approves the final customer reports. The laboratory manager ultimately holds the responsibility for the release of the final report. This responsibility includes the verification of the sample results which, include:

- Verification of sample number
- Correctness of sample result
- Check for typographical errors
- Completeness of chain of custody

It is the full responsibility of the laboratory manager/designee to ensure that the final report is accurate and complete. The laboratory manager may assign designated personnel to perform the task of final review and approval following the EMSL SOP for Final Report Approval for Electronic Signature.

The laboratory manager ensures that QA standards are established, understood and administered. He/she is ultimately responsible for ensuring that the QA program is conscientiously implemented. He/she reviews the QA program with the regional manager or national director to ensure completeness and effectiveness, and supports the QA manager/ regional manager in carrying out the program by use of authority. The laboratory manager is responsible for submitting all QC data reports on a monthly basis to the regional or QA manager as directed.

The laboratory manager contributes to the EMSL quality objectives by ensuring that the laboratory maintains compliance with the policies and procedures documented in this manual and the requirements documented in relevant quality standards (e.g., ISO 17025, NELAC). The lab manager also oversees employee qualifications ensuring they are properly qualified and trained prior to conducting analysis. The lab manager is ultimately the person at the laboratory responsible for all data reported from the laboratory and ensuring that data is accurate and error-free. The lab manager ensures that all non-conforming work, non-conformities, and complaints are resolved in a timely manner leading to continual improvement at the laboratory.

2.3.6 Regional Manager

The regional manager reports directly to the national director.

Minimum education and experience requirements:

- 2 years related analytical experience
- 1 year management experience

The regional manager assumes responsibility for the overall performance of two or more laboratory locations. He/she controls all analytical programs, reporting processes, general management and is accountable for the overall operational and financial well being of the laboratories under authority.

The regional manager reports directly to the national director and initiates and controls all operational policies in the areas of administrative, technical and fiscal matters. The regional manager may also function as a laboratory manager.

The regional manager works closely with the QA manager in developing and maintaining the QA program. He/she consults directly with the QA manager regarding of the effectiveness, and applicability of the program, recommends needed changes, if any and reports any problems with the program design. The regional manager is responsible for ensuring full annual technical QA/QC audits are performed at each of their laboratories.

The regional manager ensures that the laboratory maintains compliance with the policies and procedures documented in this manual and the requirements documented in relevant quality standards (e.g., ISO 17025, NELAC).

The regional manager contributes to EMSL quality objectives by assisting laboratories in their implementation of the quality system, improving consistency across their laboratories. The input they provide the QA manager assists in the continual improvement of the quality system.

2.3.7 National Director

The national director reports to the EMSL vice presidents.

Minimum educational/experience requirements:

- AS degree in related science
- 3 years related analytical experience
- 2 years management experience

The national director is responsible for all aspects of the specific analytical services division assigned including: fiscal performance of the division, the operation of the branch laboratories, development and compliance with corporate mandated quality control and quality assurance procedures and policies and laboratory accreditation's.

The director is responsible for designing reporting policies, the management of quality control data and the development of all technical standard operating procedures.

The director also ensures that the laboratory maintains compliance with the policies and procedures documented in this manual and requirements documented in relevant quality standards (e.g., ISO 17025, NELAC).

National Directors contribute directly to the quality objectives of EMSL by developing and overseeing the quality control programs for their departments with the QA department. In

addition, their expertise ensures that only the most appropriate methods are adopted and utilized ensuring quality data for our customers. By assisting the QA department and branch laboratories to resolve customer complaints and major technical deficiencies, they ensure that customer needs are being met.

2.3.8 Quality Control Coordinator (Corporate)

The corporate quality control coordinator reports to the EMSL quality assurance manager.

Minimum educational/experience requirements:

- 2 years related analytical experience

The corporate quality control coordinator (QCC) reports to and works under the direction of the corporate quality assurance manager. The corporate QCC is responsible for providing technical support to the Quality Assurance Department, which includes:

- Participation in the development, implementation and maintenance of QA/QC policies and procedures
- Guidance to the laboratory operations on quality issues
- The monitoring and assurance of compliance with the QA plan
- Establishing and maintaining standardization throughout EMSL locations
- Performs and/or tracks internal audits and related follow up to non-conformities
- Develops and maintains national round robin programs

The corporate QCC is responsible for ensuring compliance with the requirements of the quality control program. The corporate QCC performs the review of the monthly quality control reports which includes:

- Compliance with QC analysis frequency and on time report submittals
- Ensure QC data is within acceptance criteria
- Review and ensure all corrective actions stated in response to internal audit findings are completed
- Ensure calibration measurements are within standards
- Report to management on laboratories QC performance

The corporate QCC is responsible for maintaining the program and standard operating procedures used for QC data and TEM calibrations.

The corporate QCC provides reports of performance (frequency of report submittals and review of quality of reports) to the QA manager, regional managers, national directors and vice presidents.

The corporate QCC ensures that the laboratory maintains compliance with the policies and procedures documented in this manual and the requirements documented in relevant quality standards (e.g., ISO 17025, NELAC).

The corporate QCC contributes to the quality objectives by tracking whether quality control programs are being implemented at branch laboratories through the review of monthly and quarterly reports. This review of quality reports ensure that QC is being properly documented and reviewed thus improving the quality of data from all laboratories, and allowing corporate management to act when areas of concern are identified. The corporate QCC's participation in the annual management reviews includes feedback on individual lab performance and advice on areas for improvement.

2.3.9 Quality Programs Manager (Corporate)

The corporate quality programs manager reports to the corporate quality assurance manager.

Minimum educational/experience requirements:

- 2 years related experience with Quality Management Systems
- 1 year management experience

The quality programs manager works with the corporate QA manager to develop EMSL policies and procedures, and ensuring that these comply with accreditation requirements. The quality programs manager also assists in the management of laboratory accreditations.

The quality program manager assists the corporate QAM in communication with accrediting authorities, researching requirements and determining required accreditations for work being performed by EMSL. In addition, he/she is responsible for improving efficiencies in the management system identifying areas of improvement in the quality system to ensure compliance with relevant quality standards (e.g., ISO 17025, NELAC, NIST) and improved laboratory performance.

The quality program manager may perform internal audits of EMSL branch laboratories and attend assessments performed by outside accrediting agencies and assist in responding to assessment findings.

The quality programs manager contributes directly to the EMSL quality objectives through the development of general quality system policies and procedures that are implemented in branch laboratories ensuring consistent operations that meet accreditation requirements and through the training of EMSL staff in these procedures.

2.3.10 Quality Assurance Manager (Corporate)

The corporate quality assurance (QA) manager reports to the EMSL vice presidents.

Minimum educational/experience requirements:

- 2 years related analytical experience
- 1 year management experience
- Course work on quality programs

The corporate QA manager establishes, implements, and maintains the entire QA program as described in this manual. He/she develops statistical protocols for data reduction and acceptance criteria. He/she defines requirements for submitting QC samples, controls results reporting policies, sets standards for analytical performance and issues protocols for yearly on-site audits for the branch laboratories.

The corporate QA manager is responsible for maintaining the QA manual and all standard operating procedures (SOPs). He/she conducts and/or establishes policies for QA audits, and sets standards for laboratory practices. He/she confers with the national directors, regional managers and/or the laboratory managers on QA policies and supports the laboratory manager and quality control manager in the daily maintenance of the QC program. The QA manager oversees laboratory accreditation's including initial applications, maintenance of proficiency testing programs and responses to non-conformities identified during on site audits.

The QA manager participates in the annual management review. The QA manager also ensures

that the laboratory maintains compliance with the requirements documented in the ISO 17025 and NELAC standards.

The corporate QA manager assists top management in defining the EMSL quality objectives. As head of the quality unit, the corporate QA manager ultimately has oversight of the entire quality program of EMSL and ensures the management systems meet the quality objectives.

2.3.11 Vice President, Laboratory Services

The vice president is responsible for the overall quality performance of the entire company, including the initiation, development and maintenance of the quality management system. The vice president advises the president on quality program management issues and has the ultimate authority to ensure the integrity of the management system is maintained at all times (including when changes are made) and initiate actions to prevent or minimize departures from the quality management system.

The vice president ensures appropriate communication processes are established for implementation and effectiveness of the quality management system. He/she participates in the management review process and commits to continually improve the effectiveness of this system.

The vice president makes all decisions related to the status of laboratory certifications and accreditations.

The vice president contributes to the objectives of the also ensures that the company maintains compliance with the policies and procedures documented in this manual and the requirements documented in relevant quality standards (e.g., ISO 17025, NELAC).

As part of top laboratory management, the Vice President of Laboratory Services assists in setting the quality objectives of EMSL. In addition, the Vice President ensures that these quality objectives are adequately communicated and understood by laboratory staff and ensures that they remain aware of the effectiveness of the EMSL quality system. The vice president also contributes by ensuring they are committed to the development, implementation and continual improvement of the laboratory quality system. As part of top management, the vice president shall ensure that the integrity of the management system is maintained at all times.

2.3.12 President

The president focuses and directs the path of the company and assumes complete responsibility for the success of the quality management system.

He provides the authority and approves the resources necessary to maintain compliance with the quality assurance program policies documented in this manual and applicable accreditation standards.

The president, as part of top laboratory management, assists in setting the quality objectives of EMSL, and issues the Quality Policy under which the company operates. The President contributes to the quality objectives by ensuring adequate resources to establish, maintain and improve the quality system of the laboratory and by clearly communicating the company's commitment to its Quality Policy and quality system policies and procedures.

2.4 Roles of the Administrative Support Group

This section describes the basic role of the corporate administrative support groups in the laboratory

organization. Administrative support consists of:

- Information technology
- Human resources
- Corporate counsel
- Accounting
- Credit/collection
- Sales and marketing
- Corporate customer service
- Purchasing

The departments of the support group are located in the corporate headquarters. The managers of each department report to the vice president(s). Each department has defined roles which provide the laboratories with the support needed to maintain the business. Laboratory managers have direct access to all employees of the individual departments in the administrative support group.

2.4.1 Information Technology (IT)

The IT department is responsible for all computer and technology services at EMSL including, but not limited to servers, PCs, telecommunications, storage, security, web services, software licensing, repair, maintenance, support and custom enhancement of EMSL's LIMS system (Sample Master XP), LabConnect (report distribution engine) and all company databases. Requests for assistance are forwarded to IT through an e-mail help request system.

2.4.2 Human Resources

All human resource responsibilities are handled by EMSL's Human Resources department. Responsibilities include, but are not limited to, employee recruitment and hiring, personnel record keeping, employee benefits and career development as well as providing advice to laboratory management on topics such as employee discipline, conflicts of interest, and discrimination and harassment prevention.

2.4.3 Corporate Counsel

EMSL maintains an in-house corporate counsel. Corporate counsel advises EMSL corporate management on all legal issues related to the business of EMSL.

2.4.4 Accounting

The Accounting department has the fiduciary responsibility of ensuring the accuracy and timeliness of all accounting processes and financial reporting. This includes invoicing to customers, processing and payment of vendor bills, cash management, reconciliation of accounts, satisfying financial reporting obligations to internal and external entities. The department ensures that accounting transactions are recorded, flow through the general ledger and are properly summarized to produce financial statements for management in accordance with Generally Accepted Accounting Principals (GAAP).

2.4.5 Credit/Collections

This is a sub-department of Accounting. The responsibility of this department is to act on the outstanding accounts receivable sub-ledger, which lists out customers and their outstanding invoices. Contacts are made in an effort to ensure all outstanding debt is collected in a timely fashion. They deposit daily cash receipts and apply client payments to their accounts. They also review accounts in consideration for outside collection assistance.

2.4.6 Sales and Marketing

The Sales and Marketing department develops new business for EMSL laboratories through advertising, marketing and contacting potential customers. Each sales employee is assigned

customers for whom they are responsible for negotiating contract terms. Marketing is responsible for the development of all marketing materials including fliers, advertising and informational materials that are distributed via the web and through the laboratories, as well as in-person through EMSL's participation in conferences and exhibitions.

2.4.7 Corporate Customer Service

The Corporate Customer Service team assists Marketing, Sales, and EMSL Laboratories nationwide. Their current duties include but are not limited to: Answering incoming calls to the customer service extension, assisting customers who are seeking information on capabilities and technical questions, researching invoice discrepancies, finding and sending reports, assisting with LABConnect user issues, setting up LABConnect accounts, placing supply orders and assisting with pricing inquiries.

2.4.8 Purchasing

The EMSL Purchasing department is responsible for arranging for the procurement of supplies and services for the entire EMSL organization. Responsibilities include obtaining and reviewing suppliers for business critical supplies and services, reviewing and approving service orders submitted by branch laboratories, and tracking performance of suppliers and service providers by being the main point of contact for complaints and supply/service problems.

2.5 Training

2.5.1 Scope

This section describes the corporate procedures and policies of the EMSL training program. Additional requirements for training for each analytical methodology, if any, are discussed in the program modules.

All analysts must complete the EMSL training program in order to perform analysis independently and receive a completed Demonstration of Capability certificate.

Because the amount of training needed will vary based on the education, past experience and skills of the trainee, the times described in this section and the program specific modules are considered minimums. Laboratory managers are responsible for ensuring that appropriate training is provided to every analyst and that they are completely competent, qualified and signed off to perform analysis.

2.5.2 Types of Training

2.5.2.1 "In-House" Course

These are organized EMSL courses designed for a classroom setting (they can be scheduled in workshop type modules) with syllabus and course materials. These courses contain recommended contact hours. A certificate is issued which documents attendance.

Formal in-house courses are developed and implemented under the direction of corporate management. The trainer must follow the requirements of the EMSL training program and ensure that all topics are covered according to the workshop outline or qualifications training checklist. The assignment of a trainer can be performed by the laboratory manager, regional manager, national director, QA manager, vice president or president. Competency will be determined based on knowledge, experience and demonstrated technical competence. The trainer must have a thorough and comprehensive understanding of the topics involved.

2.5.2.2 "On the Job" Technical Skills Training

This is training provided at the hands on level. The amount of training time needed will vary for each method and for each trainee. If the training involves analytical procedures, the trainer must have completed all the requirements of an analyst and have at least 1 year of experience. Non-analytical procedures may be trained by any experienced EMSL employee with a thorough and comprehensive understanding of the topics involved

2.5.2.3 "Out of House" Formal Training Courses

Under some circumstances, EMSL will provide staff members with formal, outside training. The certificate of training is maintained in the employee folder along with course outline. Courses will be selected based on applicability to job responsibilities. The qualifications of the course provider and instructor shall be reviewed prior to course approval. Contact hours vary based on the course.

2.5.3 Initial Training and Authorization of Analysts

2.5.3.1 Training Checklist

Analysts must satisfy theoretical and practical knowledge requirements in order to be authorized to independently analyze samples. Each EMSL program area utilizes a set of training checklist to document these requirements and track an analyst's training. The EMSL training checklists are available on the E-link site and are referenced in the program specific modules.

The training checklist documents all aspects of the analyst's training from their understanding of the theory behind applicable concepts to their ability to capably perform analysis of each method on which they are being trained. Specific requirements for each analysis are detailed in the QAM Modules and the training checklists.

As training of an analyst proceeds, the trainer and trainee sign and initial each item on the checklist as they are completed. There are a number of ways that a new analyst can satisfy the requirements presented in the training checklist.

The date the checklist is signed is the date on which the new analyst demonstrated understanding or ability satisfying the requirement. This demonstration may be completed in a number of ways.

- The analyst may receive training on the topic from a qualified trainer (an analyst that has at least one year of experience and a completed DOC for the method being trained) and subsequent to the training demonstrates their understanding and/or ability. Once the trainer is satisfied that the analyst has met the requirement, the trainer shall initial and date the training checklist for that requirement.
- Based on previous experience and training, a qualified trainer (as defined above) or the laboratory manager, may verify that knowledge or skills are already present through interviews and observed technique and once satisfied that the analyst has met the requirement of the checklist may initial and date the training checklist for that requirement without further training.

Note: Previous EMSL training policies allowed for a "qualifications statement" from the national director in lieu of a training checklist. This option is hereby eliminated. Beginning with Revision 10 of the QAM, all analysts must have each checklist item verified by laboratory manager or trainer and initialed on the

checklist. "Qualification statements" issued prior to the removal of this option (Dec 2008) will still be considered valid and should remain a part of the analyst's training records.

Once all requirements of the training checklist have been completed and marked on the checklist by the analyst and trainer, the laboratory manager signs off on the training checklist stating that the training of the analyst has been completed.

2.5.3.2 Demonstration of Capability Certificate

Following completion of the training checklist, the signed checklist is sent to the corporate Quality Assurance Department. As of Revision 10, of the QA Manual – Section 2, formal Demonstration of Capability certificates are issued through the Quality Assurance Department.

EMSL utilizes a DOC certificate which is based on the sample provided in Appendix C of Section 5 of the 2003 NELAC Standard. The form allows for the recording of all analyses for which demonstration has been completed for a particular analyst.

The certificate is prepared by the QA department and signed by the corporate QA manager against the information provided by the laboratory manager on the training checklist and supporting documentation for each matrix and method for which the analyst is authorized to perform analysis. Each analyses type is listed along with the date upon which Demonstration of Competency was completed. The date of the QA manager signature signifies the date upon which the information contained on the form was updated and the form reissued by the QA department.

The DOC certificate is then sent to the laboratory manager who signs the form thus authorizing the analyst to perform work for those methods listed on the DOC certificate. (Note: When the analyst being authorized is the laboratory manager, the DOC certificate shall be signed by either the regional manager or national director.) The date of laboratory manager signature signifies the date upon which the laboratory manager confirms the information listed on the DOC certificate.

The DOC certificate shall be revised whenever an analyst completes a new demonstration of capability or when their capability to perform the analysis is revoked. In such cases, the supporting material shall be sent to the QA department along with the most recent version of the DOC certificate. Once updated, the QA department will re-sign and send to the laboratory manager for re-affirmation of the information contained on the form. Thus the dates of the signature always correspond to the date that the certificate is issued and the information contained therein confirmed, and not necessarily the date upon which specific demonstrations were completed.

Prior to Revision 10, Demonstration of Competency certificates were generated by each individual laboratory and issued by the laboratory manager. These certificates may still be in place in laboratories and will be considered to meet the requirements above if issued prior to the publication date of Revision 10. Any revision to these certificates as a result of changes to the scope of the Demonstration of Competency shall be issued through the QA department as required above.

2.5.3.2.1 Exception to Certification Form:

Where a method has been used in the laboratory since July 1999, and there have been no significant changes in instrumentation type, personnel or method, evidence of ongoing performance (see below) will be acceptable. The Laboratory Manager

must have a record on file to demonstrate that an initial DOC is not required.

2.5.3.3 Authorization to Perform Analysis

Analysts must receive formal authorization to perform analysis. This is performed with the signature of the laboratory manager, regional manager or national director and corporate QA manager on the Demonstration of Capability certificate.

2.5.4 Ongoing Training and Continued Demonstration of Capability

2.5.4.1 Ongoing Training

Ongoing training of our staff is a very important piece of analytical quality. It provides an opportunity to sharpen skills and keep all employees up to date with the current procedures, techniques, regulations, etc.

Laboratory managers are to ensure that ongoing training is provided to all employees on a consistent basis. The opportunity for ongoing training occurs in many different forms. The following list suggests a number of different types of ongoing training:

- Laboratory staff meetings - these can cover a variety of technical topics. There is no organized agenda and interaction between all attendees is encouraged (much like an open forum). Examples of topics could include technical subjects/analytical method updates, customer service issues, health and safety, etc. This training must be documented.
- Laboratory audits – the staff can consult with the auditor (of both internal and external audits) and ask questions to be advised on many topics.
- Workshops provided by professional organizations, regulatory agencies or instrument/equipment vendors. Prior to approval of a workshop, the national director or QA department will review the credentials of the workshop provider and/or trainer to ensure competency in the area to be covered. If a certificate is not provided by the outside trainer, such as in a workshop, an open use training form is completed for each described topic covered during the training. A copy of this training record is maintained in the laboratory files.

2.5.4.2 Ongoing Demonstration of Capability

Continuous demonstration of capability by each analyst is achieved through the QC reanalysis of samples by the same analyst (intra-analyst), different analyst (inter-analyst), inter-laboratory analysis, the analysis of standard reference samples/LCS's and performance in proficiency testing programs. This is performed at a minimum of every six months and is documented with:

- copies of reports of individual analysts performance in proficiency testing programs (stored in employee training files)
- copies of reports of individual analysts performance in round robin programs (stored in employee training files)
- analytical quality control reports (QC results, standards analysis, etc.) generated during the course of analysis. *Note: This data is normally stored with the laboratory quality control data vs. in the individual analyst's files.*

Whenever possible, inter-analyst QC should be performed by analysts that have completed their training and for whom certifications of demonstration have been completed.

2.5.4.3 Recertification Statements

Every 12 months (or 6 months for AIHA accredited methods), the laboratory manager

shall sign a Recertification Statement for each analyst to document continued authorization to perform analysis. If the laboratory manager is also authorized to perform analysis, the national director shall review and sign the Continuing Certification Statement for the laboratory manager. The Recertification statement will be attached to the original DOC certificate in the analyst folder.

2.5.5 Measurement of the Effectiveness of the Training Program

The effectiveness of our training program is evaluated using a number of identifiers. These include:

- Analysts performance in the quality control program (inter/intra analyst, analysis of standards, blanks)
- Performance in proficiency testing programs
- Evaluation of data generated in round robin programs
- Analysis of blind QC samples
- Performance at internal and external onsite site audits

The evaluation of any of these identifiers may identify the need for additional training or modifications to the training program. Some examples of findings that may indicate training needs include:

- Poor performance in the quality control program
- Outliers reported in proficiency testing programs or round robin programs
- Findings noted during internal and external audits
- Feedback from laboratory staff self-identifying training needs
- Trends in non-conformities reported in the laboratory

2.6 Authorizations Log

Laboratory managers are responsible for maintaining an authorizations log which compiles all authorizations into one document for quick reference. The log lists lab personnel and critical tasks on one chart along with dates of authorization and the laboratory manager's initials authorizing personnel to perform these tasks. The log contains both technical tasks (preparation and analysis of samples) as well as any non-technical tasks which are critical to the operations of the laboratory (e.g., ordering supplies, discussing reports with customers, logging in samples). Laboratory managers are authorized and responsible to grant the authorizations for non-technical tasks not covered by the Demonstration of Competency policies above.

The Authorizations Log spreadsheet and its "Instructions" tab, is available on E-link.

2.7 Ethics and Data Integrity Procedures

This section describes one of the key elements of this quality assurance program. A proper ethics and data integrity program establishes the principals which ensure the well being of the company and all of its staff members. It presents the company values on honesty, integrity, excellence and trust.

2.7.1 Ethics Policy

As a condition of hire, every employee is required to sign an acknowledgement of the Corporate Ethics Policy. The policy, along with the signature is to be maintained in the personnel files. This policy is as follows:

EMSL Analytical, Inc
Corporate Ethics Statement

In order to comply with The NELAC Institute and ISO 17025 standards and to provide the highest level of proper, honest, reliable, legal and ethical service to EMSL Analytical, Inc.'s customers, EMSL requires that each employee comply with the following Corporate Ethics Statement ("Ethics Statement"). This Ethics Statement mandates that each EMSL employee perform their jobs honestly, properly, ethically, and legally and that each EMSL employee perform their assigned responsibilities with the utmost regard for the standards set forth in this Ethics Statement and in the EMSL Employee Handbook. Under no circumstances will any EMSL employee act dishonestly, unreliably, unethically, or unprofessionally while engaged in employment with EMSL. Without limiting what EMSL may consider acts that violate this Ethics Statement, examples of prohibited acts follow:

1) Fabrication of data of any kind, including but not limited to,
- Reporting data for samples not analyzed
- Quality control or customer results
- Training records
- Calibration measurements
- Maintenance records

2) Intentional misuse of company resources, including but not limited to:
- Changing documents without proper authorization or embezzling documentation (Manuals, Standard Operating Procedures, company generated forms)
- Performing unauthorized services for personal use or for use by an EMSL competitor or for any other non-EMSL purpose or use
- Misuse of office resources (phone, fax, internet etc.) for any non-EMSL purpose or use

3) Back-dating data

4) Misrepresenting or fabricating performance (e.g., sample volume, billing, etc.)

5) Misrepresenting qualifications (e.g., experience, academic training, etc.)

6) Disclosing information in contravention to, or in disregard of, customer confidentiality agreements

EMSL prohibits these and any other act that violates the Ethics Statement or the EMSL Employee Handbook. The officers, managers and employees of EMSL will not condone, tolerate, encourage or ignore: any unprofessional, illegal or unethical actions that are directed towards or impact a person's work at EMSL, EMSL customers or potential customers, or a person's co-workers; or any act that violates the Ethics Statement or the Employee Handbook. In addition, no officers, managers or employees of EMSL shall be offered, given or accept any encouragement, monetary or otherwise, to perform acts which violate the Ethics Statement or the Employee Handbook.

The management of EMSL strives to ensure laboratory employees (especially analysts) are not exposed to undue pressures such as:

- Impossible time constraints (turnaround times)
- Customer influences that may effect analysis
- Pricing/marketing issues
- Productivity rates*

If employees feel that they are exposed to any undue pressure, the situation should be brought to the attention of that staff member's immediate supervisor. If the supervisor is unable or unwilling to resolve the issue, or if the source of pressure originates with the supervisor and the staff member feels they can not bring it to their attention, the situation may be reported to the lab manager or corporate management for review.

NOTE: The corporate management of EMSL must monitor analyst's productivity rates as a normal course of business. Reasonable rates of analysis are used as guidelines to help determine analysts' ability. At no time are analysts given productivity goals that are unreasonable.

Employees are required to report to managers located at EMSL branch offices, EMSL Corporate Officers/Managers or human resources department located in Westmont, New Jersey all acts by EMSL employees, managers or officers that may violate this Ethics Statement. The failure to report such actions may subject that person(s) to the punishments set forth below and in the Employee Handbook. Reporting unprofessional and/or unethical behavior will not negatively impact employment and will not jeopardize the employment status of any EMSL employee.

If an unfortunate event occurs where a customer or fellow employee asks a staff member to perform in an unethical manner, the situation will be brought to the attention of that staff member's immediate manager. If the cause of pressure comes from the immediate manager, the situation may be brought to the next level manager for resolution. At all times, an ethics issue may be brought to the human resources department or other corporate management by any staff member.

If a violation or potential violation of this Ethics Statement has been reported, it will be investigated by the Laboratory Manager and/or by corporate management. Depending on the findings of that investigation, any violation of the Ethics Statement may subject the offending employee to disciplinary or corrective action as outlined in this Ethics Statement or the Employee Manual. Following investigation, if it is determined that a violation has occurred, EMSL, in its sole discretion, may determine appropriate disciplinary or corrective action as outlined in the Ethics Statement or Employee Handbook, which may include:

- Verbal warning
- Written warning
- Termination of employment

In addition to the above, EMSL reserves all rights to take appropriate legal action when it deems necessary. Employees must also be aware that breeches of personal and legal data integrity may lead to civil liability/criminal prosecution and fines/punishment.

2.7.2 Data Integrity

The data integrity policy is a piece of the ethics policy relating to fabrication of data and misrepresentation of results. EMSL complies with the NELAC standard requirements addressing data integrity procedures as described below.

Training: The training policy and procedures are described in the "Ethics and Data Integrity Training" section of this Manual.

Signed data integrity documentation: The ethics statement is signed by each employee as a condition of employment. In addition, a Quality Assurance Manual compliance disclosure form is executed by each employee (see "Compliance Disclosure" at end of the QAM). This compliance disclosure states that: "In executing this Compliance Disclosure, I attest and confirm that I have read and understand the entire contents of this document" (i.e., this manual).

Periodic monitoring of compliance with the data integrity and documentation policies is performed through:

- Review of monthly quality control reports: Reports are submitted to the Quality Assurance Department for review. This review includes a check on integrity such as misrepresentation of data, falsification of results, etc. Reports of review are completed and made part of the annual management review report.
- Monitoring of proficiency testing performance: Scores of PT samples are summarized in a report and reviewed by the QA manager, the national director and vice president.
- Investigations initiated by a customer compliant: see section of this Manual – "Procedures for Dealing with Non-conformities and Corrective Actions."
- Internal audits.
- Periodic submittal of blind samples by the QA Department.

2.7.3 Ethics and Data Integrity Training

One of the objectives of the quality assurance program is to ensure the staff of EMSL is provided training in the aspects of ethics and data integrity as they pertain to corporate policy. The goals of this training program are:

- 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)
- The understanding of the impact of our actions

Training will be provided in the form of required readings, staff meetings and corporate issued newsletters. Corporate management and the laboratory manager are responsible for ensuring that this training is provided to the staff and that records are maintained documenting the training.

2.8 Training & Personnel Files

Personnel and training files shall be maintained for all technical employees. Personnel files shall contain all general documentation associated with the employee. Training files shall include all files associated with the initial and ongoing training of the employee.

A completed personnel file must contain at a minimum:

- Job Description (signed)
- Resume/CV
- Signed Ethics Acknowledgment
- Diplomas for degreed employees (transcripts may also be included)
- Copies of any registrations/certifications held by analyst

A completed training file must contain at a minimum:

- Training checklists for all analyses for which the analyst is qualified
- Demonstration of Competency certificate (DOC) showing all analyses for which the analyst is authorized
- Raw data supporting initial DOC for all analyses*
- Summaries of data reviewed to demonstrate ongoing capability*
- Misc. training records (certificates from classes taken and in-house training sheets)
- For Asbestos: NIOSH 582 training certificates
- For Lead: 4 independent runs for each matrix

- Results of performance on proficiency testing samples/round robin samples.

***Note:** Copies of raw data shall be included in all personnel folders supporting the initial demonstration of competency for the analyst. For some instrumental IH and chemistry analysis this may be impractical due to the volume of documentation from the instrument. As a result, these may be summarized in the training folder with reference made to where the original data can be found. Copies of the original raw data shall be maintained for the length of employment and for five (5) years after the end of employment. For ongoing demonstration of competency, summaries of data reviewed with references to the original data are sufficient in the training folders.

Files are to be maintained and updated by the laboratory manager.

2.9 Relevance of Personnel Activities and Communication by Management

Management communicates to the staff the importance of their role in customer needs, regulatory requirements and involvement to the achievement of the objectives of the management system through this QA Manual, newsletters, management meetings and teleconferences and periodic phone conversations.

Communication between staff and management is also performed on a regular basis through scheduled regional conference calls, periodic phone conversations with the EMSL national director, quality assurance manager and vice presidents.

Correspondence is also performed through the monthly quality control reports (for asbestos, microbiology and lead), the quarterly quality control reports and the annual management review.

Management ensures that employees are aware of their role in the achievement of the objectives of the quality management system by requiring employees to sign acknowledgment of understanding of this QA Manual.

Revision History below begins with Revision 10 of all modules. All prior revision history is available through the corporate QA department

Revision	Date	Changes
10	12/19/08	Minor editorial changes throughout. Added Revision History. Divided QAM into separately controlled sections for simplified revision. Revised language of Section 2.2.1 to clarify relationship of LA Testing . All references to "Quality Control Coordinator" in Section 2.3.4 changed to "Quality Manager" to better define the position and match accrediting body terminology, references to "QC" in responsibilities updated to "QA/QC". New Section 2.3.9 added, subsequent section numbers updated. Sections 2.4.1-8 added. Section 2.5 restructured and reorganized. • 2.5.2 becomes 2.5.2.1 and second paragraph added incorporating info previously found in 2.5.7. • 2.5.3 becomes 2.5.2.2 and clarifies qualifications of trainer previously found in 2.5.7. • 2.5.4 becomes 2.5.2.3 and adds sentence on selection and approval of courses. • New Sections 2.5.3 and 2.5.4 absorb previous sections 2.5.6, 2.6

		and 2.5.5, 2.6 respectively. Sections expanded to better explain training and demonstration of competency (DOC) requirements and procedures. DOC certificates are now to be issued by corporate QA Dept and recertification statements are to be used instead of re-issuing the DOC certificate itself. • 2.5.8 becomes 2.5.5 and examples of effectiveness evaluation findings that may trigger additional training are included. New Section 2.6 included which requires use of an authorizations log. Sections 2.7.1.1 and 2.8 moved into Ethics Policy itself as found in Section 2.7.1. Also added procedures for reporting undue pressure, and ability to report any ethics issues to the human resources department.= Section 2.8 title and content updated to refer to personnel & training files, and provide minimum contents for these files.

3.0 STANDARD OPERATING PROCEDURES

3.1 Scope

Instructions or procedures for the activities affecting the quality of our analytical services shall be developed by management. This quality assurance program shall be used as a guideline for their development, use and revision.

Technical 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.

General and Administrative SOPs include:

EMSL Complaint Resolution SOP – *Standard Operating Procedures for Complaint Handling and Resolution*

EMSL Corrective Action SOP – *Standard Operating Procedures for Non-Conformities and Corrective Actions*

EMSL Preventive Action SOP – *Standard Operating Procedure for Preventive Actions*

EMSLQCPRGMSOP – *Standard Operating Procedures for the Quality Control Program*

EMSL Electronic Sig - *Procedures and Policy for Final Report Approval Using Electronic Signature*

EMSL.Controlled Document SOP – *Standard Operating Procedures for Document Control Program*

EMSL.DocumentMasterList SOP – *Standard Operating Procedures for Maintaining Master Lists of Documents*

EMSL.Control of Records SOP – *Standard Operating Procedure for Control of Laboratory Records*

EMSL.QAAUDSOP – *Standard Operating Procedure for Internal Quality Assurance Audits*

EMSL Annual Management Review – *Standard Operating Procedure for Annual Management Review Reporting*

Analytical SOPs – A list of relevant analytical SOPs for each analytical method is found in the appropriate modules. These SOPs cover methodology for analytical procedures, calibrations, contamination checks, reporting procedures and quality control frequency.

The laboratory manager is responsible for ensuring the SOP's reflect the actual laboratory procedures. Managers are to submit suggestions for revisions to the QA manager for review. The QA manager is responsible for controlling revisions and distribution of the SOPs. (See “Document Control and Control of Records” section of this manual).

If analysis is performed using modifications to the EMSL SOP or the standard published methods, the final report will describe the modification in the report title or in the form of a disclaimer. See method SOPs for specific detail.

3.2 Method Validation

The majority of the procedures utilized by EMSL laboratories are based on published methods issued through governmental regulatory agencies and independent standards organizations. Our procedures rely on the validations provided in these methods. Methods used by EMSL are continually validated through the review of QC analysis including analysis of known standards, inter/intra analyst reanalysis of samples, participation in round robin programs and proficiency testing programs.

3.3 Non-standard Methods/Departures from Standard Operating Procedures

3.3.1 Use of Non-standard Methods

Before any non-standard method is implemented, the customer (or other recipient) must be consulted on the new procedures. The customer should provide approval prior to beginning the work.

Non-standard analytical procedures must be written and validated. The method validation process should prove that the alternate method:

- Meets acceptable criteria for precision and accuracy (see validation section below)
- Meets or exceeds analytical sensitivities required by the customer
- Does not introduce uncontrolled or unknown biases, including matrix interferences

3.3.2 Departures from Standard Operating Procedures

Major departures from the EMSL standard operating procedures must go through a review by the national directors, regional managers or quality assurance manager prior to use. Major departures include but are not limited to:

- Different sample preparation procedures
- Use of alternative analytical instrumentation
- Use of additional or different reagents.

Departures from standard operating procedures may be a result of a customer request. Review and documentation of major departures include:

- Reason for deviation from method
- Validation of procedure
- Applicability of alternative method
- Availability of needed resources (if applicable)
- Assurance that data is reported with appropriate references and disclaimers (if applicable)
- Record of alternative procedure or policy is maintained as part of the corporate files.

3.3.2.1 Validation of Non-standard Methods or Departures from Standard Operating Procedures

A validation study must be performed for any non-standard method or departure from method. A validation study involves:

- Comparison against established methods (if available)
- Effects of deviation
- Results are equal to or better than the original method (if original method exists)

The procedure used to validate a method can be an ongoing process with continuous review of the QC data - including analysis of standards, inter/intra analyst reanalysis of samples, participation in round robin programs and proficiency testing programs.

Standard quality control acceptance criteria are applied to monitor performance of the method unless other QC criteria are established. If other criteria are used, it should follow general Good Laboratory Practice (GLP) guidelines.

Revision History below begins with Revision 10 of all modules. All prior revision history is available through the corporate QA department

Revision	Date	Changes
10	12/19/08	Minor editorial changes throughout. Added Revision History. Divided QAM into separately controlled sections for simplified revision. Updated list of General and Adminstrative SOPs. Revised last sentence of 3.2 to describe how validation is conducted.

4.0 ACCEPTANCE OF WORK

4.1 Scope

Our services are generally offered as line item tests which reference documented methodologies. Laboratory services are typically requested by the customer as "open order" requests. 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. Management review procedures for open orders, verbal contracts and for the cases where a written contract is established are discussed in this section.

4.2 Procedures for Review of Contracts, Requests and Tenders

A request or contract for services may be made directly to the laboratory manager, corporate management or sales staff. In either case, before the samples are accepted, laboratory management or corporate management must review the request. This review must cover:

- Requirements for analysis - method requested is a standard method (i.e., available on price list) and understood. Special handling procedures (if any) are noted.
- Applicability of the method requested - method is available and applicable for the sample type and result(s) will provide the customer with required information.
- Technical capabilities- training, experience and qualifications of the staff.
- Understanding of the method(s) requested.
- Equipment resources - equipment is available, in working order and calibrated.
- Staff resources – number of personnel to perform the work is suitable.
- Subcontracting - identification of outside services needed to support the request or contract (including other EMSL laboratories).

Under general circumstances, the status of the laboratory capabilities is well established. For example, technical ability and equipment resources are monitored with performance of QC analyses, proficiency testing and compliance with the QA policies documented in this manual (e.g., documentation of SOPs, training requirements, analyst's qualifications, and calibration requirements). Applicability of method and staff resources is more subjective. It is the responsibility of the laboratory management to review the requests and ensure that the laboratory (or laboratory that will be subcontracted to) can perform the services.

4.2.1 Documentation of Review

These management reviews are documented in a manner appropriate to the type of request. The majority of the work being received by EMSL laboratories is established as line item, open ended requests. Requests are generally made by the customer through the sales representative, corporate management or laboratory management. Requests are reviewed and checked against the requirements listed above in section 4.2.

This review - and ultimately the acceptance of the work - is documented with the acceptance of the samples by the laboratory. The acceptance of a sample batch constitutes the review and acceptance of the request (or contract). The initials of the responsible laboratory staff member recorded on the internal chain of custody (in the 'sample accepted' box) document the contract review.

For more formal or complex contracts which involve review by the president or vice president (s), documentation of review is evidenced with the signature of president or vice president on the contract.

4.2.2 Changes to Contracts, Requests and Tenders

If a laboratory is providing services under a written or verbal contract, that contract must be acceptable to both the laboratory and the customer. Any differences identified shall be resolved before the work begins. The customer shall be informed of any deviations to the contract or requests.

Documentation of changes (or resolutions) is to be made as appropriate to the type of request. A simple notation on the chain of custody is sufficient for a change in turnaround time requirements, for example. More complex changes must be more formally recorded.

If a written contract needs to be amended after the commencement of the project, both the laboratory management and customer must agree to those amendments. These amendments must be documented.

4.3 Beginning New Work

The Laboratory Manager must not accept any new work without evaluating the current resources. This includes the availability of not only equipment, but staffing as well. For example, a laboratory must not accept an increase in workload, if the laboratory staff is currently at capacity.

Any question regarding the capability of the laboratory to perform such new work must be brought to the attention of corporate management. The corporate management will either:

1) Provide the additional equipment and/or staff
2) Allocate work through the EMSL network
3) Reject the new work

4.4 New Technical Service

Prior to the implementation of any new technical service, corporate management performs a comprehensive review. This review includes market applicability and availability of resources. The vice president of laboratory services or the president must grant approval. The Quality Assurance Department will ensure that standard operating procedures are written and quality control parameters are established for new methods.

Revision History below begins with Revision 10 of all modules. All prior revision history is available through the corporate QA department

Revision	Date	Changes
10	12/19/08	Minor editorial changes throughout. Added Revision History. Divided QAM into separately controlled sections for simplified revision. Updated section headers to refer to Contracts, Requests and Tenders to mirror 17025 terminology

5.0 SAMPLE TRACKING & CHAIN OF CUSTODY

5.1 Scope

Rigorous sample tracking is fundamental to a QA program. The most thorough and complete analysis is useless if performed on the wrong sample.

Our sample-tracking program is designed, to the extent that it is possible, to meet all litigation requirements. It is also designed to have redundancy safeguards wherever possible.

The procedures summarized below are described in detail in the EMSL Sample Chain of Custody SOP.

5.2 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. The custody of the sample will be tracked via the completion of a chain of custody form.

EMSL Analytical, Inc. does not collect samples. Therefore, the chain of custody begins with the customer in the field. EMSL maintains Chain of Custody documents that customers are encouraged to use where they do not have their own form. Customers delivering samples without a chain of custody form will be required to complete a chain of custody prior to samples being logged-in at the laboratory. EMSL takes possession of samples by signing the "Received" section of the chain of custody form. The chain of custody then accompanies the samples through the laboratory until analysis and final reporting is complete. Original chain of custody forms are returned to the customer with the final test report.

5.3 Sample Receipt

Upon receipt of samples, the administrative coordinator will verify receipt of all samples against the chain of custody form and will check for obvious signs that the samples have been compromised. Any problems with the samples will be reported to the customer immediately. Once samples are deemed acceptable the Chain of Custody will be signed indicating samples have been received by the laboratory.

5.4 Sample Acceptance

Samples are not accepted for analysis until they have been received and reviewed by the analyst or preparatory personnel. If samples are found to be unacceptable for analysis (see SOP for examples of reasons for unacceptability) this will be communicated to the customer immediately and this communication and any resulting instructions recorded.

Before a sample can be analyzed for compliance purposes, it must fall under the scope of the required analytical method. It must be suitably sampled, properly preserved (if appropriate), packaged and have a proper chain of custody. Customers are instructed to ship samples in clearly labeled, non-breakable airtight containers and to package such samples so as to minimize damage or change in condition of the samples. Samples shipped by air must be placed in containers that minimize jostling and damage. Samples should be packaged in non-static packaging. Sampling guides are available in the EMSL Products and Services Catalog.

5.5 Log-In & Internal Chain of Custody

Log-in of samples is accomplished by authorized personnel using the Laboratory Information Management System (Sample Master XP or SMXP). It is at this point that unique order ID numbers and Sample ID numbers are assigned. This order number is physically attached to the sample batch and

serves to identify the sample set throughout the analysis. This, in combination with the customer ID number uniquely identifies each sample. An internal chain of custody is also generated at log-in which documents the handling of samples throughout the laboratory. See the EMSL Sample Chain of Custody SOP for additional details on log-in and internal chain of custody procedures.

5.6 Samples Shipped to Other EMSL Branch Laboratories

Specific procedures are established for situations where a laboratory has received a sample and subsequently chooses to ship out to another EMSL laboratory. Because each of our labs (except NVLAP sub-facilities) maintains their own accreditations, this constitutes a 'subcontracted laboratory'. See section "Subcontracting" in this manual.

5.7 Archival and Disposal of Samples

Once the analysis is complete and the analytical worksheet is signed, the analyst stores the sample in the appropriate storage area. All storage boxes are to be stored in a safe manner for the period indicated for that category of waste, in accordance with regulatory requirements. When a storage box is full, the month in which the samples were analyzed (or similar reference numbering system as appropriate for the operations, i.e., billing number) is marked on it. A new storage box replaces the old one, which is then stored until time of disposal. All samples will be stored so as to provide protection from any possible contamination or loss of integrity.

Specific storage requirements for each analytical method are discussed in the program modules.

Upon request, samples will be returned to the customer.

Revision History below begins with Revision 10 of all modules. All prior revision history is available through the corporate QA department

Revision	Date	Changes
10	12/19/08	Minor editorial changes throughout. Added Revision History. Divided QAM into separately controlled sections for simplified revision. Changed title by adding "Chain of Custody". Much information previously in this section moved to the EMSL Sample Chain of Custody SOP. Modified Section 5.2 by removing most information and replacing with a summary of policy and procedure. Reference to sampling guides in EMSL Services and Products Catalog has been added. Changed references to "Sample Receiving Coordinator" to "administrative coordinator" to correspond to Section 2.0 of QAM. New Section 5.3 added which summarizes sample receipt procedures. Subsequent sections are renumbered as necessary. Section 5.3 renumbered to 5.4 and renamed "Sample Acceptance." Summary of policy replaces first paragraph. Sample Rejection Criteria removed to Sample Chain of Custody SOP. Reference to sampling guides added to last paragraph. Section 5.4 renumbered to 5.5 and renamed "Log-In & Internal Chain of Custody". Replaced contents with summary of policy and procedure. Moved procedure to Sample Chain of Custody SOP. Sections 5.4.1, 5.4.2 deleted.

		Section 5.5 renumbered to 5.6. 5.6 deleted and moved to Sample Chain of Custody SOP. Added final sentence to Section 5.7 noting that upon request samples may be returned to customers.

6.0 SUBCONTRACTING

6.1 Scope

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

The receiving laboratory is responsible to the customer for the subcontractor's work, except in the case where the customer or a regulatory authority specified which subcontractor is to be used.

A summary of qualifications of each EMSL laboratory can be found in the "EMSL Laboratory Qualification Summary" available on E-link.

6.1.1 Subcontracting Analysis to Outside Laboratories

The Quality Assurance Department or national director must perform final approval for use of a non-EMSL subcontract vendor for laboratory services. The customer must be notified and provide approval prior to any subcontracted work that is performed. This approval must be documented. The final report submitted to the customer must be that from the subcontract laboratory.

Subcontract labs will be deemed competent to perform analysis if they hold accreditations appropriate to the analysis being subcontracted or if they can otherwise demonstrate competency through their quality system and performance. If subcontracting analyses for which EMSL is accredited, the subcontract lab must hold equivalent accreditation to EMSL for that analysis. The QA department or national directors must approve all outside subcontract laboratories.

6.1.2 Subcontracting Analysis to EMSL Laboratories

The network of EMSL laboratories provides the customer with a valuable resource. Samples may be shipped out for analysis to other EMSL laboratories when a laboratory is at workload capacity, turnaround time can not be reached or the laboratory does not have the analytical capability.

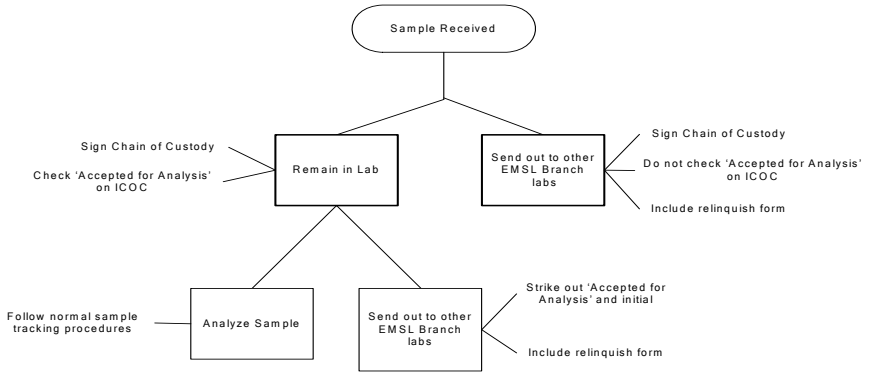
Where a laboratory subcontracts samples to another EMSL facility, a 'contract review' must be performed. This review consists of:

- Verification that the subcontract lab maintains the applicable accreditations
- Check on available staffing resources
- Check on available equipment

When samples are received by a laboratory and the samples cannot be analyzed in that laboratory, the receiving laboratory signs the chain of custody acknowledging receipt (continuing the custody) but does not approve for analysis. The laboratory completes the EMSL relinquish form. This form must be faxed to and signed by the customer – acknowledging notification. If there is a standing relationship with the customer where it is understood that samples will be shipped (for example: where a customer routinely submits samples which will automatically be shipped to another EMSL laboratory for analysis at the customers direction), one relinquish form may be completed covering the whole project.

If the laboratory manager chooses to send the samples out to another branch laboratory after the samples are accepted for analysis, the laboratory must strike out the 'Accepted for Analysis' on the internal chain of custody.

A relinquish form is completed, including customer approval, and then form is shipped with the samples. All relinquish forms are filed in one folder or binder.



When selecting an EMSL laboratory to which to subcontract, the receiving laboratory must ensure that the laboratory maintains the appropriate certifications for the type of work being subcontracted (see "EMSL Laboratory Qualification Summary" available on E-link). The qualifications and capacity of the lab should be verified prior to samples being sent.

6.2 Turnaround Time

The turnaround time for the subcontracted analyses begins at the time the samples are received by the original lab, not the subcontract laboratory. If the requested turnaround time can not be met, this should be discussed with the customer immediately and a new turnaround time agreed upon. The conversation and agreed upon turnaround time shall be documented and communicated to the subcontract laboratory.

6.3 Reporting

The final report submitted to the customer must be generated by the analyzing laboratory.

For analysis performed by another EMSL laboratory, the analyzing laboratory may issue the report directly to the customer using the normal EMSL reporting procedures and format.

When subcontracting to an outside laboratory, reporting will be done from EMSL using the report from the subcontract lab and a cover page from EMSL containing order and customer information and the name of the subcontract lab used.

6.4 Retention of Subcontracted Samples

When samples are sent to another EMSL laboratory for analysis, the samples will be retained by the laboratory conducting the analysis unless otherwise documented in project specific instructions. The original laboratory shall ensure that sample retention policies at the subcontract lab require retention for length of time equivalent or longer than EMSL policies.

When samples are subcontracted to an outside laboratory, the original laboratory shall ensure that EMSL retention policies are communicated to the subcontracting lab and samples retained for the stated period of time.

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Revision	Date	Changes
10	12/19/08	Minor editorial changes throughout. Added Revision History. Divided QAM into separately controlled sections for simplified revision. Reference to the laboratory qualifications summary has been updated in Section 6.1. Paragraph added to 6.1.1 regarding selection of outside subcontract laboratories. Section header 6.1.2.1 removed. Content remains in 6.1.2. Moved Section 6.1.3 (“Subcontracting Equipment”) to Section 9.0. New Sections 6.2, 6.3 and 6.4 added dealing with “Turnaround Time”, “Reporting” and “Retention of Subcontracted Samples” respectively.

7.0 DATA PROCESSING AND VALIDATION

7.1 Scope

EMSL utilizes an automated Laboratory Information Management System (LIMS) to record, document and assimilate pertinent field, laboratory, and administrative data. The LIMS system is referred to as Sample Master XP (SMXP).

The validation of the SMXP software, including final report templates are performed by the corporate IT Department and the Quality Assurance Department. The IT Department is responsible for maintaining updates and revisions and for tracking distribution. Release notes for each release of SMXP are prepared and distributed by the IT Department. A complete release history and historical release notes can be obtained from the IT Department at any time.

Data validation is 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.

Note: Sampling is a significant factor in the meaningfulness of results; however, because sampling is not performed by EMSL, this aspect is out of EMSL's control and will not be dealt with in this section.

7.2 Validation of Computer Software, Data and Final Reports

Analytical data storage, processing, and reporting are facilitated through use of SMXP. SMXP software is run on Windows-based, PC computers. The corporate IT staff are responsible for ensuring that all computer systems, hardware and software, are documented, inventoried and adequate for use. All systems are operated in safe environments and maintained to ensure proper operation. The computer systems responsible for handling of analytical data have been set up to process data in a way that ensures integrity.

All computerized systems, especially the software used for data reporting, must be initially validated prior to use and then subsequently periodically re-checked during the ongoing validation process.

7.2.1 Initial Validation

All calculations and reporting performed by the software is implemented by the laboratory management, the corporate IT staff or the QA manager. This coordination between the QA Department, laboratory management and the IT Department allows the software to be reviewed and altered as necessary to comply with regulatory agencies and/or accrediting organizations requirements.

EMSL employs a system to periodically test and verify that the software used for sample log-in and report generation is performing properly. To do this, a "dummy" set of samples has been created for each type of analysis that the lab performs. Each set has a sufficient number of samples to be able to test as many variables as possible. Examples are:

- No volume
- Low volume / low sample weight
- High volume
- Low concentration
- High concentration
- None detected
- Overloaded sample

The "dummy" sample reports are proofread for accuracy of all text fields and all results have

been verified by hand calculation. The results of each periodic software validation are documented along with the date performed. If there is any discrepancy from the master that cannot be attributed to data entry error, the QA Department is notified and corrective actions implemented.

7.2.2 Continuous Data Validation

In addition to the initial verification, there is a continual validation process that occurs each time that the laboratory manager proofs a report prior to release to the customer. If any of the errors that are found during this proofing process are not traced back to transcription or analytical error, then the computer system is suspect and will be investigated. The processes that undergo this continuous validation include:

7.2.2.1 Sample Receiving

At completion of the log-in phase, the internal chain of custody and bench sheets appropriate to the analysis requested are produced by SMXP. Also at this time an internal chain of custody is produced. This document summarizes the sample set with customer and sample information (including ID's), and generates a chain of custody log that is initialed and dated by everyone that handles the samples in the laboratory. The laboratory manager checks the accuracy of this information generated SMXP.

7.2.2.2 Sample Preparation

After log-in, the samples and all its corresponding paperwork are sent to the lab for preparation prior to analysis. Upon receipt, the prep person and/or analyst initials and dates the internal chain of custody. At this stage too, any problems with the samples or paperwork are noted and brought to the attention of the laboratory manager.

7.2.2.3 Sample Analysis

After sample prep, the samples and all corresponding paperwork are sent to the analyst. Upon receipt, the analyst initials the requested analytical method on the original chain of custody and dates the internal chain of custody in the appropriate section. At this stage too, any problems with the paperwork (or samples) are documented on the sample paperwork and also brought to the attention of the laboratory manager.

The analytical process is obviously one of the most important stages in assuring data validity. The procedures taken to ensure the validity of the sample result include calibration of equipment, formulation of method detection limits, instrument detection limits, determination of analyst qualifications, instrument, and lab precision and bias, etc. are very specific to the particular analysis being performed. Details of these procedures can be found in the SOPs for the various analyses.

7.2.2.4 Analytical Results Entry

Once sample analysis has been completed, all paperwork including field data sheets, field chain of custodies, internal chain of custodies, sample bench sheets, and any other paperwork that was generated to this point is sent to the data entry personnel. At this stage results are transcribed from the bench sheets and instrumental printouts into the LIMS (or Excel) reporting spreadsheet. Analytical results are entered either by approved data entry personnel, or by the analysts themselves. The software stores the analytical data, performs calculations, and generates the final report. The person performing the data entry would be aware of any error or unusual performance of the LIMS system and would bring this to the attention of the laboratory manager.

This final report is reviewed by the laboratory manager (or designee) and approved before being forwarded to the customer. Chains of custody are copied and placed in the laboratory master files along with the analytical worksheets and raw data.

7.2.2.5 Proofing of Reports

After data entry, reports are sent to the laboratory manager or designee for review. The reports are scanned for completeness and accuracy. A check on the quality control analysis performed in association with the results is performed. This is also the point where transcription errors are caught and corrected. In addition, if the analytical data looks questionable for any reason, hand calculations are performed to verify results. If errors are found, the report is returned to data entry for transcription error corrections or back to the lab if there are problems with the data. The laboratory manager is to investigate the error and the cause determined and corrected. All corrective actions must be documented whether analyst, instrument, or LIMS related.

7.3 LIMS (SMXP) Data & Security

SMXP data is retained in a "live" redundant replicated instances of SQL Server 2005 in a Master database for a minimum of 2 years. Data older than 2 years is migrated to an archive instance of Sample Master LIMS data. This production database contains analytical data for all local and remote company labs. All data from the remote labs is consolidated into the Publisher and Master database using Microsoft SQL Server replication services.

Although our computer equipment has proven to be reliable, unexpected problems do occasionally occur. In the event a problem should arise, the IT staff follows specific procedures to deal with such situations. All SMXP data is replicated to a central SQL Server 2005 database, which functions as the primary backup for the LIMS data. LIMS data is also copied (backed up) onto a backup disc subsystem nightly and transferred to high density tapes which are relocated to secure, temperature controlled, fire proof vaults within Iron mountain to prevent permanent data loss in the case of systems failure, accidents or disasters. The IT staff has the ability to failover to hot spares providing the ability to replace or repair malfunctioning or damaged equipment with a minimum of down time. In most cases, duplicate equipment has been provided, so that if one computer experiences unexpected problems, a duplicate computer can be utilized while the other is being repaired. Systems are in place that ensures computer-related difficulties do not negatively impact the performance of the laboratory.

More information on the backup and archiving of SMXP data can be found in the EMSL Control of Records SOP.

The security of the software is controlled by the corporate IT staff and the laboratory manager. Each computer user is assigned password protected rights and privileges specific to the tasks that the user is allowed to perform. Access to all LIMS analytical related software is password protected on a user-by-user basis to ensure security. The IT staff is responsible for ensuring access to SMXP is controlled and assignments are held secure, using laboratory management approval.

The corporate IT staff are responsible for ensuring that all computer systems, both hardware and software, are documented, inventoried and adequate for use. All systems are operated in safe environments and maintained to ensure proper operation. The computer systems responsible for handling of analytical data have been set up to process data in a way that ensures data integrity with password specific approval assignments. Data integrity is also maintained by performance of daily tape backups as discussed in the Records Management SOP.

7.4 Changes to LIMS (SMXP) Final Report Templates

Changes are made to the SMXP Final Report Templates by way of a “Sample Master Change Request Form” submitted to the QA manager or national directors. The QA manager or national director reviews the requested changes for applicability to methodology, technical validity and regulatory compliance. The QA manager may also consult with the sales and marketing staff on the impact of any change to the

customer and/or business market. Once a Change Request is approved it will be forwarded to the IT department in order to implement the change in the SMXP system.

7.5 Electronic Record Retention Policies

Record retention policies for electronic records are analogous to policies for retention of non-electronic records maintained by EMSL laboratories. These policies are discussed fully in the "Document Control and Control of Records" section of this manual and the EMSL Control of Records SOP, including retention times and disposal.

All digital analytical records are permanently archived. The data is transferred to a disk-to-disk back-up system nightly, and once a week is transferred to high density tapes and transferred to Iron Mountain for storage. Access to these records are restricted and controlled by EMSL record policies and procedures. The record keeping system allows for the reconstruction of all activities required to produce an analytical result.

7.6 Exported Data

Exported data is provided in a variety of formats, depending on the specific needs of our customers. Export formats for data deliverables are implemented and controlled by the corporate IT 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 customer 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 as documented in this manual.

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Revision	Date	Changes
10	12/19/08	Minor editorial changes throughout. Added Revision History. Divided QAM into separately controlled sections for simplified revision. Clarified that SMXP is the LIMS system used by EMSL. First paragraph in Section 7.3 moved from "Electronic Data" section of 7.6. Information on backup of LIMS data extracted from section and reference to the "Control of Records SOP" added. Updated form name in Section 7.4. Added last sentence of section. Changed name of Section 7.5 to "Electronic Record Retention Policies", removed text from this section and moved to the "Control of Records SOP" and referenced this SOP. Added final two paragraphs of this section. Deleted old Section 7.6 and moved to "Control of Records SOP". Renumbered subsequent section.

8.0 QUALITY OF MATERIALS AND SERVICES/PURCHASING

8.1 Scope

The high quality of materials used in the laboratory shall be assured through specific purchasing and verification procedures and proper handling techniques.

8.2 Reagents, Reference Materials and Reference Standards

Selection of the appropriate grade of reagent(s) is designated in the reagent section of each analytical 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, reference standards and reference materials shall be purchased in accordance with the analytical needs of the laboratory as determined by the laboratory manager. Reference materials and standard reagents shall be obtained from the vendor with a certificate of analysis (certificate must identify the lot number). This certificate will be maintained in the laboratory files.

When received by the laboratory, the labels of the reagents and reference materials are dated and initialed with date received and expiration dates provided by the manufacturer. Labels are also dated and initialed when opened and/or when reagent mixtures are prepared.

If no expiration date is given by the manufacturer, one must be assigned. Using a relatively subjective method, the lab manager assigns a date, depending on the material. For example, an expiration date for an (extremely stable) asbestos standard could be assigned at 10 years. At the 10 year date, the standard would be evaluated for possible contamination, change in concentration (if a mix of materials) and verified by calibration. In all cases, every reagent and standard must have an expiration date assigned.

Laboratory managers are to purchase reference materials and reagents in the smallest quantities practical to help reduce inventory. A reduced inventory will be used up more frequently, avoiding the possibility of having the standard stored in the laboratory past the expiration date.

Reference standards shall be NIST-traceable and include a certificate showing traceability. This certificate shall be stored in the laboratory.

8.2.1 Verification of Reagents and Reference Materials

Verification will consist of confirming that the purity grade recorded on the reagent or reference material label conforms to the requirements of the SOP unless analysis difficulties indicate a possible problem (with QC or sample analysis) or regulatory agency requirements specify otherwise. In the latter case, the analytical SOP will identify the appropriate reagent.

8.2.2 Storage and Handling of Reagents, Reference Materials and Reference Standards

Reagents, reference materials and reference standards are to be stored in a manner which will conserve the purity and integrity. Reagents and reference materials are stored following manufacturers requirements (temperature, humidity, etc.). Care must be taken when handling reagents to avoid contamination or evaporation. Lids must be kept secure when not in use. Reference standards shall be stored according to manufacturer requirements and used only for calibration unless it can be shown that their performance as reference standards would not be invalidated.

8.3 Consumable Supplies

Consumable supplies are to be purchased based on laboratory needs as determined by the laboratory manager. SOPs will indicate the specific grades and classes of consumable supply items to be used. Analysts are not to re-use expendable materials intended for single use purposes such as microscope slides, plastic centrifuge tubes, etc.

8.4 Purchasing

Supplies are purchased through the corporate Purchasing Department based on requests made by the laboratory manager. This allows for company wide control and standardization of consumable supplies. EMSL purchases critical supplies from well-known industry vendors such as VWR, Fisher and Health Link. For the most part, EMSL relies on the vendor's certification in ISO programs and business reputation for the quality of products and services. Evaluation is also performed during the actual application of the product during the laboratory's daily work. This type of product quality evaluation is an effective and on going process. The quality of the products purchased is continuously monitored with the normal quality control checks. These checks include:

- Laboratory blank analysis data
- Calibration measurements
- The analysis of standards
- Review of reanalysis data

The laboratory manager will notify the corporate Purchasing Department if any product is found to be defective or not within standard acceptance criteria, The Purchasing Department maintains records of consumable supplies that have not met the standards set forth in the analytical SOP or have been identified by the laboratories as not meeting the quality criteria. This department is responsible for ensuring these types of supplies are not purchased, or otherwise utilized by the laboratory facilities.

The laboratory manager is responsible for approving supplies used for analysis (such as reagents, slides, disposable funnels, etc.) once received. The manager is to ensure that the product received meets the requirements for grade and quality according to the QA policies, SOPs and published methods. The approval is documented by the lab manager (or designee) with his/her signature on the packing slip received with the product. This packing slip is then forwarded to the corporate Accounting Department.

8.5 Service Providers

Where outside services are contracted that effect analytical testing such as calibrations, repairs to equipment, adjustments to instrumentation, checks on performance, etc., the vendor must be accredited under the ISO 17025 standard, where applicable.

The laboratory and/or the corporate Purchasing Department maintains list of approved service providers. Considerations for the approval of providers include:

- accreditation in the ISO standard (where relevant)
- reputation
- history of performance
- referrals

All service must be documented and filed by the laboratory.

Revision History below begins with Revision 10 of all modules. All prior revision history is available through the corporate QA department

Revision	Date	Changes

10	12/19/08	Minor editorial changes throughout. Added Revision History. Divided QAM into separately controlled sections for simplified revision. Section 8.2 title revised. Section updated to take account of reference materials in addition to reference standards. Last sentence added to Section 8.2. Section 8.2.1 updated to apply to reference materials. Section 8.2.2 updated to apply to reference materials and standards. Last sentence added to section.

9.0 ANALYTICAL EQUIPMENT/INSTRUMENTS

9.1 Scope

The quality and maintenance of equipment plays a critical role in providing quality analytical services. This section discusses the overall policies and procedures used to ensure that laboratory equipment meets quality standards.

9.2 Equipment Maintenance

The laboratory manager in cooperation with the corporate QA department shall determine whether an instrument is maintained and repaired in-house or by an outside service firm. Servicing will also be performed when a need has been identified by calibration or other QC checks. When special service is needed, the laboratory manager should notify the national director and corporate QA manager of the need and reasons for service.

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. Each instrument service entry shall contain the following information:

- Date and time.
- Initials of servicing individual (include if in-house or outside agency).
- Description of problem.
- Maintenance element examined and if any repairs/replacement of component were made.
- Pertinent comment(s).

Where regular maintenance schedules are necessary (spectrophotometric instrumentation, for example), the schedules are documented in the analytical SOP. The laboratory manager is responsible for ensuring maintenance schedules are met.

9.3 Instrument Calibration

Accrediting authorities and standard published methods have specified the frequency and manner in which a laboratory must calibrate their instruments. Specific calibration requirements are found in the appropriate program module. Generally, outside calibration services (for example, Mettler) are used for calibrating a single reference thermometer per laboratory, as well as a set of weights which can be used as standard references which are in turn used by the laboratory to calibrate all working thermometers and balances. EMSL laboratories service all analytical balances in-house.

9.4 Defective Equipment

Analytical and support equipment found to be defective or performing poorly (out of calibration) is removed from operations until they can be repaired. The defective equipment is to be clearly labeled as "out of service". The laboratory manager is to investigate whether the defect has effected any reported analytical results.

9.5 Instrument Manuals

The laboratory manager is responsible for maintaining and reviewing all instrument manuals pertaining to use, calibration and maintenance. Instrument manuals are to be made available to the analysts. The laboratory manager is responsible to be informed of, and keep current with, all new releases of information on all equipment.

9.6 Authorization to Operate Equipment

The laboratory manager is responsible for ensuring that only authorized personnel operate the major laboratory instrumentation. Authorization is granted based on training and experience as detailed in each of the method sections. Authorization may be given to personnel through the completion of the qualifications checklist or verbally, depending upon type of instrumentation. For example, approval for operation of the transmission electron microscope or spectrophotometer is recorded on the training checklist while the approval for an acetone vaporizer or water bath may be done verbally.

9.7 Equipment Serviced or Calibrated by an Outside Vendor

In the event any major equipment is sent out of house for repair, the laboratory manager will maintain a file documenting:

- Date of shipment
- Vendor information
- Service needed
- Date of return

This information is to be recorded on the "Equipment Maintenance Log" form.

The laboratory is responsible for ensuring all equipment is calibrated prior to placing back into service. Calibrations must meet the acceptance criteria established for that equipment.

Where reference materials or equipment is sent to an outside vendor for calibration, the calibration must be performed by an ISO accredited company. The certificate of calibration must indicate the calibration had been performed following the ISO standards.

9.8 Subcontracted or Leased Equipment

Any laboratory equipment, which is to be used during analysis, other than EMSL equipment, (e.g., equipment borrowed/eased from an outside organization such as an academic institution), must undergo complete calibration, applicable start-up procedures and QC checks, as described in the laboratory SOP for the utilized instrument. These procedures must be performed prior to the start of any sample analysis. All maintenance records, manuals, and performance records must be made available for review and approval by EMSL staff.

Records are to be maintained which include:

- Type of instrument subcontracted
- Date and purpose
- All raw QC data generated including calibration information

9.9 Equipment Handling, Transport and Storage

The management of major laboratory instrumentation is performed at the corporate level by the Department of Instrumentation and Planning. This department purchases, tracks and ships primary analytical instrumentation and a variety of support equipment.

9.9.1 Shipping

Equipment is assigned a serial number and inventoried. Packaging and shipping is handled internally for equipment which is relatively easy to handle such as optical microscopes, hot

plates, etc.

A professional hauling service vendor may be used for large equipment (generally > 100 lbs.) such as TEMs, spectrophotometers and fume hoods or where equipment is fragile.

Once equipment has been received by the laboratory, the instrumentation must undergo performance checks including:

- Calibrations
- IDL and MDL study (where applicable)
- Quality control checks.

These performance checks may be completed by the Laboratory Manager and/or the Department of Instrumentation and Planning depending on the type of instrument and the ability of the laboratory manager. All checks are documented in the laboratory equipment maintenance log. *(Note: see also the analytical SOP for that test applicable to the specific instrumentation*).

9.9.2 Storage

Laboratories are to adhere to the manufactures' requirements for the storage of instrumentation.

9.9.3 Local Equipment Inventory

Each laboratory is required to maintain an inventory of all critical equipment in use at the laboratory. Since each laboratory's inventory varies according to size and scope of work performed at the laboratory, it is the responsibility of the lab manager to ensure that this equipment inventory reflects actual equipment at that laboratory and includes wherever available the manufacturer, model, serial number, date put into service and date taken out of service. This equipment inventory is maintained in the "Equipment Inventory" spreadsheet.

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Revision	Date	Changes
10	12/19/08	Minor editorial changes throughout. Added Revision History. Divided QAM into separately controlled sections for simplified revision. Section 9.2 updated to clarify decision making authority for equipment maintenance requests. Last two sentences added to Section 9.3. Section 9.7 - Updated name of Equipment Log template used to record service and/or calibration of equipment. New Sections 9.8 and 9.9 (and subsections) added addressing "Subcontracted or Leased Equipment" and "Equipment Handling, Transport and Storage", respectively.

10.0 CONTAMINATION MANAGEMENT

10.1 Scope

This section describes reagent control and contamination management. Proper observance of these procedures is necessary to guarantee accuracy of results and the safety of laboratory staff members.

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

Contamination control is focused both on sources and on targets of contamination.

Sources would include:
- Samples
- Laboratory debris

Targets would include:
- Samples
- Equipment, such as tools
- Supplies, such as microscope slides and reagents
- Work areas

Contamination control consists of 3 parts:
- Avoidance
- Detection
- Resolution

10.2 Contamination Avoidance

To avoid contamination, the following procedures must be followed:

- Maintain good housekeeping
- Clean all tools before and after preparing each sample
- Clean tool sets at the end of the workday
- Dispose of wipers after use. Do not let them pile up during the workday
- Wipe all work surfaces before and after sample preparation. Surfaces include bench tops, slide trays, stereo microscope stage, and slide preparation surface
- Controlling work areas
- Work only on clean surfaces

Only one active sample should be processed at each time. The sample containers are kept closed when not being processed. Inactive samples are stored in a suitable, out-of-the-way area. Target items – samples, reagents, and containers are opened one at a time as practical.

10.3 Detection of Contamination

Contamination control is verified by the evaluation of blank sample analysis and results of air/surface sampling.

10.3.1 Blank Analysis

The number of blank samples analyzed is specified in the quality control section in the appropriate SOP. This data is generated and tracked for the purposes of monitoring any possible contamination only and is not to be used for statistical quality control.

10.3.2 Ambient Air Monitoring/Wipe Sampling

On a quarterly basis, or if there is a reason to suspect contamination, the laboratory is to perform ambient air monitoring and/or wipe sampling through out the facility. This procedure not only helps to monitor possible sample contamination, but also provides data to evaluate any possible personnel exposure.

For air samples, a sampling pump is set up in a location that represents areas of most activity. The pump's rotometer must be calibrated against a primary standard, annually. Sampling is conducted according to the appropriate NIOSH, OSHA or other published method as available. Flow rates, sampling times, media and all other parameters will be in accordance with appropriate methods and good scientific practice.

Specific sample volume, method of analysis and acceptance criteria for the targeted compounds are listed in the individual modules.

Results of these samples are filed in the laboratory. If any result is above the contamination/exposure limit, the laboratory manager must immediately notify the Quality Assurance Department and/or the corporate health and safety officer. An investigation into the source of contamination/exposure is performed and a corrective action implemented. All actions are documented.

See the program specific modules for additional details on quarterly contamination monitoring.

10.4 Resolution

If contamination is detected in any situation, the source of contamination must be traced and the problem resolved to prevent reoccurrence. A Corrective Action Record (CAR) should be completed to document the analysis of the source of the contamination as well as actions taken to resolve a contamination circumstance.

After corrective actions have been completed, and the contaminated areas have been cleaned, re-sampling and analysis shall be performed in order to ensure that the contamination has been eliminated. A subsequent contamination check prior to the scheduled quarterly check may be warranted depending on source and/or type of contamination in order to ensure effectiveness of corrective actions.

Revision History below begins with Revision 10 of all modules. All prior revision history is available through the corporate QA department

Revision	Date	Changes
10	12/19/08	Minor editorial changes throughout. Added Revision History. Divided QAM into separately controlled sections for simplified revision. Section 10.2 updated to require that only a single sample be process at one time. Section 10.3.2 updated to require re-sampling after corrective

		actions for contamination. Also, added reference to the Modules. Section 10.4 revised to address actions to be taken if contamination is detected.

11.0 DOCUMENT CONTROL and CONTROL OF RECORDS

11.1 Scope

EMSL document and record control procedures have been established to meet the requirements of ISO 17025:2005 and the accreditation requirements of AIHA, The NELAC Institute and NVLAP. Procedures and policies apply to all EMSL laboratories.

11.2 Document Control

The EMSL document control procedures are documented in the Document Control SOP and Master List of Documents SOPs. EMSL's document control program covers the initiation of new controlled documents, annual review and maintenance of controlled documents, and retirement of obsolete documents.

EMSL controls documents to ensure the laboratories are performing analysis and reporting data following EMSL quality standards. The controlled document program also helps ensure the laboratories are using the latest methodologies and following the most recent procedures. This program also establishes company wide standardization and preserves company property.

The system is briefly described below.

11.2.1 Document Inventories

A corporate Master List of documents will be maintained by the corporate QA department for all controlled documents distributed by corporate which will list how documents are distributed to branch laboratories. Each laboratory will also maintain a local Master List showing distribution of documents within the laboratory.

11.2.2 Initiating New Documents

New documents may be initiated by any EMSL employee but are ultimately approved by the corporate QA manager or national directors following a review for technical applicability, compliance with requirements, and impact on business processes. Once approved, an authorizing signature will be included on all corporately approved SOPs and controlled headers and footers will be added to the document.

11.2.3 Protection of Controlled Documents

Controlled documents will be protected based on the type of document. SOPs and other documents which are text-based are usually converted to PDF prior to distribution. Excel spreadsheets and form templates will be protected using the write protection tools included in Word, Excel and Adobe Acrobat, usually locking the form except for data entry fields. Templates such as bench worksheets which are printed from Sample Master XP (SMXP) are protected through the permissions for accessing Sample Master which restrict the ability to alter the templates.

11.2.4 Distribution of Controlled Documents

Most corporately issued controlled documents are distributed through the E-link site. Once posted an e-mail notification is sent to laboratories notifying them of the new or revised document. In addition, the document is updated on or added to the Corporate Master List of Documents which is also available on the E-link site.

11.2.5 Review of Controlled Documents

Controlled documents will be reviewed once every 12 months to determine their continued suitability. For corporately issued documents, the QA department or national directors will conduct these reviews although they may assign review of documents to other EMSL employees with sufficient experience to determine the suitability of the document. Whenever a document is revised, it will be considered reviewed as of the revision date.

11.2.6 Amendments and Revisions

Documents may be changed through the use of revisions and amendments. Amendments are intended to be minor changes made to a controlled document interim to a full document revision. Revisions will be a complete re-issue of a document.

11.3 Control of Records

The EMSL control of records procedures are documented in the Control of Records SOP. The SOP outlines the requirements of record maintenance but each laboratory is responsible for the logistics of record control in their laboratory. Each laboratory is responsible for maintaining a Records Management Log which documents where records are located and how they are indexed, accessed and stored in the laboratory. General policies include:

All laboratories will retain records of original observations in addition to derived information.
If a record contains a mistake that must be corrected, the mistake shall be crossed out and signed, initialed and dated using indelible ink and the correction made alongside.
Records must never be corrected by erasing, deleting or otherwise making the mistake illegible (e.g., use of correction fluid, correction tape, scratch outs).
Records shall be retained in order to ensure that sufficient information is maintained to allow for an audit trail which includes calibration records, staff records, test report, etc.
Records shall be retained for a minimum of 5 years or for the period of time established by relevant accrediting authorities or contract requirements.
Records shall be protected against fire, theft, loss, environmental deterioration, vermin, and, in the case of electronic records, electronic or magnetic sources.

11.4 Signature/Initials Log

A log of the signatures and initials of laboratory staff will be maintained on file in the laboratory and the QA Department. This log contains:

- Printed name
- Signature
- Initial
- Date of entry

This log facilitates the identification of initials and/or signatures entered on laboratory documentation such as chain of custodies, analytical worksheets, final reports, etc.

Revision History below begins with Revision 10 of all modules. All prior revision history is available through the corporate QA department

Revision	Date	Changes
10	12/19/08	Minor editorial changes throughout. Added Revision History. Divided QAM into separately controlled sections for simplified revision. Section 11.1 updated to reference those agencies for which the

		policy has been designed to meet document and record control requirements. Old sections 11.2-11.9 and 11.11 deleted. Previous content has been moved to the "EMSL Control of Records SOP" and "EMSL Document Control SOP". New Section 11.2 added containing a summary of document control policy and procedures as found in "EMSL Document Control SOP". Reference to SOP included. New Section 11.3 added containing a summary of record control policy and procedures as found in "EMSL Document Control of Records SOP". Reference to SOP included. Section 11.10 renumbered to 11.4.

12.0 REPORTING RESULTS

12.1 Scope

The customer report is, ultimately, our "final product". This report reflects on our standard of quality. This section describes EMSL corporate policy on the procedures, policies and formats for reporting analytical data. Additional, test specific requirements are listed in the program modules.

12.2 Recording Analytical Information

Before beginning analysis of a batch of samples, the analyst is responsible for checking that the labels on the sample containers agree with the data recorded on the chain of custody for that sample. The analyst is also responsible for checking (to the extent possible) that the samples have been collected on appropriate sampling media. Any discrepancies are to be noted on the chain of custody and reported to the laboratory manager.

All analyses must be carried out in accordance with the SOP(s) indicated. All SOPs used in the laboratory will be found in the EMSL Laboratory Standard Operating Procedure Manuals or online via e-link.

Data generated in the laboratory shall be recorded on preprinted analytical data worksheets. Each analytical procedure has its own specific worksheet. Many of these worksheets are generated by the LIMS system at the time of log-in.

Observations, data and hand calculations are recorded at the time they are made and are identifiable to the task. The analyst is to ensure entries on all records are made legibly and using indelible ink. Corrections are made using a single line strikeout with the correct entry written in. Corrections are to be initialed and dated. Obliterating data using ink or correction fluid is prohibited.

12.3 Customer Report Requirements

Each final report will have at a minimum the following information:

- Laboratory identification and address
- Name and address of customer
- Date of receipt by laboratory (or original chain of custody attached)
- Unique sample IDs
- Description of sample (or original chain of custody attached)
- Identification and description of test procedures performed
- Results of testing and analysis
- Any deviations or additions to test specifications
- Name and signature of responsible person (Laboratory Manager or designee)
- Date of issue
- Any applicable disclaimers and statements (See specific SOPs)
- For reports issued under the NVLAP, a statement that the report must not be used by the customer to claim product certification, approval, or endorsement by NVLAP, NIST, or any agency of the federal government.
- Information on any analyses that had been subcontracted (attach subcontract labs report)

The signature of the analyst is not made a part of the final report unless requested by the customer. Analysts accept responsibility for the data generated by signing the worksheets.

Any modifications to the methods cited on the report will include all applicable comments and disclaimers as issued by the QA manager. Approved lists of disclaimers are documented in the analytical SOPs.

12.3.1 Listing of Accreditation/Required Statements

Laboratory accreditation is presented on the report with a reference to the agency, followed by the Lab ID code (such as: NVLAP Lab Code 000000-0).

The citation of the accreditation will not be used in a manner, which misrepresents a laboratory's accreditation status. Citation of accreditation will be provided for the type of analytical test applicable to that accreditation only. If a particular analysis is performed which is not covered by an accreditation program, the report contains no reference to that accreditation agency or contains the statement, "This report contains data that are (is) not covered by the XXXX accreditation". If a final report contains a combination of data for both accredited and non-accredited analysis, the non-accredited tests will be marked as such.

Reference to an accreditation by an applicant laboratory that has not yet achieved accreditation shall include a statement accurately reflecting the laboratory's status. Certificates of accreditation (applicable to the analysis) may be made part of the report if requested by the customer.

The title of the approval signatory shall appear on the final report that displays the accreditation.

In the rare cases where the analysis (or part of the analysis) has been subcontracted, the report will clearly state that the data had been subcontracted. The report will include the statement "This report contains data that were produced under subcontract by Laboratory X." If the subcontract laboratory is accredited, the report will cite the accreditation agency and the Lab's ID code.

12.3.2 Proficiency Testing

Ambiguous reference to a Proficiency Testing Program (PAT) must be avoided. For example, listing of a PAT Identification number must be clearly identified with a statement such as **"EMSL XXXX (location) Participates in the AIHA Proficiency Analytical Testing (PAT) Program for Asbestos: ID #123546"** to avoid inappropriate representation of full accreditation.

12.3.3 Certification of Test results for NELAC labs

For those laboratories, which maintain NELAC certification, final reports will state "the test results contained within this report meet the requirements of NELAC unless otherwise noted".

12.3.4 Statement on Quality Control Results – ELLAP AIHA requirements

For those laboratories, which maintain the ELLAP AIHA certification, final reports will state: "The QC data associated with the sample results included in this report meet the recovery and precision requirements established by the AIHA, unless specifically indicated otherwise."

12.3.5 Suspension of Accreditation

In the unlikely event that a laboratory's accreditation is revoked or suspended, reference (logo and lab code number) to the accreditation and the scope of accreditation will be removed from all applicable documentation until accreditation is reinstated. Documentation includes:

- Final reports
- Marketing materials such as brochures, mailers, etc.
- EMSL website

12.3.6 Reporting to Governing Agencies (Notification of Compliance Reports)

At the request of the customer, EMSL can report analytical results directly to a compliance agency (state water authority, state environmental department, etc.) Results can be submitted on

the agencies specialized forms if requested. In these cases, the original EMSL report must also be submitted.

12.4 Approval/Report Clearance

Final customer reports are released only after the ldata has been reviewed by an approved reviewer. For AIHA accredited analysis the data reviewer must be different from the analyst. This review includes:

Quality Control Review
Quality control analysis performed for that specific batch of customer samples, if any QC was performed related to that sample batch, is compared against acceptance criteria. (*Note: Our quality control program is designed to comply with the requirement of State, Federal and independent accrediting authorities' policy for reanalysis. A minimum of 10% of the total sample volume analyzed by the laboratory is reanalyzed. The analysis of standard and blank samples are also included in the total number required for QC, therefore, this number may vary. The laboratory randomly selects the number of quality control samples out of all the samples analyzed within any given time period for this reanalysis. The quality control samples may or may not include samples associated with the set of results being approved for reporting).*

In addition to QC review, analytical data is reported with confidence based on compliance with this QA program. The traceability of the data reported is ensured through the procedures and policies as documented in this manual, including:

- Delineation of responsibility
- Compliance with analytical standard operating procedures
- Following calibration protocols
- Fulfillment of the required amount of quality control analysis
- Satisfaction of training requirements

Review of Data
A review of raw data (from bench sheets, prep logs, printouts from instrumentation) and the information on the chain of custody is reviewed for correctness and compared against the typed information on the final report.

Appropriate Methodology
Verification that the correct methodology was performed on the samples. This is done with a check on the customers request documented on the chain of custody.

12.4.1 Approved Signatories

An approved signatory is responsible for the technical content of the report and is the person to be contacted by the accrediting authorities or customers in case of questions or problems with the report. Signatories shall be persons with responsibility, authority and technical capability for the results provided. Technical capability is defined as the having the aptitude for understanding the analysis and to be able to recognize an error. It does not mean that the approval signatory must be an approved analyst.

The Quality Assurance Department, regional manager or national director can qualify the laboratory manager as an approved EMSL signatory. (See "Final Report Approval Form and Electronic Signature Sample.")

The laboratory manager may assign designated personnel to perform the task of final review and approval. This designation must be clearly documented (See "Final Report Approval Form and Electronic Signature Sample.")

12.4.1.1 Peer Review by Second Analyst (for AIHA Accredited Laboratories)

Results of analysis must be checked by a second analyst onsite before the final report is

released to the customer. This review is in addition to the laboratory manager's report approval process (resulting in the signing of the final report). The peer reviewer may be the laboratory manager.

This peer review process shall be an independent review, conducted by a qualified individual other than the analyst. The review will consist of a check on raw data, check of calculations (may be brief overview), typographical errors and the 'sensibility' of the results.

This review is documented with the initials of the reviewer, which is placed on the internal chain of custody or the analytical worksheet.

12.5 Verbal Results

Where it is necessary to provide verbal results, it is EMSL policy to discuss analytical methodology and results only. Results are provided 'verbatim' by giving sample number and concentration only. Under no circumstances are results given as fail, pass, meeting acceptance criteria, etc. Interpretation of results is the responsibility of the customer. A note to the file must be made each time verbal results are given (note on the chain of custody and a customer communication log).

12.6 Preliminary Reports

Corporate policy discourages the issue of draft or preliminary data (for example, results that have not yet gone through a quality control review). However, there are circumstances where this may be unavoidable as a result of turnaround time issues, staffing situations etc. If the laboratory manager chooses to provide preliminary data, the report is not signed and will clearly state "preliminary results".
A report is defined as 'preliminary' when it has not been reviewed following the procedures in section 12.4 (i.e., QC checks, manager's review, peer review).

A final, signed report must eventually be provided to the customer. If any changes are made between the preliminary and final reports, the customer is notified with a statement on the final report or by verbal contact.

12.7 Amendments to Final Reports

In the event of any change to the final report after issue, the amended report must indicate that the report is revised, the date of that revision and the reason for the amendment. The revisions must include the original reference number. The statement: "Amended report – this report is an amendment to the test report dated 00/00/00" and the reason for amendment must be included in the report. This statement is added in the report comments area of the report. Customers must be informed immediately of the changes.

The laboratory sample set is not re-logged into the LIMS program. Tracking is done with the laboratory files, which include a printout of the original and amended report. When amendments to the final report result from a non-conformity, a corrective action form will be completed and filed by appropriate personnel following the EMSL Corrective Action SOP.

Changes requiring an amended report include but are not limited to:

- Errors in sample results
- A typographical error (sample location, sample volume, sample id, etc.) that impacts the final results
- Reports issued to incorrect customer

- Changes requested by customer

12.8 Confidential Transmission of Results

In order to ensure that customer confidentiality is maintained when results are reported, a confidentiality statement is included with the results report.

There are a number of forms of result transmission used by EMSL. These include:

1) Fax through Sample Master - A fax cover sheet is automatically included with the transmission. The fax cover sheet includes the standard confidentiality statement. - *"If you are not the stated recipient of this fax and have received this in error, please discard immediately and contact EMSL Analytical, Inc."*

2) Email through Sample Master – The confidentiality statement is (automatically) included in the body of the e-mail - *"If you are not the stated recipient of this email and have received this in error, please discard immediately and contact EMSL Analytical, Inc."*

3) Manual fax – the cover page and report is printed through Sample Master and manually faxed to the customer. The cover page includes the confidentiality statement. *"If you are not the stated recipient of this fax and have received this in error, please discard immediately and contact EMSL Analytical, Inc."* Note: Evidence of transmittal (fax receipt or email record) is to be retained and will serve as a formal record of receipt.

4) Use of LabConnect – The user must agree to the terms before using this service. The agreement includes the statement: *"The results available on this site are provided as a matter of service and convenience for customers of EMSL. They are intended for use only by authorized parties and are confidential in nature. It is the responsibility of our customers to maintain and update their user accounts to ensure that no unauthorized access is allowed by its employees. If you are not an authorized user, do not attempt to enter. While the results have been verified for accuracy against our analytical reports, they are not intended as substitute for a hardcopy or approved electronic report. Please contact your Account Representative if you have any questions regarding the available information*"

5) Mail (US Postal Service) – the front of the mailing envelope includes a statement – *"The information contained in this correspondence may contain privileged and confidential information and is solely for the use of the sender's intended recipient'). If you received this correspondence in error, please notify EMSL Analytical and return to sender".*

Revision History below begins with Revision 10 of all modules. All prior revision history is available through the corporate QA department

Revision	Date	Changes
10	12/19/08	Minor editorial changes throughout. Added Revision History. Divided QAM into separately controlled sections for simplified revision. Section 12.3.1 reference to NVLAP lab code corrected. Note to "Quality Control Review" section of Section 12.4 updated from "Approximately 10%" to "A minimum of 10%". Updated name of "EMSL authorization for report approval" form to "Final Report Approval Form and Electronic Signature Sample."

		Section 12.7 updated to remove required corrective actions for amended reports. Corrective actions are only required when the amendment was the result of a non-conformity. Deleted sections 12.9 & 12.9.1 which have been moved to Control of Records SOP.

13.0 NON-CONFORMITIES, CORRECTIVE AND PREVENTIVE ACTIONS, AND COMPLAINTS

13.1 Scope

This section describes the mechanisms used to identify, prevent and communicate conditions adverse to quality (a non-conformity), determine cause, initiate corrective action, document and report the activities, and verify implementation of the corrective action.

A nonconformity is defined as any failure to meet stated requirements whether these be technical (e.g., failure to meet internal statistically derived limits, use of wrong testing method), regulatory (e.g., AIHA, NVLAP, NELAC requirements) or managerial requirements (e.g., corrective action procedures, log-in procedures).

This section summarizes the requirements set forth in the EMSL SOP on Non-Conformities and Corrective Actions.

13.2 Identification of Non-conformities

A non-conformity is an error or a lack of compliance with the procedures or policies documented in this manual or other requirements as set forth in SOPs or external agency requirements. Errors and other non-compliance issues which are the results of customer actions are not considered non-conformities under this program.

Non-conformities can be identified by anyone. Laboratory technical and support staff, internal and external auditors, and customers may all identify non-conformities in the laboratory's operation.

Non-conformities are detected in a variety of ways. Detection can occur during an audit (external and internal), review of QC data, reported by a customer and evaluations of proficiency testing results.

13.3 Documenting Non-conformities and Corrective Action

Whenever a non-conformity is identified, it will be documented using the Non-Conformity/Corrective Action Record (CAR) form. The template for the CAR is available on e-link, and its use is discussed in detail in the Non-Conformities and Corrective Action SOP. It is used to document the non-conformity, the investigation of the non-conformity, and what actions were taken to resolve the non-conformity and prevent its recurrence.

13.4 Effect of Non-conformities/Stop Work

In order to evaluate the extent of effect a deficiency may have on a result, the laboratory management will consider the following:

1) The significance of the nonconforming work
2) The acceptability of the nonconforming work (is it suitable for use?)
3) Whether customer notification is required
4) The most likely root cause of the corrective actions
5) Whether it is necessary to stop work to prevent additional nonconforming work
6) Determine what is required to resume work (if work is stopped)

A stop work order may be given where a breech in the quality system jeopardizes analytical quality or a failure in procedures presents an eminent safety concern. Any EMSL employee is authorized to stop their own work immediately upon finding a non-conformity that may affect other work or for safety concerns and shall immediately notify laboratory management. The necessity of broader work stoppages will be determined by laboratory and corporate management.

13.5 Root Cause and Corrective Actions

All non-conformities must be handled in a manner which will provide a way to help ensure the deficiency is not repeated. This includes identification of the root cause of the error, determination of corrective actions which will eliminate those root causes and the initiation of those corrective actions. The investigation of the non-conformity will consist of a review of all steps leading up to the non-conforming condition or event. This will include review of QC data, sample tracking, data transcription, instrument calibration, training documentation, and discussion with personnel. See "Corrective Action SOP" for additional details.

13.5.1 Root Cause

Identification of root cause is one of the keys to corrective action and prevention. It helps identify the actual reason for the error. Some examples of a root cause might be human error (e.g., a basic lack of attention by the analyst), or shortage of resources, improper maintenance of equipment, or insufficient training. The Non-conformities and Corrective Action SOP contains a discussion of root cause analysis.

13.5.2 Corrective Actions

When a non-conformity occurs, corrective actions must be initiated and documented. The type and extent of corrective action put into place will depend on the severity and type of non-conformity and determined root cause. Corrective actions may include: additional training of staff, repairs to equipment, additional personnel resources, etc. Corrective actions should not only resolve the non-conformity, but eliminate the root cause of the error in order to prevent its recurrence.

In some cases, a deficiency may be cause to initiate an audit of related activities in order to: 1) help identify cause of the error, 2) ensure no other areas are effected by the error, or 3) provide direction for preventative actions. For example, if a customer makes a complaint about a test result, an audit may be conducted involving:

- Review of calibration measurements and QC data associated with the analysis
- Check on analyst qualifications
- Inspection of log-in procedures

The audit can be 'free flowing' (no use of checklist) but must be documented.

13.6 Time Frame and Follow-Up to Corrective Actions

Corrective actions are to be documented and carried out within a reasonable time frame so as to not jeopardize the quality of results. For example, if a primary instrument calibration is not within stated acceptance criteria (and will effect the sample results), work is to be stopped immediately and the problem corrected.

The laboratory quality control coordinator and/or laboratory manager are responsible for ensuring that corrective actions have been addressed in a timely matter. The lab quality manager must include proof of compliance with the Corrective Action Report.

The laboratory quality manager (QM) and/or laboratory manager is responsible for tracking and reviewing the corrective actions filed for non-conformities. The lab QM and/or laboratory manager must indicate when corrective actions are complete. Follow-up to the corrective action shall also be scheduled and completed in order to determine whether the actions taken have been effective in preventing its recurrence.

The QA Department is responsible for following up on those corrective action reports submitted to the department by the laboratory (see "Reporting of Corrective Action Form" section above). The follow-up shall indicate that the corrective action has been satisfactorily completed and will include a review of the effectiveness of the correction action.

13.7 Preventive Actions

It is EMSL's intention to maintain an active program to prevent occurrences which require corrective actions or where there is a trend in QC data or activities which can eventually result in an error. A proactive program is an important part of the objectives of this EMSL quality program. All staff members are encouraged to assist in identifying potential sources of non-conformities and to identify opportunities for improvement.

Preventive actions consist of the policies discussed in this QA Manual. For example, the quality management system procedures and policies require:

- Analysts satisfy training requirements
- Laboratories perform QC activities at required frequencies
- QC data is reported to the QA Department for review
- Management reports are submitted to corporate management
- Laboratories participate in proficiency testing programs
- Laboratories maintain accreditations from regulatory and other independent agencies

Preventive action measures also include those specific actions taken outside of the normal quality assurance/quality control activities. These actions are those opportunities for improvement associated with a potential non-conformity. This policy requires laboratory staff to attempt to identify potential non-conformities, and apply actions which will prevent an occurrence. These actions are documented using the "Preventive Actions" form.

See "EMSL Preventive Action SOP" for additional information.

13.8 Complaints

Complaints are considered any statement of dissatisfaction with the product or processes of the laboratory for which a reply is expected. Complaints may be received from any party, inside or outside of EMSL. They may be submitted in any form.

It is the policy of EMSL to take all reasonable actions to resolve complaints as quickly as possible. Whenever a complaint is received, it is immediately investigated to determine whether the complaint is factually sound and able to be resolved by EMSL. If a complaint is not factually sound or EMSL is incapable of resolving the complaint (for example, the complaint is not about EMSL, or would require violating regulatory requirements), EMSL will follow-up with the complainant to ensure they are aware of why EMSL cannot resolve their complaint.

If a complaint is sound and capable of being fairly resolved, EMSL will take all reasonable actions to come to a resolution with the complainant that satisfies the complainant's needs while not damaging or

threatening the integrity of the laboratory, its personnel or its results. EMSL's complaint resolution procedure is documented in the EMSL Complaint Resolution SOP.

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Revision	Date	Changes
10	12/19/08	Minor editorial changes throughout. Added Revision History. Divided QAM into separately controlled sections for simplified revision. Added discussion of complaints to section revising section title and adding Section 13.8. Revised definition of "nonconformity" in Section 13.1. Section 13.2 restructured and re-written. Much of the information found in this section removed to Non-conformity/Corrective Action SOP. • New 2nd paragraph added • Old 13.2.1-13.2.3 deleted. New Section 13.3 added based on a modified Old Section 13.3.3. Section contains a reference to CAR form and Corrective Action SOP. Old Section 13.5 becomes 13.4. Clarified that any employee may stop their own work, need to notify laboratory management, and management responsibilities for broad work stoppages. Reference added to Corrective Action SOP. Old Section 13.3 becomes 13.5 with modifications. • Reference to Corrective Action SOP added. • Re-numbered Section 13.5.1 "Root Cause" contains a modified list of root cause examples and reference to SOP discussion of root cause • Re-numbered Section 13.5.2 revised to include severity in determination of extent of corrective actions taken. Sentence added clarifying need to eliminate root cause. • Old Sections 13.3.2.1 – 13.3.2.3 deleted. Old Section 13.4 becomes 13.6. Clarified requirement for scheduled effectiveness follow-up. Added reference to "Preventive Action SOP" to Section 13.7

14.0 ANALYTICAL PERFORMANCE CRITERIA

14.1 Scope

The procedures and policies for the measurement of performance are discussed in this section.

14.2 Performance Criteria and Standards

Performance will be determined by the following criteria:

- Results from intra-lab and inter-lab testing
- Performance in on-site assessments from accrediting agencies
- Performance in proficiency testing programs
- Completion of internal quality audits
- Continued analysis of standard and reference materials traceable to third party programs
- Quality control reanalysis
- Calibration measurements

Quality control is performed continuously throughout the course of laboratory operations regardless of laboratory productivity and is made part of the normal course of laboratory sample analysis. Frequency and volume of QC analysis is based on regulatory requirements and good laboratory practice. The frequency of QC analysis must be consistent and reflect the sample volume at any given time (QC is not performed all at one time - in preparation of an audit, for example).

Performance criteria will be maintained for both individual analysts and for the entire laboratory. The standards for acceptance criteria, frequency and volume are documented in the program modules.

14.3 Quality Control Program and Review

The overall quality control program is established and managed by the QA manager in order to ensure that the laboratory produces quality data. This process ensures fulfillment of our commitment to our customers, that our data is legally defensible, and that all personnel perform their responsibilities properly.

In addition to the review of quality control data for final report approval, the overall QC performance of the laboratory shall be reviewed on a regular basis in accordance with regulatory agency requirements. Specific quality control procedures are detailed in the program modules.

In general, QC analysis represents at least 10% of all analysis performed. QC analysis will entail inter-analyst reanalysis, intra-analyst reanalysis, intra-laboratory reanalysis, analysis of reference standards and blanks at the frequencies required by the analytical method and/or program specific QAM Modules.

In the event a small number of samples have been received for a particular test (<10 samples for example), the laboratory manager and/or the lab quality manager must ensure that at least one of the samples are subject to quality control. Inter-analyst reanalysis is performed by authorized analysts. Re-analysis by a trainee is not to be considered as true duplicate analyses.

The laboratory manager reviews the data sheets and the reanalysis data on a monthly basis (minimum). If the quality control analyses are within control limits, the results will be cleared for reporting. As long as those statistics are deemed acceptable, customer reports will continue to be processed.

If the difference between analyses exceeds control limits, the laboratory manager and the analyst will

review the sample data and resolve the differences. A detailed corrective action report recording all activity is submitted to the QA manager. (See "Non-Conformities, Corrective and Preventive Actions" section of this manual.)

The quality review also includes a check on calibration data. Measurements are checked against the acceptance criteria. If any measurement is out of compliance, the Laboratory Manager is responsible for investing the cause and initiating a corrective action.

In cases where analysts are transferred temporarily to another laboratory, QC data produced by that analyst will be associated with the laboratory at which the data was produced for purposes of determining percentages of QC analysis performed. Likewise, inter-analyst data produced by that analyst will be associated with the lab at which it was produced. The analyst's CV from their original lab shall be utilized when applicable.

However, a transfer analyst's QC data will also be associated with the analyst for purposes of determining on-going competency. A copy of the data may be held by the analyst and placed in their ongoing training records at their home lab. This may include intra-analyst samples as well as analysis of known samples or PT/RR results.

14.3.1 Internal Quality Audits

An audit is an on-site, qualitative review of the various aspects of the total laboratory system. It represents a subjective evaluation using an interactive program with respect to strengths, deficiencies and potential areas of concern.

EMSL performs annual internal audits in all laboratory facilities to verify that work activities are being performed in full compliance with the established standard operating procedures, this quality assurance program, and ISO 17025 and NELAC standards. Non-conformities identified during the internal audit will be corrected through the corrective action process.

EMSL's internal audit procedures are located in the EMSL SOP for Internal Quality Audits (EMSL.QAAUDSOP).

14.3.2 Annual Management Reviews

Management reviews are designed to provide the top management of EMSL with an overview of the performance of the management system and laboratory operations. It addresses the quality topics documented in the ISO 17025 and the NELAC standard for each laboratory location and includes:

- The suitability of policies and procedures
- Reports from managerial and supervisory personnel
- The outcome of recent internal audits
- Corrective and preventive actions
- Assessments by external bodies
- Results of inter-laboratory comparisons or proficiency tests
- Changes in the volume and type of work
- Customer feedback
- Complaints
- Recommendations for improvement
- Other relevant factors, such as quality control activities, resources and staff training

In the first quarter of each year, the Quality Assurance Department, national directors, and vice presidents of laboratory operations and laboratory services meet to review labs for the previous calendar year.

The report shall be based on the recorded information and non-recorded observations made by the QA department, national directors, outside accrediting agencies and customer feedback. It is a tool to ensure the laboratory activities comply with the procedures and policies of the quality assurance program, ensure the programs continued effectiveness and to introduce any necessary changes or improvement.

Follow-up on action items identified in the management review is performed by the corporate management, QA Department and EMSL branch laboratories. Those action items must be completed according to the schedule set forth by the corporate QA manager and Vice President of Laboratory Services.

Management Review procedures can be found in the "EMSL Management Review SOP".

14.3.3 Quarterly Report

The person responsible for overseeing the QA in the lab (i.e., the lab quality manager or laboratory manager) completes a report every quarter for the laboratory manager. In the cases where the laboratory manager is the QA person, the report is written for the regional manager. In the cases where there is no regional manager assigned, the report is written to the national director or corporate QA manager. These reports are designed to express concerns, address needs and report any major changes to management.

Format shall include the following topics:

- Summary of quality control data (e.g., QC reanalysis that may been out of control limits and the corrective action)
- Calibration/Instrument Maintenance: report any calibrations out of acceptance criteria or equipment problems and the corrective action
- Contamination: problems with checks and the corrective action
- Customer Problems
- Report of internal audits (where applicable or planned)
- Report of external audits (where applicable or planned)
- Results of proficiency testing analysis
- Corrective actions
- Preventative actions (where applicable)
- Misc.

14.3.4 Proficiency Testing Programs

Laboratories participating in proficiency testing (PT) programs will ensure the analysis is performed using the same sample tracking procedures, analytical methodology and analyzed by the same analyst(s) as under normal, customer sample conditions. At no time is there inter-laboratory exchange of samples.

EMSL laboratories participate in PT programs administered by:

- NVLAP – for PLM bulk and TEM airborne asbestos analysis
- AIHA – for environmental microbiology, environmental lead, organics, metals, silica, asbestos
- New York State ELAP – for asbestos in air, bulk and water
- RTC – for asbestos in drinking water
- Micro Check – for microbiology
- ERA – for microbiology
- Bowser-Morner – for radon

Samples with instructions and accompanying report sheets are distributed to the appropriate laboratory staff or designee. The samples are incorporated into the normal sample load and

analyzed as would a normal customer sample. Results are calculated and reported on the supplied forms. The result forms are double-checked against the raw data for data entry transcription or omission errors.

Records of proficiency testing analysis are to be completed and maintained in a separate laboratory PT file. This data is also maintained for each participating analyst in his or her personal training file.

Laboratory managers are to ensure that all PT results prepared for submittal are carefully reviewed prior to release. Any calculations are to be reviewed and checked closely.

This review will include a check of raw data against final concentrations for final reporting. All qualified analysts shall analyze the proficiency samples. One result is submitted to the providing agency for scoring. Results from all analysts are reviewed by the laboratory manager, but are not averaged. The laboratory manager indiscriminately (randomly) chooses which result to submit to the agency for scoring.

The data is reported using the appropriate format and method. Data may be reported by mail, fax or by the internet depending on the requirements. If email results are required – the instructions given by the submitting agency are followed. Data will be submitted via Internet connections by the laboratory manager or designee. Copies of confirmation of "data sent and received" are place in the file with the data. The laboratory manager is responsible for submitting the scored results from each PT round to the Quality Assurance Department where it is tracked and evaluated against acceptance limits.

The laboratory must maintain Proficiency status "P" for all parameters tested and reported. If the laboratory becomes non-proficient, this will be indicated in the report to the laboratory containing the results of a given study. The QA manager will investigate the reasons for the poor performance. A corrective action plan will be developed by the QA manager and the lab manager. The plan will be written by the laboratory manager who will submit the plan to QA manager. The plan will include all actions that will be taken (along with a timetable) to bring the quality of data to an acceptable level.

All records for proficiency samples are kept in files for each analyst along with the scored results.

EMSL authorizes the release of proficiency testing results from the proficiency testing provider to its various accrediting authorities whenever such disclosures are required. When possible, standing authorizations are granted. The QA department is responsible for ensuring the distribution of proficiency testing results to outside agencies when requested or required.

14.3.4.1 Round Robin Proficiency Testing Programs

For fields of testing not covered by a proficiency testing program provider, laboratories participate in a round robin program designed to demonstrate competency. One of the participating laboratories shall generate and distribute the round robin samples to other participating laboratories. Results must be reported for all analysts. The originating lab shall also be responsible for receiving and processing resulting data and distributing a report of results to all participating laboratories. The round robin program shall have a minimum of three participating laboratories (can be all EMSL laboratories).

14.3.5 Standard Reference Materials

Having multiple laboratory operations can facilitate the cost savings associated with the variety of standard materials required to calibrate both instrument and analyst. EMSL Analytical allocates and distributes these standard reference materials, where possible from 3 sources:

- The corporate laboratory facility
- The Quality Assurance Department
- The regional managers or national directors

In order to track the transfer of standards and reference materials between the original sources and the laboratory(ies) a chain of custody type form must be completed (see "EMSL Standard and Reference Material Traceability Form"). This form ensures traceability of measurements to a national standard and verification of measurements to reference samples. Reference materials are to be clearly labeled and stored as to maintain integrity.

14.3.6 EMSL Round Robin Programs

Periodically, the Quality Assurance Department and/or national directors will provide a company-wide round robin program. Samples are to be analyzed by all active analysts. The laboratory manager is to choose one result for submitting to the Quality Assurance Department, where it will be scored and graphed using standard deviation statistics.

The laboratory manager is responsible for ensuring that the individual results of the participating analysts are compared against the national report, once the program is completed (using the mean and standard deviations generated by the national program).

Revision History below begins with Revision 10 of all modules. All prior revision history is available through the corporate QA department

Revision	Date	Changes
10	12/19/08	Minor editorial changes throughout. Added Revision History. Divided QAM into separately controlled sections for simplified revision. Section 14.3 – Added requirement that interanalyst reanalysis shall be performed by authorized analysts. Added final two paragraphs to Section 14.3 on QC performed by transfer analysts. Removed final two paragraphs from 14.3.1, and subsequent subsections 14.3.1.1 – 14.3.17 and replaced with reference to the EMSL Internal Audit SOP (EMSL.QAAUDSOP). Section 14.3.2 revises the timing and responsibility for annual management review in 2nd paragraph. Changed time allowed for responding to action items from management review from a set 30 days to timeframe set by QA manager. Added reference to "EMSL Management Review SOP." Last paragraph added to Section 14.3.4 discussing authorization to release PT results to outside agencies.

15.0 DEMONSTRATION OF TRACEABILITY

15.1 Scope

This program is designed to provide a method, which achieves traceability of data to national standards. This is accomplished by setting specific requirements, including:

- Use of Standard Reference Materials (SRMs) as certified and traceable to the National Institute of Standards and Technology (NIST). SRMs are used for QC analysis and training for achieving measurements 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

Revision History below begins with Revision 10 of all modules. All prior revision history is available through the corporate QA department

Revision	Date	Changes
10	12/19/08	Minor editorial changes. Added Revision History. Divided QAM into separately controlled sections for simplified revision.

16.0 CUSTOMER COMMUNICATIONS

16.1 Scope

The key to any successful quality assurance program is communication. This is especially true for communication with the customer. This section provides the policies and procedures for effective communication.

16.2 General

Clear, continuous and open communication between the laboratory and the customer is one of the keys to maintaining a successful, quality operation. Communication should be established prior to the start of any work. Information must be clearly understood between laboratory management and the customer. This information should include (but not be limited to):

- Type of analysis requested
- Turnaround times
- Expected deliverables (any requested changes to the standard report format)
- Sampling guidelines (media, recommended sample volume, etc.)
- Type of packaging for sample shipping
- Submission of final report (via fax, hard copy, mail, overnight shipment)

EMSL will cooperate with customer requests to monitor laboratory performance on their projects. Upon request, customers may be granted accompanied access to the laboratory to witness performance of testing so long as doing so does not jeopardize the confidentiality of other customer information.

16.3 Documentation of Customer Correspondence

Correspondence with customers shall be recorded by each EMSL laboratory. Project related information may be recorded on the Chain of Custody forms for the project to ensure that the information is available and associated with the project. Other correspondence may be manually recorded utilizing the Customer Correspondence Log template available on E-link. The customer correspondence log shall be maintained at each laboratory according to the instructions included in the template document. Correspondence may also be recorded using electronic means when available to the laboratory (e.g., Outlook Journal feature.) Regardless of how correspondence is recorded, the date of correspondence and initials of person making the entry is required.

Customer complaints shall be documented utilizing the EMSL Complaint Resolution procedure and recorded on the Complaint Record form available from E-link. Where customer correspondence leads to corrective action, these corrective actions will be documented via the EMSL Corrective Action system.

16.4 Technical Support

EMSL provides quality assurance information and technical support to the customer 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

EMSL also provides a variety of sampling equipment and procedures to support the customer's needs. Equipment is available such as sampling pumps, sampling cassettes and sampling media. Instructions are provided along with the equipment.

16.5 Notification of Non-Compliance

If a major deficiency in policy or procedure is identified which directly effects customer results, the customer will be notified immediately of the problem. Major non-conformities may be discovered during an internal audit, external audit or a regular quality control review. A major deficiency may be defined as (but not limited to):

- Quality control reanalysis data outside acceptance limits
- Calibration measurements outside acceptance limits
- Sample contamination (positive blanks)
- Analysis performed outside the scope of accreditation
- Analysis performed by unqualified personnel
- Incorrect method performed on samples

16.6 Confidentiality (see also "Confidential Transmission of Results" section)

It is understood that confidentiality and proprietary rights must be respected throughout the performance of services for any customer 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 customer will be protected. Data reports and/or other related information will not be given out to any person or agency other than the customer unless we have received prior approval from the customer.

The laboratory manager is responsible for ensuring that the sample results and related information is disseminated appropriately. In the event there is a question regarding applicability of confidentiality, the quality assurance manager, national director and/or vice president are to be consulted.

16.7 Notice of Performance

The laboratory manager shall provide the customer with information as it relates to the performance of the analysis and turnaround time. The laboratory must notify the customer if:

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

16.8 Customer Feedback Program

The EMSL customer feedback program includes:

- Continuous correspondence between customer and the client service representatives
- Communication tools available on company website
- Direct contact with customer and laboratory manager
- Collecting comments offered by customers during seminars and conferences
- Periodic use of active solicitation of feedback such as through the use of customer survey.

Revision History below begins with Revision 10 of all modules. All prior revision history is available through the corporate QA department

Revision	Date	Changes
10	12/19/08	Minor editorial changes throughout. Added Revision History. Divided QAM into separately controlled sections for simplified revision. Added active solicitation of feedback to Section 16.6. New Section 16.2, 16.3 added.

COMPLIANCE DISCLOSURE

In executing this Compliance Disclosure, I attest and confirm that I have read and understand the entire contents of this document. My signature represents that I agree to fully comply with, implement, and enforce all requirements, procedures, and protocols specified in these procedures set forth in this document and any supporting reference materials or methodologies. I acknowledge the proprietary nature of this document. Furthermore, I understand that this document is the most recent version and any revisions, modifications, additions, or amendments to this document will only be recognized and executed upon review, final approval, and reissue of this document by the Quality Assurance Department management.

LABORATORY MANAGEMENT				
#	Print Name	Signature	Department	Date
1				
2				
3				
4				

LABORATORY STAFF				
#	Print Name	Signature	Department	Date
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				

APPENDIX A

Glossary:

ACS – American Chemical Society

AHERA – Asbestos Hazard Emergency Response Act

AIHA – American Industrial Hygiene Association

Alternative Method (procedure) - A major modification to standard methods and EMSL Standard Operating Procedures

Amended Report (see also revised report) – A report which reflects a change or correction to an original report

Analytical Sensitivity - The lowest concentration that can be detected by the method, based upon the amount or portion of sample analyzed (e.g., for methods involving a count = 1 raw count per amount or portion of sample analyzed, calculated and expressed in the final reporting units).

Analytical Worksheet (Bench Sheet) – The form used by the analyst to collect the raw analytical data during analysis.

Bench Sheet- (see Analytical Worksheet)

Branch Laboratory – All EMSL laboratories excluding those located at 107 Haddon Ave. Westmont NJ and 3 Copper St. Westmont, NJ

Chain of Custody – An unbroken trail of accountability that ensures the physical security of samples, data and records.

Chemical Hygiene Plan – A program which defines the work practices and procedures to ensure that employees of EMSL Analytical are protected from health hazards associated with hazardous chemicals with which they may work or be exposed.

Consensus standards – Samples with values assigned based on a statistically significant number of repetitive analysis.

Corporate Management – Staff members which include the Company President, Vice Presidents, QA Manager, National Directors, MIS Manager, Controller, Collection Manager and Equipment Manager.

Coefficient of Variation - Standard deviation divided by the mean

Culturable - Capable of, or fit for, being cultivated. (antonym: non-culturable).
Note: Prior to Revision 10 of the QAM the terms Viable/Non-viable were used in place of Culturable/Non-culturable. This terminology may still occur in some documents published prior to the date of publication of Revision 10.

Customer – Any person or entity that receives products or services from EMSL.

EMSL Environmental Laboratories – Laboratory facilities/locations performing the analysis for the analytical programs including asbestos, environmental lead, environmental microbiology, various IH parameters (organics, metals, etc.) and environmental chemistry parameters (metals, organics, inorganics, wet chemistry).

Integrity – Sound, honest, true

Inter – analyst/lab – Re-analysis of the same sample by a different analyst/lab

Intra – analyst/lab – Re-analysis of the same sample by the same analyst/lab

Method Detection Limit (MDL) - The minimum concentration of an analyte that, in a given matrix and with a specific method, has a 99 percent probability of being identified, qualitatively or quantitatively measured, and reported to be greater than zero.

NIST – National Institute of Standards and Technology

NLLAP- National Lead Laboratory Accreditation Program.

Non- conformance – A deficiency, error or a lack of compliance with the procedures or policies documented in this manual.

Non Standard Method – An analytical procedure which has little or no relationship to a procedure documented by a regulatory agency, a recognized group or organization, a known industry expert or previously established corporate method. Examples of these type of documented procedures are those released by Federal and State authorities, groups such as the ASTM or ISO or industry experts, i.e., Chatfield.

NVLAP – National Voluntary Laboratory Accreditation Program

NYS ELAP – New York State Environmental Laboratory Approval Program

Proficiency Testing (PT) – As systematic program in which one or more standardized samples is analyzed by one or more laboratories to determine the capability of each participant.

Program Module – Sections of the Quality Assurance Manual which address analytical method specific requirements, i.e., asbestos, lead, microbiology, IH organics and IH inorganics.

Quality Assurance (QA) – The total integrated program for assuring reliably of the measurement and monitoring of data.

Quality Assurance Department - The QA Department is headed by the Quality Assurance Manager. The Department minimally consists of the QA Manager and Administrative Assistant, but may also include other EMSL staff members or outside consultants assigned to special projects or teams as assigned.

Quality Control (QC) – The routine application of procedures for obtaining prescribed standards of performance in the monitoring and measurement process.

Quality Management System – A set of policies, processes and procedures required for planning and execution.

Reagents – A substance reacting with another substance. Lab reagents are compounds such as hydrochloric acid used in the analysis.

Reanalysis – A second analysis of the same sample (see also inter or intra).

Red Line Document – A document which shows the changes from one revision to the next.

Reference materials – General term used to describe samples, which have a known value. These could include standards, proficiency testing samples and consensus standards.

Reporting Limit – The lowest concentration of analyte in a sample that can be reported with a defined, reproducible level of certainty. This value is based on the low standard used for instrument calibration. For environmental lead analyses, the reporting limit must be at least twice the MDL.

Revised Report (see also amended report) – A report which reflects a change or correction to an original report.

Round Robin – An exchange of samples with other laboratories. May be 2 or more.

RPD – Relative Percent Difference. Calculated as $RPD = \frac{R1 - R2}{R} \times 100$

R1-R2 = absolute difference in two values
R = average of the two values

SRM – Standard Reference Material

Standards – Samples (materials) of known concentrations

Standard Methods - Methods published by regulatory agencies such as EPA, NIOSH, OSHA, State agencies. Also includes methods developed by recognized scientific agencies and/or individual groups such as ASTM and Chatfield.

Standard Operating Procedure – A written document that details the method of an operation, analysis or action whose techniques and procedures are thoroughly prescribed and which is accepted as the method for performing certain routine or repetitive tasks.

Sub-facility – Term used associated with the NVLAP program. A sub-facility is considered an extension of the Main Facility (Westmont – 107 Haddon Ave.). It receives technical direction and quality management from the Main Facility.

Revision History below begins with Revision 10 of all modules. All prior revision history is available through the corporate QA department

Revision	Date	Changes
10	12/19/08	Minor editorial changes throughout. Added Revision History. Divided QAM into separately controlled sections for simplified revision. Added definitions for “Analytical Sensitivity”, “Culturable”, “Customer”, “Method Detection Limit”, “Reporting Limit.”

APPENDIX B

Forms Referenced in this Manual

1) Demonstration of Capability Certificate
2) Corrective Action Report Form
3) Preventive Action Form
4) Final Report Approval Form and Electronic Signature Sample
5) Standard/Reference Material Traceability Form
6) Sample Master Change Request
7) Relinquish Form
8) Equipment Maintenance Log Form

Revision History below begins with Revision 10 of all modules. All prior revision history is available through the corporate QA department

Revision	Date	Changes
10	12/19/08	Previous Appendix B & C made obsolete. Information from Appendix B moved to Corrective Action SOP, information from Appendix C moved to QAM Section 1.7. This appendix renamed Appendix B (previously Appendix D). Divided QAM into separately controlled sections for simplified revision. Added Revision History. Updated forms to newest revisions and names.

1) Demonstration of Capability Certificate

EMSL Demonstration of Capability Certificate
Revision 6
November 10, 2008

EMSL Demostration of Capability Statement
Certification Statement

Analyst Name: _____

Lab Name: _____

Lab Address: _____

Matrix	Technology	Method	Analyte	Date

We, the undersigned, CERTIFY that:

1. The analyst identified above, using the cited test method(s), which is in use at this facility for the analyses of samples under the National Environmental Laboratory Accreditation Program and the EMSL Quality Program, have met the Demonstration of Capability
2. The test method(s) was performed by the analyst(s) identified on this certification.
3. A copy of the test method(s) and the laboratory-specific SOPs are available for personnel on-site
4. The data associated with the demonstration of capability are true, accurate, complete and self-explanatory.
   True: Consistent with supporting data.
   Accurate: Based on good laboratory practices consistent with sound scientific principals/practices.
   Complete: Includes the results of all supporting performance testing.
   Self-Explanatory: Data properly labeled and stored so that the results are clear and require no additional explanation
5. All raw data (including a copy of this certification form) necessary to reconstruct and validate these analyses have been retained at the facility and that the associated information is well organized and available for review by authorized assessors

This Demonstration of Capability is issued by the EMSL Quality Assurance Department

Lab Manager	**Signature**	**Date** *(date the information listed above was verified as correct)*

Patricia Kirkland

QA Manager	**Signature**	**Date** *(date the information listed above was verified as correct)*

This certification form must be completed each time a demonstration of capability study is completed.
Note: This Certificate is modeled after the 2003 NELAC Quality System standard.

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2) Corrective Action Report Form

Non-conformance/Corrective Action Report

Section 1: Complete at time problem is identified					
Lab:		CAR# (Assigned by Lab Mgr):			
Date:		Person Reporting Problem (Last Name, First Initial):			
Description of Non-conformance/ problem:				Nature of Problem (Select One):	
				Auditing Body:	
				Policy Reference(s):	

Section 2: Complete at time problem is identified (if applicable)			
Analyst: (Last Name, First		QC Analyst (Last Name, First Initial)	
Order Number:		Sample(s):	
Method of Analysis:		Reported to Corp QA?:	

Section 3: Complete when initial evaluation is performed							
Evaluation/ Investigation Details							
Evaluating Party:				Date Evaluation Completed:			
Corrective Action Required (Yes/No)?							
Work Stop Necessary?		Person stopping work (Last Name, First Initial):					
Date of work stop:		Time of work stop:		Corporate Acknowledgment of Stop (more than 1 hr.):			
Client Notification Required?		Date Notified:		Report Change Needed?			
Report Re-issued?		Date of re-issued report:				Revised Report #:	

Section 4: Complete whenever a corrective action is required				
Root Cause:				
Corrective Action:				
Corrective Actions Assigned to (Last Name, First Initial):		Corrective Actions Due Date:		
Proof of Compliance (e.g. a policy, memo):		Evidence of Compliance (e.g. specific record):		
Lab Signoff:		Date:		
Corporate Signoff (where necessary):		Date:		
Date Work Can Resume:				
Time Work Can Resume				
Authorization for work resumption:				

Section 5: Complete after implementation of corrective action					
Follow-Up Due Date:		Follow-up Notes (i.e., how was effectiveness determined, findings):			
Follow-Up Completed By:					
Date Completed:		Outcome:		New CAR # (when necessary):	

3) Preventive Action Form

EMSL Preventive Action
Revision 1
Effective Date: July 9, 2007

EMSL Analytical, Inc.
Preventive Action Form

Lab:

Department:		**Equipment:**		
Order Number:		**Sample(s):**		
Issue:		**Date:**		
Name of Person Reporting Action		**Reported to Corporate QA:**		
Preventive Measure:				
Effectiveness of Measure (include non-conformities avoided, if applicable) :				
Evidence of Compliance:	**Lab Signature:**	**Date:**	**Corporate QA Approval (if needed):**	**Date:**
Does work need to be stopped: YES / NO	**Lab Signature:**	**Date:** **Time:**	**Corporate QA Approval:**	**Date:** **Time:**
Date & Time work can resume:	**Lab QAC Signature:**	**Date:** **Time:**	**Corporate QA Approval:**	**Date:** **Time:**

Revision Notes:
7/5/07: Added Footer "Page 1 of 1", Added "Revision Notes", Added "Effective Date" to header

4) Final Report Approval Form and Electronic Signature Sample

EMSLrptapprove
Revision 2
October 23, 2006

Final Report Approval Form and Electronic Signature Sample

The Employee listed below has been given the authority to approve the final client report(s) identified .
This Employee is qualified to validate the accuracy of the information in the final report for every report he/she approves.

Authorized by: _____
Laboratory Manager or Quality Assurance Department Representative

Employee:		Date:	
Lab:			
Authority: *What type of results can you approve?*	❑ All results for the lab ❑ All Asbestos results ❑ PLM results only ❑ PCM results only ❑ TEM results only ❑ Microbiology ❑ Chemistry ❑ Industrial Hygiene ❑ Lead		

As an employee with permission to authorize laboratory results, a sample of your signature and initial is needed.
Please keep the signature centered inside the box, as anything outside the box will not be scanned into the system. Use as much of the box as possible (the larger the signature, the better the scan). Please use blue ink only to ensure a high-quality scan.

Sign here

Initial here

Please return this sheet to: EMSL Analytical
107 Haddon Ave.
Westmont, NJ 08108
Attn: MIS department

Do not fax or send a photocopy or scan this sheet. MIS must have the original.

[revision notes: removed black ink (use blue only)

5) Standard/Reference Material Traceability Form

EMSL Standard and Reference Material Traceability Form
Revision 1
Effective Date: January 8, 2008

STANDARD/REFERENCE MATERIAL TRACEABILITY FORM

This form is intended to track the transfer of standards and reference materials between the original sources and the laboratory(ies). It maintains chain of custody of these materials. This form insures traceability of measurements to a national standard and verification of measurements to reference samples. (see section: Standard and Reference Materials *in the QA manual)*

This form is stored along with the material at all times

Standard Material/Identification:_____

Source:_____

Handling:

Date	Responsible Person	Custody transfer Notes

Revision Notes:
(REV 1) 1/8/08: Added Control Document Identifiers

6) Sample Master Change Request Form

Sample Master Change Request
Revision 2
February 28, 2008

Sample Master Change Request

To be submitted to corporate QA department (pkirkland@emsl.com)

Method Identifier		Version	
Requested by		Date	
Description of Change (please include only one change on each form)			
Reviewed by		Date	
Status	☐ Approved	☐	Rejected
Reviewer Notes			

MIS Department Use Only

Accepted by		Date	
Design notes			
Completed by		Date	
New Version		SM Build (if applicable)	
Objects changed			

Revision Notes:
REV 1 (7/5/07): Added Footnotes, Added "Revision Notes", Added EMSL to Document name.
REV 2 (2/28/08): Added "To be submitted to corporate QA Department (pkirkland@emsl.com). Revised title name.

7) Relinquish Form

EMSL Relinquish Form
Revision 2
Effective Date: July 9, 2007

EMSL Analytical, Inc.
Relinquish Form

Initial Lab:		Phone Number:	
		Fax Number:	
Relinquished to:		Phone Number:	
		Fax Number:	
Does new Lab hold equivalent or additional accreditation*			Yes/ No

Client Name:			
Client Project:			
Date Received:			
Date Relinquished:			
Date Due:			
Special Instructions:			
Relinquished by (Signature):	Date:	Received by (Signature)	Date:
Relinquished by (Signature):	Date:	Received by (Signature)	Date:

Client Notification- Please sign this form and fax to the original laboratory. By signing below you agree to allow the above named laboratory to relinquish the samples to a new laboratory with equivalent or additional certification.			
Name (please Print)	Signature	Agent of:	Date:
If this is a reoccurring project or sample type that will require samples to be relinquished on a regular basis please sign below and the laboratory will keep this form on file.			
Name (please Print)	Signature	Agent of:	Date:

- All accreditation information and certificates can be found at www.emsl.com.

8) Equipment Maintenance Log Form

EMSL Equipment Maintenance Log
Revision 2
December 7, 2008

Equipment Maintenance Log

Equipment Description: _____
Manufacturer: _____
Model: _____
Serial Number: _____
Equipment Location: _____
Current Working Condition: _____

ISSUE			ACTION TAKEN		
Description of Problem	Reported by (initials)	Date	Description of Action	Performed by (initials)	Date

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