NOTE: All current Amendments to Revision 16 of this QMS Manual are referenced throughout the document as applicable and included as additional pages at the end of the document.

EMSL Analytical, Inc.

LABORATORY
QUALITY MANAGEMENT SYSTEM
(QMS) MANUAL

REVISION 16 – June 14, 2013

For Laboratory located at:

Lab specific Cover Pages can be found on E-link:
Quality Assurance>Quality Management System Manual>Lab Cover Pages

Laboratory Manager _____ Date _____

Patty Kirkland _____ Date _____
Quality Assurance Manager

Issued by: EMSL Analytical, Inc.
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Dr. Peter Frasca/President

Contains: QMS Manual Main Section

Mod A: Asbestos	Mod F: Radon
Mod B: Lead	Mod G: Food Sci.
Mod C: Env. Micro	Mod H: Relationship Test
Mod D: IH	Mod I: Materials Sci.
Mod E: RadioChem	

Click to go to Mod

COMPLIANCE & COMMITMENT AGREEMENT

In executing this Agreement, 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 referenced 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.

Those individuals who have checked the column labeled "Lab Management Commitment" are further acknowledging they approve the document for use in their lab and are committed to enforcing the requirements stated herein. Those individuals holding positions of Laboratory, Department and/or Quality Manager, or who have been named to a position of authority for the purposes of state or independent accreditations shall mark this column.

After reviewing the main QMS Manual section and modules appropriate to the work you perform sign, date and check off those modules which you are acknowledging. **Print this page as many times as needed.**

Signature	*Lab Management Commitment*	*Date*	*Main QMS Manual*	*A*	*B*	*C*	*D*	*E*	*F*	*G*	*H*	*I*

Table of Contents

Click to jump to amendment

Click to jump to amendment

Click to jump to Amendment

Click to jump to amendment

Section 1.0: Scope

1.1 Scope of EMSL Quality Management System (QMS) Manual

Note: *Prior to Rev 16 of this manual, the name of this manual was "EMSL Quality Assurance Manual." References to this term or the acronym (QAM) may appear on other management system documents but shall be read to reference this document. Out of date references will be updated as documents are revised.*

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

- Quality, accuracy and integrity of analytical results.
- Conformance with 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 as set forth by of the American Industrial Hygiene Association Laboratory Accreditation Program (AIHA-LAP), the National Voluntary Laboratory Accreditation Program (NVLAP), The NELAC Institute (TNI), A2LA, NYS ELAP, NJDEP and other state and local accrediting authorities as relevant to the laboratories qualifications.

To achieve these goals, this QMS Manual directs the implementation and maintenance of the quality assurance program, describes responsibilities and duties of personnel as related to quality, and establishes the required policies of the quality assurance system. This QMS Manual covers analytical services offered in the EMSL laboratories, which include asbestos, lead, environmental microbiology, industrial hygiene organics, inorganics and radon. General policies applicable to all analytical areas are addressed in the main section of the QMS Manual while policies, procedures and requirements for each specific service area are addressed in the modules. These modules are organized as follows:

Module	Program Description
A	Asbestos
B	Environmental Lead
C	Microbiology
D	Industrial Hygiene
E	Radiochemistry
F	Radon
G	Food Microbiology & Chemistry
H	Relationship Testing
I	Materials Science

All EMSL Laboratories shall comply with the requirements detailed in this manual and the additional program requirements specified in Modules A – I as applicable to the branch laboratory operations. This manual is posted to the EMSL E-link SharePoint site and is accessible by all employees. Employees are responsible for being familiar with, and adhering to its contents.

NOTE: Analysis performed under cGMP requirements (i.e., FDA registration) shall be completed under

the EMSL cGMP Quality Management System. This is a parallel program which has been implemented in the Cinnaminson, NJ laboratory in order to comply with all cGMP requirements.

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.

1.2 Quality Management System (QMS) Manual Maintenance and Update Procedures

As defined in the EMSL Control of Documents SOP, the QMS Manual will be reviewed at least annually for continued suitability. Review will be conducted by the QA department with assistance from the national directors and select others. Any revisions shall be reviewed and approved by the QA manager. Prior to publication the QMS Manual revision will be authorized by the EMSL President. The revisions made to the QMS Manual are recorded in a Revision History which follows each section of the QMS Manual. A 'Notice from the Quality Assurance Department' may also be provided with the QMS Manual at distribution summarizing the additions and changes to the manual.

REVISION HISTORY

Previous revision histories are available from the QA department on request.

Revision	Date	Changes
16	5/30/13	Combined reference to Food Micro and Chem Modules to Mod G, Added reference to Module H-I.
15	9/16/11	Added Note to Section 1.1. Corrected table to accurately reflect combination of IH Modules in Mod D, and reservation of Mod E.
14	7/1/11	Updated reference to AIHA to AIHA-LAP.

Section 2.0: Normative References

The EMSL Analytical management system has been developed to comply with the requirements of the following current references as well as those of several other State and local accrediting agencies:

- ISO/IEC 17025:2005.
- The NELAC Institute (TNI) standards, July 2011.
- A2LA General Requirements: Accreditation of 17025 Laboratories, December 2011.
- AIHA-LAP Accreditation Policies, March 2013.
- NIST Handbook 150:2006, 150-3:2006 and 150-13:2006,.
- Applicable State Requirements

REVISION HISTORY

Previous revision histories are available from the QA department on request.

Revision	Date	Changes
16	5/30/13	Referenced current revisions for accreditation policies since these policies are often fragmented into multiple documents by the publisher.
15	9/16/11	Updated revision of AIHA-LAP policies.
14	7/1/11	Updated NELAP standard to newest TNI standard (July 2011)

Section 3.0: Terms and Definitions

See *Appendix A – Glossary*. This section reserved for future use.

REVISION HISTORY

Previous revision histories are available from the QA department on request.

Revision	Date	Changes
16	5/30/13	No Changes.
15	9/16/11	Added reference to Appendix A.
14	7/1/11	No Changes.

Section 4.0 - Management Requirements

4.1 Organization

4.1.1 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. EMSL will avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment, or operational integrity. 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 – (e.g. NVLAP, AIHA-LAP, A2LA, state authorities) and those requirements documented in the ISO/IEC 17025 and TNI standards. 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 continual improvement of the final product & the management system. 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.

Commitment to ISO Standard

Starting with corporate management and extending to regional and local laboratory management, EMSL is committed to ensuring that the standards documented in ISO/IEC 17025:2005 (or the most recent revision of the 17025 standard) 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.

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

4.1.2 Relevance of Personnel Activities and Communication by Management

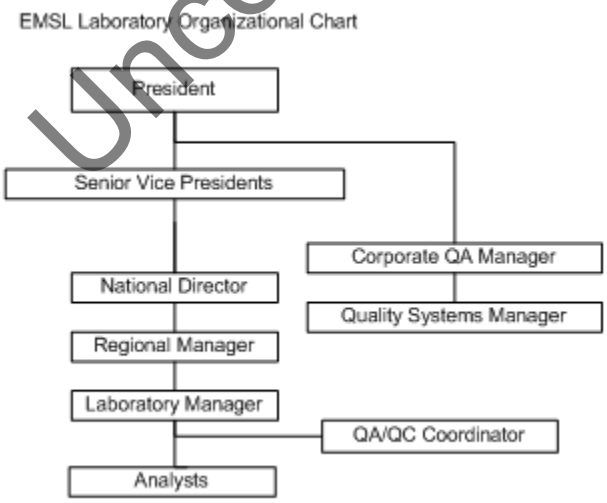
Management communicates to the staff the importance of their role in customer needs, regulatory requirements and involvement to the achievement of the objectives of the management system through this QMS Manual, newsletters, management meetings and teleconferences and periodic phone conversations.

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), 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 QMS Manual as well as relevant policies and procedures.

4.1.3 General Organization Chart



Individual Lab Organizational Charts are available on E-Link in Quality Assurance > QMS Manual > Org Charts

4.1.4 Corporate Organization

The corporate headquarters of EMSL Analytical operates out of the New Jersey 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 and are available on the company intranet (E-link). 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.

4.1.4.1 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.

4.1.4.2 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.

4.1.4.3 Roles of Administrative Support Groups

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.

4.1.4.3.1 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. In addition, the IT department is responsible for instruction by means of SOPs or other instructions for use of their products.

4.1.4.3.2 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.

4.1.4.3.3 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.

4.1.4.3.4 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, and 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).

4.1.4.3.5 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 customer payments to their accounts. They also review accounts in consideration for outside collection assistance.

4.1.4.3.6 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.

4.1.4.3.7 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.

4.1.4.3.8 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. See § 4.6 for additional information.

Click to Jump to Amendment

4.1.5 Confidentiality, Ethics and Data Integrity Policy

4.1.5.1 Confidentiality (see also § 5.10.5)

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 or are legally obligated to do so.

This attention to confidentiality extends beyond the workplace. Employees shall be aware that revealing confidential information in a non-work social setting is still considered a breach of confidentiality requirements.

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 (including requests from government agencies or legal representatives), the quality assurance manager, national director and/or vice president are to be consulted.

4.1.5.2 ***Ethics and Data Integrity Policies & 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.

4.1.5.2.1 Ethics Policy

As a condition of hire, every employee (part-time or full-time, temporary or permanent, including interns) 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 productivity, billing)

5) Signing acknowledgements of policies or procedures (e.g., QMS Manual, SOPs, work instructions, policy statements) without having read, understood and committed to their contents.

6) Knowingly failing to follow said policies and procedures for any reason including, but not limited to, the sake of productivity.

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

8) 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 affect 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 cannot bring it to their attention, the situation may be reported to the lab manager or corporate management for review. These items may always be brought to the attention of the human resources department.

**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 <u>required to report</u> to managers located at EMSL branch offices, EMSL Corporate Officers/Managers or human resources department located in Cinnaminson, 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, or the immediate manager is

unable to resolve the issue, 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. Issues will be handled confidentially whenever possible.

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. Investigations will be conducted confidentially until they are concluded. The findings shall be documented. Where customer data may have been affected, the customer shall be notified as soon as practical (no more than 15 days after close of investigation.) These communications shall be documented in the integrity investigation records.

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.

4.1.5.2.2 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 TNI standard requirements addressing data integrity procedures as described below.

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.

Signed data integrity documentation: The ethics statement is signed by each employee as a condition of employment. In addition, a QMS Manual compliance disclosure form is executed by each employee (see *Compliance Disclosure* at beginning of this document). 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:

- 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 complaint
- Internal audits
- Periodic submittal of blind samples by management.

Confidential Reporting

As noted in the ethics agreement, issues that cannot be discussed directly with local lab management may always be directed to the corporate human resources department for review. Issues will be handled confidentially whenever possible.

Data Integrity Investigations

When data integrity issues are reported, they will be reviewed by the party receiving the report. The issue shall be investigated as appropriate in order to determine its extent and impact, both potential and actual. Where detailed investigation is necessary, the person receiving the integrity complaint shall inform the corporate QA Manager or human resource department to assist and review the investigation. Investigations shall be conducted in a confidential manner until they are completed. The investigation shall be documented including details on any notifications made to customers receiving affected data.

4.2 Management system

4.2.1 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.

4.2.2 Management System Review

The Management System is reviewed by the QA Manager and other management staff at least annually. In addition to periodic reviews arising in response to corrective and preventive actions, the appropriateness of the management system is reviewed at the quarterly and annual management review meetings. In addition, as per the EMSL document control program, all documents which are part of the management system are reviewed at least once every three years and the QMS Manual itself is reviewed annually. Revisions to the management system are discussed with technical and management personnel with the expertise to discuss the feasibility and acceptability of any requested changes.

4.2.3 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 (backups)
- Assignment of deputies or designated second person

4.2.4 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.

4.2.5 Roles & Responsibilities of Technical and Quality Management

The roles and responsibilities of the technical and quality management of EMSL are described in the Personnel section of this manual (§ 5.2).

4.3 Document control

4.3.1 General

EMSL document control procedures have been established to meet the requirements of ISO 17025 and the accreditation requirements of AIHA-LAP, A2LA, The NELAC Institute (TNI), NVLAP and state agencies. Procedures and policies apply to all EMSL laboratories.

The EMSL document control procedures are documented in the EMSL Document Control SOP and Master List of Documents SOPs. EMSL controls documents to ensure the laboratories are performing analysis and reporting data following only the most up-to-date corporately approved EMSL policies and procedures. EMSL's document control program covers the initiation of new controlled documents, review and maintenance of controlled documents, and retirement of obsolete documents. This program also establishes company-wide standardization and preserves company intellectual property.

4.3.1.1 Initiation and Approval of Documents or Revisions

New documents or revisions 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. The EMSL SOP Template should be used which sets the standard format ensuring the proper format is used including the controlled headers and footers.

4.3.1.2 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 via E-link. 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 and non-essential text. 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 to all but approved QA and IT department personnel.

4.3.1.3 Distribution of Controlled Documents

Corporately issued controlled documents are distributed through EMSL's E-link SharePoint site which is accessible in all laboratories. Once a document is approved, it is

posted to E-link and 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. Once notification is received it is the responsibility of the branch laboratory manager to ensure that staff is made aware of the change, any local hardcopies which may be present in the lab are updated, and that the Local Master List of Documents is updated.

If local copies are maintained (as opposed to having only the one controlled copy available on e-link), then the distribution information within the lab will be recorded on the Local Master List of Controlled Documents along with revision information.

4.3.1.4 Obsolete Documents

As discussed above, documents which are made obsolete either because they are revised or taken out of service should be either removed from the laboratory or, if they are to be maintained for historical reference, isolated so that they are not accidentally used by laboratory personnel. Hard copies which are available in a lab but retained shall not only be physically isolated, but clearly marked "OBSOLETE" to prevent accidental usage.

E-link controlled documents when made obsolete are removed from the public folders where they are accessed by branch staff and moved to electronic "Archive" folders which can only be accessed by approved personnel.

4.3.1.5 Review of Controlled Documents

Controlled documents will be reviewed once every 3 years to determine their continued suitability. One exception is this QMS Manual and related modules and documents which are reviewed annually. 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 listed on the EMSL Master List of Controlled Documents.

4.3.1.6 Amendments and Revisions

Documents may be modified or supplemented 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 and usually take the form of an additional page which is amended to the original issue, or maintained locally by the laboratory. Revisions are a complete re-issue of a document.

Hand written changes to controlled documents are generally prohibited. The only marks which will be acceptable are marks which indicate that there is a corporately approved amendment to the procedure available or that a revision is pending. All handwritten changes must be initialed by the lab manager and dated.

4.3.1.7 Changes to LIMS 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.

4.4 Review of requests, tenders and contracts

4.4.1 General

EMSL 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.

4.4.2 Procedures for Review of Contracts, Requests and Tenders

Requests, tenders and contracts are three parts of the transaction process. Requests for service are made by the customer for a scope of work. The tender is the proposal from the lab to the customer which could include clarifications of the work desired, proposal of turnaround time, and costs for the service. The contract is the actual agreement between customer and lab on finalized terms.

The customer's request for services may be made directly to the laboratory manager, corporate management or sales staff. In any case, before the samples are accepted for analysis signifying acceptance of the contract, laboratory 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 and required QC 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 to which the work will be subcontracted) can perform the services.

4.4.2.1 Documentation of Review

These reviews of customer requests 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 according to standard terms and conditions, or to prices which are negotiated with sales representatives ahead of time. 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.

When work is received at the laboratory, the customer's COC defines the requested analysis and turnaround time. In addition, any requested deviations from standard terms and conditions or defined contractual requirements will be defined. If any clarification or modification of the request is necessary, the modified tender will be communicated to the customer and documented in writing along with the customer's approval of these altered terms.

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.

Where standard terms and conditions are modified (e.g., special reporting requirements, non-standard pricing, modified methods, etc.), this shall be approved by a corporate sales representative. These approved contracts are maintained by the sales department and communicated to the laboratory as appropriate through special notes in Sample Master. 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.

4.4.2.2 Changes in 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 any pertinent discussions with the customer shall be documented.

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.

4.4.3 Beginning New Work

The Laboratory Manager must not accept any new work without evaluating the current resources. This includes the availability of equipment and staffing. 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

4.4.4 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.

4.5 Subcontracting of tests

4.5.1 General

The EMSL subcontracting procedures are documented in the *EMSL Subcontract SOP*. This SOP defines when a laboratory accepts samples to be subcontracted.

The network of EMSL laboratories provides the customer with a valuable resource. As per EMSL standard Terms and Conditions, EMSL reserves the right to subcontract samples to any EMSL branch lab as long as the laboratory receiving samples holds equivalent relevant accreditations as the laboratory receiving the samples from the customer. By submitting samples for analysis customers agree to these Terms and Conditions. In this way, samples may be shipped out for analysis to other EMSL laboratories when a laboratory is at workload capacity, turnaround time cannot be reached or the laboratory temporarily does not have the analytical capability (e.g. instrument is down, personnel are out). This flexibility is an added benefit to the customer allowing drop off of samples at any lab with the knowledge that all of their requirements will be met.

The laboratory receiving samples maintains responsibility for the subcontract lab's work except in those cases when the customer or regulatory authority specify which subcontractor is to be used or when the receiving EMSL Lab is simply acting as a courier service (i.e., when they do not perform the analysis requested by the customer.)

In the event an outside lab is required, the laboratory manager will ensure all testing is performed by qualified laboratories. Laboratories must subcontract only to outside laboratories that maintain accreditations appropriate for that analysis.

4.5.2 EMSL Courier Service

EMSL laboratories offer a courier service to customers that wish to drop off samples that are intended to be transferred to another EMSL laboratory for analysis. When a lab is acting as a courier they are not seen to be part of the contract review for analytical process and are not responsible for analytical results provided to the customer.

4.5.3 Selecting a Competent Subcontractor

Regardless of the situation, when subcontracting samples, the samples shall always be placed with a competent subcontractor. Where the customer specifically designates a laboratory to perform the analysis, this will override any other considerations and relieve the receiving laboratory of any responsibility for the selection.

In all other cases, the receiving laboratory shall select a laboratory which holds at least equivalent qualifications for the analysis. Relevant qualifications will depend on the needs of the customer and should be determined prior to subcontracting. Where a laboratory is accredited for an analysis, the laboratory selected shall hold equivalent accreditations. If not accredited, it should be determined which accreditations are required by the customer and select a laboratory meeting those requirements.

Qualifications of EMSL laboratories are included on the EMSL website as well as in an *EMSL Laboratory Qualification Summary* available on E-link.

If subcontracting to an external laboratory, the laboratory's qualifications shall be reviewed prior to selection. If the laboratory maintains accreditation for the analysis in question, a copy of their accreditation certificate shall be reviewed and kept on file. Where no accreditations are relevant to the analysis, information on laboratory personnel qualifications, quality system and proficiency testing participation shall be requested, reviewed and approved.

4.5.4 Customer knowledge and approval

As noted above, the EMSL standard terms and conditions reserves EMSL's ability to transfer samples between EMSL laboratories with equivalent relevant qualifications. By submitting samples, customers agree to these terms. Unless otherwise documented on the chain of custody by specifying the lab to do the work, the transfer of samples may occur at the discretion of the laboratory manager as discussed in the EMSL subcontracting SOP.

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Under ordinary circumstances, the customer will be made aware of the laboratory that will be performing the analysis at the time samples are submitted for analysis. In rare instances, a decision to subcontract may be made after the submission as a result of lab capacity, instrument problems, etc. In these cases the laboratory will contact the customer to inform them that the samples will be transferred. This communication will be documented in the customer correspondence logs, or via e-mail.

In the case of outside subcontracting, the customer will be informed of the subcontract lab prior to sample submission. Unless the customer specifies the laboratory to be used, it is the lab or department manager's responsibility to select a competent laboratory for the work.

In any case, the test report submitted to the customer will make clear the location and identity of the laboratory which performed the work.

4.5.5 Responsibility to the customer

The receiving laboratory is responsible to the customer for the work of the subcontractor, except in the case where the customer specifies which subcontractor is to be used.

In the case of subcontracting between EMSL laboratories, this responsibility is maintained regardless of whether the receiving laboratory is involved in the invoicing or direct reporting to the customer. Due to the corporate structure of EMSL, reporting and invoicing will be done directly from the subcontract lab. Direct reporting from the analyzing laboratory ensures that there is no confusion about the location at which the analysis was performed.

In all cases, the receiving laboratory remains the point of contact for the customer and will be involved in resolving disputes, arranging for reanalysis if requested, and generally acting as the responsibility party for interacting with the subcontract laboratory.

4.5.6 Subcontract register

As noted above, only competent laboratories shall be selected for subcontracting. Since EMSL laboratories may transfer samples to other EMSL laboratories with equivalent accreditations, the "EMSL Qualifications Summary" and list of EMSL labs and qualifications on the EMSL website will be considered the registry of EMSL subcontract labs. This list is maintained and updated by the EMSL corporate quality assurance department.

In the case of outside laboratories used for subcontracting, a list of these labs shall be maintained in each branch laboratory that conducts external subcontracting. In addition to the list, the information reviewed in making the determination of competence will be maintained and available for review. This evidence may include but are not limited to: accreditation certificates, statements of qualification, copies of quality documents including their quality manual (however named), or proficiency testing results.

4.5.7 Retention of Subcontracted Samples & Records

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. Technical records relating to the analysis (e.g., bench sheets, raw data, QC data) shall be retained by the analyzing lab unless otherwise specified and documented.

When samples are subcontracted to an outside laboratory, the receiving laboratory shall ensure that EMSL retention policies (for both samples and data) are communicated to the subcontracting lab and samples are retained for the required period of time.

4.6 Purchasing services and supplies

4.6.1 General

The EMSL procedures on purchasing and evaluating of supplies and services that are critical to the analysis of samples is documented in the *Purchasing of Supplies and Services SOP*. This

procedure helps ensure that purchasing and vendor selection is consistent across all EMSL laboratories.

4.6.2 Purchasing

Prior to placing a purchase order for supplies the laboratory manager shall refer to the EMSL List of Approved Vendors available on e-link. This list contains vendors for the following types of critical supplies and services:

- Laboratory equipment (consumable and permanent equipment)
- Subcontracted analytical work
- Proficiency testing providers
- Onsite services such as balance calibration and repair
- Outside calibration services
- Reagents and Standards

Approved vendors on the list have been evaluated by laboratory managers and the purchasing department on product/service quality, customer service and delivery. New vendors will be added to the list after the quality assurance department has verified that the vendor has the necessary qualifications and then evaluated with the next annual evaluation survey. Any complaint regarding a vendor (e.g. defective product, poor customer service) will be communicated to the purchasing department who will then investigate and help resolve the issue. Depending on the significance of the problem a decision will be made between the national director, the purchasing department and the quality assurance department, to discontinue use of the product or place the vendor on probation.

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.

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. (See § 5.6.3 on more info on selecting reference material providers). Reference standards shall be NIST-traceable (where applicable) and include a certificate showing traceability. Reference materials and standard reagents shall be obtained from the vendor with a certificate of analysis (certificate must identify the lot number). These certificates shall be maintained in the laboratory files prior to initial use. If no certificate is received, laboratory shall contact vendor immediately.

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.

Purchasing documents (e.g., order form submitted to purchasing via intranet, purchase order requests) shall contain technical details about the product or service being ordered. Prior to releasing to the vendor these documents are reviewed for technical suitability by the laboratory management and/or the purchasing department.

4.6.3 Approval of Service Providers

Where outside services are contracted that affect analytical testing such as proficiency testing services, 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.

Note: When arranging calibrations with an external calibration provider, EMSL requirements for calibration certificates should be discussed with the provider at the time of contracting. See § 5.6.2 for requirements of a traceable calibration certificate.

4.6.4 Reception, Inspection and Storage of Reagents and Consumable Supplies

When received by the laboratory, the labels of 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 could 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.

Materials shall be assigned an EMSL ID number and added to the Stock Standard and Reagent Log for the laboratory along with required information.

4.6.4.1 Verification of Materials

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.

Verification will consist of confirming that the purity grade recorded on the reagent or reference material label conforms to the requirements of the SOP and the product ordered 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.

4.6.4.2 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.

All reagents shall be stored with bottle caps or stoppers securely sealed. If reagent materials have been spilled on the exterior of storage containers, containers should be wiped clean before being placed in storage. Storage cabinets shall be cleaned periodically to prevent deterioration. If storage cabinets show significant deterioration (e.g., rust) these shall be repaired or replaced to ensure their integrity.

General procedures for storage of reagents require the separation of incompatible materials. Organic solvents (e.g., acetone, THF, reagent alcohols) shall be maintained in a storage cabinet suitable for flammable materials. (metal). Acids (e.g. nitric, hydrochloric) shall be stored separately from organic solvents in a cabinet away from them. Materials may be stored together when they are of similar classes that will not cause interferences or increase risk of cross contamination (e.g., hydrogen peroxide with acids).

4.6.4.3 Solution Preparation

Solutions prepared from neat materials shall be recorded on the EMSL Preparation Log available on e-link. The log shall include a description of the solution, date of preparation, concentration and/or purity of solution, identification of parent material (i.e., the ID assigned on the Standards and Reagents Log), preparer's initials, and expiration date. Solutions shall be labeled with the ID, ID number from preparation log, and expiration date (usually the expiration date of component materials which is closest to the date of preparation). Using preparation log and standards log, solutions shall be traceable back to parent material and certificates of analysis for that material.

4.7 Service to the Customer

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.

Customer requests should be carefully considered and followed as long as doing so is not detrimental to the business, integrity of the results, misleading or in violation of any statutory, regulatory or accreditation requirements.

4.7.1 Documenting 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 or commercially available bound phone message pads which are dated with initial and end dates once full. 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. These records shall be maintained 5 years as per EMSL Record Control SOP or for the life of the project files.

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.

4.7.2 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.

4.7.3 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.

Summaries of feedback will be shared with laboratories in such a manner that customer confidentiality is maintained while providing the labs with feedback information. Ordinarily this will be done in the Annual Management Review report.

4.7.4 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.

4.7.5 Emergency Laboratory Closings

Where a laboratory's operating hours are affected by any emergency condition (e.g. weather events) the lab manager notifies the Corporate Sr. Vice President (s), the IT Department and customers where applicable. An intra-company email is broadcast with the information. Where possible, calls are re-directed to the corporate laboratory or other unaffected laboratory. The corporate customer service group and/or sales and marketing department representatives continue to contact customers as necessary.

4.8 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.

Any complaint about the quality of reported results may be referred to the accrediting authorities who accredit the work being reported if such complaints cannot be resolved directly with the customer.

4.8.1 Documentation of Customer Requested Re-analysis

There may be times when a customer will request re-analysis of samples.

4.8.1.1 Results falling within quality control acceptance limits

If the results from the re-analysis fall within the QC acceptance criteria then the original report remains as the official report. The results should be communicated to the customer and this communication shall be documented and the supporting data filed with the paperwork from the original analysis.

4.8.1.2 Results falling outside of quality control acceptance limits

If the results from the re-analysis fall outside of the acceptable QC range, and the original results have already been reported, the customer will be notified and an amended report should be generated and submitted to the customer (See section on "Amendments to Test Reports"). The discrepancy will need to be addressed with a corrective action report. All customer communication should be documented and the supporting data filed with the paperwork from the original analysis.

4.9 Control of non-conforming testing

The control of non-conforming testing is addressed in detail the *EMSL SOP on Non-conformities and Corrective Actions*. Non-conforming work can be identified by any person working in the laboratory, or brought to the attention of lab staff through an outside party (e.g., a complaint). Upon identification of any non-conforming work, it should immediately be documented using a *Non-Conformity/Corrective Action Record (CAR)* and forwarded to the lab or department manager for review. Any employee of EMSL may initiate a temporary work stoppage if it is believed that non-conforming work will continue to be produced. The work stoppage shall be reported to the lab manager immediately. If the work stoppage is required for more than an hour, the lab manager must report the stoppage to Corporate Management immediately.

The review of non-conforming work shall be documented on the CAR form and will include:

- an evaluation of the significance of the non-conforming work,
- a determination of acceptability of non-conforming work, and
- an evaluation of whether the non-conforming work could recur or whether it is a result of a failure to comply with EMSL policies or procedures.

Remedial action will be taken immediately to correct non-conforming work. If a work stoppage was necessary, the lab or department manager will determine what action is necessary to begin work and document this on the CAR. Only the lab manager or corporate management has the authority to resume work once a stoppage is required.

If the evaluation determines the non-conforming work could recur or is a result of a failure to comply with EMSL policies or procedures, formal corrective action is required. This shall be recorded on the CAR form according to the *SOP on Non-conformities and Corrective Action* and § 4.11 below.

4.9.1 Notification of Non-Compliance

If a major deficiency in policy or procedure is identified which affects customer results, the customer will be notified in a timely manner (no later than 30 days from the date that the problem is identified.) Major non-conformities may be discovered during an internal audit, external audit or a regular quality control review. In some cases, the report will require a disclaimer in order to ensure that test results can be interpreted properly. Examples of major deficiencies may include (but are not limited to):

- Quality control reanalysis results outside acceptance limits which call into question test results.
- Calibration measurements are outside acceptance limits and may have a negative impact on the results provided to customer.
- Sample contamination is suspected (e.g., as a result of positive blanks).
- Failure to follow procedure as written resulting in possible erroneous results.

4.10 Improvement

EMSL is committed to the continual improvement of the effectiveness of our quality system. As noted previously, the management system is reviewed annually as part of the annual management review along with the continued efficacy of the Quality policy and what progress was made on quality objectives. Management system documents are reviewed periodically and updated as necessary. In addition, EMSL utilizes the feedback from customers, employees and assessors in making changes to the management system in order to improve its efficiency. Other systems which are designed to provide feedback on both the design and implementation of the quality system include:

- Corrective and Preventive Action
- Internal Audit Program
- Customer Feedback Survey
- Monthly & Quarterly QC Reports

4.11 Corrective Action

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-LAP, NVLAP, TNI 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*.

4.11.1 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.

4.11.2 Documenting Non-conformities and Corrective Actions

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 (if any) were taken to resolve the non-conformity and prevent its recurrence.

4.11.3 Evaluation of Non-conformities & Nonconforming Work

In order to evaluate the extent of effect a non-conformity 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 breach 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.

4.11.4 Cause analysis

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 may include review of QC data, sample tracking, data transcription, instrument calibration, training documentation, and discussion with personnel. See *Corrective Action SOP* for additional details.

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 shortage of resources, improper maintenance of equipment, or insufficient training. The *Non-conformities and Corrective Action SOP* contains a discussion of root cause analysis.

4.11.5 Selection and implementation of corrective actions

Corrective actions are those actions which are taken to eliminate the root cause of a non-conformity and prevent its recurrence. This should be contrasted with a remedial action which is taken to eliminate the effects of a non-conformity (e.g., reissuing a corrected report is a remedial action, while improving the review process which allowed the faulty report may be a corrective action).

Corrective actions may include: additional training of staff, repairs to equipment, additional personnel resources, etc. Corrective actions should be changes which will eliminate the deepest cause possible and that are within the control of EMSL. The corrective action should be proportional to the severity of the non-conformity and the likelihood it will recur.

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 affect the sample results), work is to be stopped immediately and the problem corrected.

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

The laboratory QAC and/or laboratory manager is responsible for tracking and reviewing the corrective actions filed for non-conformities. The lab QAC and/or laboratory manager must indicate when corrective actions are complete.

4.11.6 Monitoring of corrective actions

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. Follow-up actions shall be scheduled on a case-by-case basis as soon as practical but far enough in the future that a recurrence has the opportunity to occur.

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. The scheduled date for follow-up, date follow-up was conducted, and effectiveness of corrective action is documented on the CAR form.

The QA Department is responsible for following up on those corrective action reports submitted to the QA department by the laboratory for further action.

4.11.7 Additional audits

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 affected 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
- Review of other results that may be affected by the root cause as determined

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

4.12 Preventive action

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 QMS 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.

4.13 Control of records

4.13.1 General

The EMSL control of records procedures are documented in the *EMSL 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.
- All handwritten data shall be recorded using permanent ink.
- If a record contains a mistake that must be corrected, the mistake shall be single-line 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. Therefore, records such as employee records, certificates of

analysis for standards, calibration certificates, etc. shall be retained for the life of the activity to which they are related (e.g., until 5 years after an employee leaves, until 5 years after the standard is disposed of or completely used, until the next calibration is completed.)

- The majority of records shall be retained for a minimum of 5 years or for the period of time established by relevant accrediting authorities or contract requirements (see *Control of Records SOP* for any exceptions to the 5 year hold time).
- Where records are removed from storage (e.g., archive boxes, file drawers) for any reason, the laboratory shall insert a Record Out Log card in place of the records and record on the Log card the name of the person removing the file, the files removed and the date removed. When replacing the file, the card shall be updated by noting "Replaced" and the date it was replaced in the file.
- Records shall be protected against fire, theft, loss, environmental deterioration, vermin, and, in the case of electronic records, electronic or magnetic sources.

Click to Jump to Amendment

- Records shall be disposed of in a manner that maintains customer confidentiality.
- Electronic records are considered equivalent to paper records and are to be maintained and controlled in an analogous manner. Backups of electronic records are to be protected according to the procedures in the Control of Records SOP.
- All hardware and software necessary for the historic reconstruction of data must be maintained by the laboratory for the same period of time as the data produced.

4.13.2 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.

Data generated in the laboratory shall be recorded on preprinted analytical data worksheets or, where available, directly into the computer system via a Direct Data Entry (DDE) system (iL@b). Each analytical procedure has its own specific worksheet or iL@b module. Many of these worksheets, when used, 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.

Where iL@b DDE is available, data is recorded directly into the lab database. Any additional information recorded manually in hard-copy shall be maintained along with the COC and ICOC in project records.

4.13.3 LIMS (SMXP) Data & Security

SMXP data is retained in a "live" redundant replicated instance of SQL Server 2005 in a Master database for a minimum of 16 months. Data older than 16 months 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 *Control of Records SOP*.

4.13.4 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 *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.

4.13.5 Signature and 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.

4.13.6 Use of Electronic Signatures

Signatures are provided to the IT Department using the *Final Report Approval Form and Electronic Signature Sample Form*. Signatures are scanned, stored as an image and forwarded back to the signatory via e-mail. The signatory maintains responsibility for the use of their signature. They may provide approval for its use through an e-mail or verbally. Documents are printed to PDF to secure signatures from alteration.

4.14 Internal 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, ISO 17025, TNI standards and additional requirements as set forth by relevant accrediting authorities (e.g. AIHA-LAP, NVLAP). Audits will be conducted by laboratory management or by 3rd party personnel approved by the QA department.

The internal audit is scheduled by the Quality Assurance Department and covers all aspects of the management system including testing activities. Audit findings are recorded on the *EMSL Internal Audit Checklist* which is based on ISO 17025 requirements with additions made for additional requirements of accrediting agencies. Non-conformities identified during the internal audit will be corrected and followed-up according to EMSL corrective action process.

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

4.15 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 TNI 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
- Review of quality policy objectives
- Other relevant factors, such as quality control activities, resources and staff training

Usually during 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.*

REVISION HISTORY

Previous revision histories are available from the QA department on request.

Revision	Date	Changes
16	5/30/13	Changed QAM to QMS Manual. Changed Client to Customer. 4.1.3 – Updated General Org Chart. 4.1.4.3.1 – Last sentence added. 4.5.5 – Removed 3rd paragraph. 4.8.1.2 – Modified to make explicit condition that results were reported. 4.11.3 – 3rd and 4th paragraphs deleted. These items are addressed in CA SOP. 4.13.6 – Added from previous amendment.
15	9/16/11	4.1.2 – Added reference to relevant policies and procedures to last paragraph. 4.1.4 – Noted that org charts can be found on E-link. 4.1.5.1 – Added exception for legal obligations to confidentiality policy. Clarified that requests from government agencies or legal representatives are not necessarily proper cause for giving out data. 4.3.1.2 – Minor clarifications. No substantive changes. 4.3.1.5 – Clarified that most recent review date is documented on Master List. 4.3.1.6 – Clarified changes that may be made by amendment or revision. Clarified that these changes may be locally maintained by lab after approval. 4.6.3 – Added Note. 4.6.4.3 – Clarification on assigning expiration date for prepared solutions.

		4.7.1 – Clarified customer correspondence shall be retained as a controlled record. 4.7.5 – Added note that in Emergency closings, calls will be transferred when possible. 4.11.7 – Added last bullet. 4.13.1 – Clarified that some types of records need to be retained beyond the standard retention period.
14	7/1/11	References to AIHA changed to AIHA-LAP. References to NELAC standard changed to TNI standard. 4.1.1 – Added statement on commitment to "most recent revision" of 17025 standard. 4.1.5.2.1 – Clarified ethics policy applies to all employees including FT/PT, permanent and temps. 4.1.5.2.1. - Ethics Statement – Updated to include references to falsely signing SOP acknowledgements, and knowingly failing to follow policies and procedures as ethical issues. Clarified that ethics or data integrity issues can always be brought to the HR department for confidential handling. Added requirement that customers be notified when ethical or data integrity issues may impact results received. 4.1.5.2.2 – Added new sections to Data Integrity section on Confidential Reporting and Data Integrity Investigations. 4.6.2 – Added reference to Section 5.6.3 on selecting reference material providers. 4.13.1 – Added requirement that all handwritten data on records must be made using permanent ink. Added requirement that hardware and software needed for historic reconstruction of data must be retained for life of data produced (according to record maintenance requirements).

Section 5.0: Technical Requirements

5.1 General

This section discusses the general technical requirements of the EMSL management system which are applicable to all lab operations. Specific and additional requirements for certain areas will be found in the program specific modules at the end of this manual.

5.2 Personnel

5.2.1 Laboratory Job Responsibilities/Descriptions

5.2.1.1 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.

All descriptions discussed in this section include the responsibility to ensure compliance with the policies documented in this manual and the requirements of the quality standards including ISO/IEC 17025, TNI, A2LA, AIHA-LAP LLC-specific requirements, NVLAP and state accreditation agencies where applicable.

5.2.1.2 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:

5.2.1.2.1 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 and informs lab or department manager if there are any concerns noted regarding sample integrity.
- Ensures that laboratory has ability, capability and capacity to analyze samples prior to log-in (with Laboratory or Department Managers).
- Logs in all samples in a timely manner based on turnaround time.
- Delivers incoming samples to the laboratory.
- Ensures all samples are placed in the proper storage area to await analysis.

- Informs the laboratory manager or analyst of any special priorities regarding the samples.

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.

The administrative coordinator is also responsible for ensuring that proper sample numbering and labeling is performed and that sample information is 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 as related to job responsibilities.

5.2.1.2.2 *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 manner.
- Reviews the information in the report and checks 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 as related to job responsibilities

The administrative coordinator contributes to the EMSL quality objectives by ensuring that they act as a professional interface between technical personnel and 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 non-conformities, opportunities for improvement and customer complaints and report these to the personnel authorized to handle these situations.

5.2.1.3 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 familiarity and compliance with all relevant quality standards as related to job responsibilities by reading and following EMSL policies and procedures which adopt these standards.

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 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.

5.2.1.4 Quality Assurance Coordinator (QAC)

The QAC works under the direction of the laboratory manager (or regional manager /national director if the QAC is the laboratory manager) with periodic interaction with the corporate 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 QAC is responsible for ensuring that all QA/QC procedures are performed at the required frequencies for the laboratory or departments under their supervision. 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 QAC.

The QAC 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 QAC ensures that the laboratory maintains compliance with the policies and procedures documented in this manual and the requirements documented in all relevant quality standards.

The QAC contributes to the EMSL quality objectives by ensuring that all quality system requirements are being followed in the laboratory. The QAC 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.

5.2.1.5 Quality Control Coordinator (QCC)

The laboratory quality control coordinator (QCC) reports directly to the lab manager and indirectly to the QAC. Generally, they oversee the QC program for one or more departments.

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 QCC ensures that all QC requirements are being met including the types and frequency of QC analysis as defined in the QMS Manual and analytical procedures, that acceptance criteria are established and utilized, and monitors QC data for trends. .

The QCC will report on QC performance to the QAC or lab or department managers for the departments which they are assigned. They may assist in the assembly of monthly and quarterly quality reports.

5.2.1.6 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 shall ensure that adequate supervision is provided for all laboratory technical personnel and 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. 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 non-conformities and complaints are resolved in a timely manner leading to continual improvement at the laboratory.

In accredited labs, if the person identified as the lab manager (or technical director for TNI) will be absent for more than thirty (30) days, EMSL shall contact the accreditation body to notify them how requirements will be met in the interim.

5.2.1.7 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.

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.

5.2.1.8 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.

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.

5.2.1.9 Corporate Quality Control Administrator

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

Minimum educational/experience requirements is 2 years related analytical experience.

The corporate quality control administrator (QCA) reports to and works under the direction of the corporate quality assurance manager. The corporate QCA 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 QCA is responsible for ensuring compliance with the requirements of the quality control program. The corporate QCA 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 QCA is responsible for maintaining the program and standard operating procedures used for QC data and TEM calibrations.

The corporate QCA 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 QCA ensures that the laboratory maintains compliance with the policies and procedures documented in this manual and the requirements documented in relevant quality standards.

The corporate QCA 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 QCA's participation in the annual management reviews includes feedback on individual lab performance and advice on areas for improvement.

5.2.1.10 Corporate Quality Systems Manager

The corporate quality systems 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 systems manager works with the corporate QA manager to develop EMSL policies and procedures, and ensuring that these comply with accreditation

requirements. The quality systems manager also assists in the management of laboratory accreditations.

The quality systems 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 and improved laboratory performance.

The quality systems 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 systems 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.

5.2.1.11 Corporate Quality Assurance Manager

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 has the authority to:

- Develop and implement quality assurance and quality control policies
- Implement change to ensure the effectiveness of the quality management program
- Participate in business decisions related to the development of additional service areas, accreditations, etc.
- Report non-conformities and breeches in ethics policies to Senior Management
- Direct other departments in order to achieve the goals of the quality program
- Write and/or issue Standard Operating Procedures

The corporate QA Manager is responsible for establishing, implementing, and maintaining 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 also responsible for maintaining the QMS manual and all standard operating procedures (SOPs). He/she is responsible for conducting and/or

establishing policies for QA audits, and setting the standards for laboratory practices. They confer with the national directors, regional managers and/or the laboratory managers on QA policies and support 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 all relevant quality 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.

The corporate QA Manager is granted the authority by EMSL Sr. Management to perform these tasks and ensure that the EMSL management system as it relates to quality is being implemented and followed at all times.

5.2.1.12 Senior Vice President, Laboratory Services

The Senior Vice President (SrVP), Laboratory Services is responsible for the overall quality performance of the entire company, including the initiation, development and maintenance of the quality management system. The SrVP, Laboratory Services 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 SrVP, Laboratory Services 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 SrVP, Laboratory Services makes all decisions related to the status of laboratory certifications and accreditations.

The SrVP, Laboratory Services contributes to the quality objectives of the laboratory by ensuring that the company maintains compliance with the policies and procedures documented in this manual and the requirements documented in relevant quality standards.

As part of top laboratory management, the SrVP, Laboratory Services assists in setting the quality objectives of EMSL. In addition, the SrVP, Laboratory Services 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 SrVP, Laboratory Services 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 SrVP, Laboratory Services shall ensure that the integrity of the management system is maintained at all times when changes are made to laboratory operations.

5.2.1.13 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.

5.2.2 Training

5.2.2.1 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. Details on documenting training for analysts is available in the "Training on Analytical Methods SOP" available on E-Link.

All analysts must complete the EMSL training program in order to perform analysis independently and receive a completed Demonstration of Capability certificate. All employees (full-time or part-time, permanent or temporary, including interns) must read the QMS manual and SOPs which are related to the work with which they will be responsible, ensure these are understood and acknowledge the document stating their commitment to follow the procedures and policies outlined therein.

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.

5.2.2.2 Identification of Training Needs and Goals of Training

The need and goals for training are determined by the laboratory manager or corporate management. Needs are identified considering:

- Cross training to increase laboratory productivity
- Decreasing trend in quality
- Change in type of work

- Change in requirements or procedure
- Addition of analytical services

The goals of training will differ based on the area of training. In general, training is intended to familiarize personnel with the policies and procedures of the laboratory, ensure personnel are aware of changes to policies and procedures, are knowledgeable and skilled in proper analytical and/or preparatory technique, and understand the theory underlying the work.

5.2.2.3 Types of Training

5.2.2.3.1 "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. Capability will be determined based on knowledge, experience and demonstrated technical competence. The trainer must have a thorough and comprehensive understanding of the topics involved.

5.2.2.3.2 "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 be a qualified analyst with 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

5.2.2.3.3 "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.

5.2.2.4 Initial Training and Authorization of Analysts

5.2.2.4.1 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 QMS Manual 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 was eliminated beginning with Revision 10 of this document. 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. Likewise, previous revisions of the training checklist are acceptable as it represents the state of training documentation at that time. Analyst performance will have been demonstrated through acceptable QC analysis. However, if no training documentation exists, the current checklist should be used to document the current competency of the analyst. Each item should be reviewed and acceptable performance/knowledge documented by the analyst and the department manager or national director in the case of department managers.

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.

Where no training checklist exists for a particular method, or if the checklist does not detail a method for initial demonstration of capability, an initial demonstration of capability shall be performed as per the method, or where the method does not specify, the method outlined in TNI Standard (July 1, 2011) Sect. 1.6.2.2 or an equivalent method.

5.2.2.4.2 Frequency of Initial DOC

An initial DOC shall be completed prior to a new method being introduced, or when there is a change in method or instrumentation. TNI also requires an initial DOC whenever an analyst or the lab has not performed a method within the past twelve (12) months. This requirement shall be taken into account when considering accepting samples for a method that has not been performed in the past year. It is strongly suggested that labs have analysts perform analysis with each method on QC samples at least once a year to maintain their capability with infrequently used methods.

5.2.2.4.3 Demonstration of Capability (DOC) 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, 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 department or lab 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 Capability was completed. The date of the Corporate QA Manager's 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 or department 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 changes. 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 Capability 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 Capability shall be issued through the QA department as required above.

5.2.2.4.4 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.

5.2.2.4.5 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.

5.2.2.5 Ongoing Training and Continued Demonstration of Capability

5.2.2.5.1 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 – scheduled as needed, 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. 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.

5.2.2.5.2 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 12 months (or 6 months for AIHA-LAP accredited methods) 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.

5.2.2.5.3 Recertification Statements

Every 12 months (or 6 months for AIHA-LAP accredited methods), the laboratory or department manager shall sign a Recertification Statement for each analyst to document continued authorization to perform analysis. If the laboratory/department manager is also authorized to perform analysis, the national director or lab quality manager (if different) 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.

5.2.2.6 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 items 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

5.2.2.7 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 Capability policies above.

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

5.2.2.8 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:

- 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 Capability 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 supporting the initial and ongoing demonstration of capability for the analyst may be referenced in the personnel folder, instead of being included. 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 capability, 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.

5.3 Accommodation and environmental conditions

5.3.1 General

EMSL is committed to ensuring that laboratory facilities are appropriate for ensuring the correct performance of tests. For example, attention will be paid to energy sources, lighting and environmental conditions, and separation between neighboring areas in which there are incompatible tests

Any specific technical requirements for a specific method are documented in the program specific modules of the QMS Manual, or in the specific technical SOPs. Examples of specific environmental conditions that may affect tests and will be documented in the modules or SOPs include sterility of work area, electromagnetic disturbances, temperature, and/or humidity, radiation, and vibration levels.

Where it is determined that controlled environmental conditions are crucial for the performance of a test or the interpretation of results, the lab will monitor, control and record these conditions as necessary (i.e., through the use of temperature logs, humidity logs, readings included on bench sheets, etc.)

Should a laboratory or department manager determine that the facility must be modified to meet requirements, these requests will be sent to the President or Senior Vice President, Laboratory Services for approval.

Access to the laboratory beyond the receiving area is restricted to laboratory employees or contracted employees. If non-laboratory personnel wishes to enter these areas they shall be accompanied by authorized lab personnel.

The laboratory manager is responsible for ensuring that good housekeeping practices are in place in the laboratory. This includes periodic wipes of areas prone to contamination, proper cleaning of lab glassware, disposal of disposable consumables following use, and general cleanliness of the laboratory facility including non-analytical areas. Where specific procedures must be followed, these will be documented in the QMS Manual program specific modules or in analytical SOPs.

5.3.2 Contamination Management

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 of contamination include samples and laboratory debris. Targets include things such as, samples, equipment (e.g., tools), supplies (e.g., microscope slides and reagents) and work areas

Contamination control consists of 3 parts:

- Avoidance
- Detection
- Resolution

5.3.3 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.

5.3.4 Detection of Contamination

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

5.3.4.1 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.

5.3.4.2 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 throughout 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 specific details on what quarterly contamination monitoring is required.

5.3.5 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.

5.4 Test methods and method validation

5.4.1 General

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, but may not be limited to:

- **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*
- **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.Internal Audit SOP** – *Standard Operating Procedure for Internal Quality Assurance Audits*
- **EMSL Annual Management Review SOP** – *Standard Operating Procedure for Annual Management Review Reporting*
- **Purchasing of Supplies and Services SOP** – *Standard Operating Procedure that addresses the purchase and evaluation of supplies and services that are critical to the analysis of samples*.
- **Prep and QC of Materials SOP** – *Standard Operating Procedure for the receipt, preparation, handling, storage, quality control and disposal of consumables, kits, media, reagents, solutions and standards*.
- **Sample Chain of Custody SOP** – *Standard Operating Procedure to track the custody of samples using the Chain of Custody form*.
- **EMSL Method Validation SOP** – *Standard Operating Procedure for Validation of Methods and Method Modifications*
- **EMSL Training on Analytical Methods SOP** – *Standard Operating Procedure for Documentation of Training on Analytical Procedure*
- **EMSL Subcontract Laboratory Procedures SOP** – *Standard Operating Procedure for the distribution of samples to other laboratories for analysis, including transfer of samples to other EMSL laboratories.*
- **Amending Final Reports SOP** – *Standard Operating Procedure to ensure all EMSL amended reports are appropriately and consistently identified as an amended report.*
- **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 corporate QA manager for review. The corporate 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.

Click to Jump to Amendment

5.4.2 Selection of method

EMSL always uses test methods which meet the requirements of its customers. Whenever published and widely accepted methods are available these standard methods are adopted and used. Any EMSL specific additions or modifications are documented in the SOP for that method.

In general, most tests offered by EMSL are included on the standard chain of custody forms and selected by the customer by use of this form, or by documenting the test number selected on their own chain of custody. If a method is not selected by the customer, the laboratory shall communicate with the customer to determine which methods are most appropriate. If a customer selects an inappropriate method they will be contacted immediately to determine the most appropriate method for their needs.

Where no standard methods are available, laboratory developed or modified standard methods may be used once they are appropriately validated and once the laboratory confirms it can operate the procedure. The customer will always be made aware of the procedure to be used prior to testing.

5.4.3 Laboratory-developed methods

As noted above, where published standard methods are not available EMSL will develop its own methods for an analysis, or modify existing methods to ensure they are appropriate for the test requested. Validation of these methods is discussed below. Development of new methods is a planned activity and assigned to personnel with appropriate expertise. The SOP will be reviewed and approved by the national director for that area of analysis.

5.4.4 Non-standard methods

5.4.4.1 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

5.4.4.2 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.

5.4.4.2.1 Validation of Non-standard Methods or Departures from SOPs

A validation study must be performed before analysis is performed on customer samples for any non-standard method or departure from method. A validation study involves:

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

The procedure used to validate a method also involves 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.

5.4.5 Validation of methods

The majority of the procedures utilized by EMSL laboratories are based on published methods issued through governmental regulatory agencies and independent standards organizations. These methods must be validated following the EMSL Method Validation SOP to verify acceptable method performance. Validation must occur before performing analysis on customer samples.

TNI requires that an initial DOC be conducted for each method and analyst prior to using any method, and at any time there is a change in instrument type, personnel or method or any time that a method has not been performed by the laboratory or analyst in a twelve (12) month period.

In cases where a lab analyzes samples using a method that has been in use by the laboratory for at least one year prior to applying for TNI accreditation, and there have been no significant changes in instrument type, personnel or method, the ongoing DOC shall be acceptable as an initial DOC. The laboratory shall have records on file to demonstrate that an initial DOC is not required.

Methods used by EMSL are also 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.

5.4.6 Estimation of uncertainty of measurement

The QMS Manual program-specific modules and SOPs address the estimation of uncertainty for each program area. EMSL's policy is to have a procedure for the reasonable estimation of uncertainty for its quantitative tests.

EMSL's uncertainty procedures address only analytical uncertainty since EMSL generally does not perform sampling for its customers, and therefore cannot account for contributors to uncertainty resulting from sampling procedures. Unless stated otherwise in the analytical procedure or QMS Manual Modules, EMSL uses results from repeated analysis of prepared standards over time as a basis for determining uncertainty for a test method (Type A approach). In general, replicate and/or duplicate quality control data are used to generate mean recoveries and standard deviations for the method over time. Using this mean recovery, each method will be evaluated upon request to determine the uncertainty and probable bias of the method. Expanded uncertainty will then be derived by multiplying the standard uncertainty by a k factor (i.e. the student t value at 95% confidence interval which is related to the degrees of freedom (v) of the data set used in the calculation (v=n-1)).

Uncertainty is determined using QC template Excel workbooks which have been designed to calculate sample results, chart control chart data for precision and accuracy of each run, and calculate uncertainty data for each measurand associated with the method. Instructions on the use of these workbooks can be found in the workbooks themselves. References to the proper workbooks can be found in the program specific QMS Manual Modules.

Each method (either in the SOP or in a separate document, such as an uncertainty worksheet) contains an evaluation of the sources of uncertainty as well as the procedure for estimating uncertainty. Uncertainty will be reported if requested by the customer, when required by the analytical method, when necessary for interpretation of results or when uncertainty affects compliance with a known specification limit. Even if not requested, all necessary data for evaluating uncertainty will be retained in the laboratory. When uncertainty is reported, it shall be reported with the analyte concentration in the same units as analyte concentration and shall include the coverage factor and confidence interval used in the estimations. Bias will be reported separately where it exists and is uncorrected.

Uncertainty shall be re-estimated when changes to operations occur that could affect it such as changes in instrumentation, modifications to methodology or technique, etc.

5.4.7 Control of data

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.

5.4.7.1 Continuous Data Validation

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. 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:

5.4.7.1.1 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.

Only labs and methods that have been approved by corporate management for remote log-in may follow this process.

5.4.7.1.2 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 customer chain of custody confirming that the requested analysis is being performed. At this stage too, any problems with the samples or paperwork are noted and brought to the attention of the laboratory manager.

5.4.7.1.3 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 method 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.

5.4.7.1.4 Analytical Results Entry

iL@b is a custom module developed for the EMSL LIMS system. It allows analysts to input data directly into the lab database rather than relying on the added step of transcribing from paper benchsheets to the database. iL@b is

being rolled out gradually to all departments. Once approved by the analyst the data is available in the database for future review as discussed below both as raw data and in the final report format.

For analyses not covered by iL@b, 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 instrument printouts into the LIMS (or Excel) reporting spreadsheet. Analytical results are entered either by personnel approved for data entry, 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. Chain of custodies are copied and placed in the laboratory master files along with the analytical worksheets and raw data.

5.4.7.1.5 Proofing of Reports

After data entry, reports are sent to the laboratory manager or designee for review. The reports are reviewed for completeness and accuracy. A check on the quality control analysis performed in association with the results is also performed. This is also another 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. Where errors are determined to be a result of non-conformities in lab process, a corrective action will be initiated. Random errors, such as typographical errors, do not need to initiate corrective action unless they occur frequently indicating a systematic problem which needs correction.

5.4.7.2 Computer Software

5.4.7.2.1 General

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 and the Sample Master Beta testing team, which consists of several EMSL Subject Matter experts.

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.

5.4.7.2.2 Validation of Computer Software & Data

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.

Additional information on the EMSL Software Development Life Cycle, which includes the validation of LIMS software, can be found in the *General Guidelines for EMSL Information Technology* document found on E-link.

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.

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.

5.5 Equipment

5.5.1 Local Equipment Inventory & Logbook

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" tab on the *EMSL Equipment Maintenance Log spreadsheet*.

In addition, a logbook shall be maintained for each piece of critical equipment in use at the laboratory. All maintenance, repairs, calibrations performed on the instrument shall be recorded, along with the identity of the equipment and software, mfg. name, type ID and serial number, and current location (if appropriate). For most labs, this is done within the *EMSL Equipment Maintenance Log spreadsheet*. However, in some circumstances this will be maintained in a separate Equipment Log notebook. Labs are strongly encouraged to use the spreadsheet whenever possible. 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).

5.5.2 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

5.5.3 Instrument Calibration

Accrediting authorities and standard published methods have specified the frequency and manner in which a laboratory must calibrate their instruments. For laboratories maintaining ISO

17025 accreditations (e.g., AIHA-LAP, NVLAP, A2LA, TNI), calibrations of equipment used in accredited tests must be performed internally by trained personnel using approved accreditation procedures or by an outside calibration firm that is accredited to the ISO/IEC 17025 standard. The calibration must be performed following the ISO standard.

Before being placed into service, or returned to service after repairs or modifications, the equipment and its software is calibrated and checked to establish that it meets EMSL & method specifications. Thereafter, calibration schedules established in this QMS Manual and related program specific modules, as well as related SOPs shall be followed. Intermediate calibrations may be required as necessary. All calibrations should be documented in the *Equipment Maintenance Log.*

Labels shall be placed on all calibrated equipment and reference standards where space permits which include date of last calibration and date calibration is next due along with any correction factor where applicable. Where space does not permit the use of a label, a label shall be placed near the instrument or standard and shall be associated with the instrument by serial number or equipment ID.

Whenever calibration leads to a set of correction factor, these correction factors shall be referenced on the accreditation label or otherwise affixed to the equipment and shall be included in any calculations for which the correction factor is relevant.

Specific analytical instrument calibration requirements are found in the appropriate program module or related SOPs. Requirements for the calibration of common support equipment are included below. Also see § 5.6 of this manual for requirements for calibration/verification of common Reference Standards.

5.5.3.1 Balances

Balances shall be calibrated upon installation then annually thereafter by an outside 17025-accredited calibration provider.

Balances are verified in the laboratory to stated tolerances each day of use against working calibration weights traceable to NIST as per *EMSL Balance Calibration.Verification SOP*. Acceptance criteria are established in the SOP and included in the *Balance Calibration.Verification Workbook* which is used to record verification data.

Where verifications do not meet set acceptance criteria, the instrument shall be cleaned and re-checked. If verification still does not pass, instrument shall be taken out of service until it can be repaired.

5.5.3.2 Pipettes

Pipettes shall be calibrated upon initial use and quarterly thereafter. Measurements of dispensed weight are taken as per the *EMSL Pipette Calbration.Verification SOP*, and results calculated using the *EMSL Pipette Calibration.Verification Workbook*.

Acceptance criteria are established in the *EMSL Pipette Calibration.Verification SOP.* Where verification results are outside acceptance limits, the instrument shall be removed from service and adjusted or replaced as appropriate. For adjustable pipettes, a failure at any check point requires the entire calibration to be repeated after adjustment.

5.5.3.3 Working Thermometers/Thermocouples
All working thermometers shall be verified against a NIST-traceable reference thermometer (See § 5.6 below) following *EMSL Thermometer Calibration.Verification SOP.* Data shall be recorded on the *EMSL Thermometer Verification Form*. If deviations between the working and reference thermometers are within acceptable criteria range as defined by the SOP, the thermometer shall be labeled with the Correction Factor (CF) and use continued by applying the CF. If acceptance criterion is not met, the thermometer shall be immediately removed from use and repaired or replaced as appropriate.
NOTE: When recording results from Thermometers/Thermocouples for which a CF is necessary, the log where temperature is recorded shall make clear whether the CF has been applied. One approach is to record as Temp + CF (Example: Instead of recording "31.8 °C", record as "32.0 - 0.2 °C CF".)

5.5.4 Requirements for Calibration Certificates from External Calibration Services

When obtaining calibration services from an outside calibration service, it is crucial that the calibration certificates received meet accreditation requirements. The following information must be present on the certificate, or if provided supplemental to the certificate it shall be explicitly related to the certificate (e.g., by use of a calibration certificate number):

5.5.4.1 Evidence that the measurements are traceable to NIST or an equivalent National Metrology Institute

5.5.4.2 The report or certificate shall be endorsed by the recognized AB's symbol (or otherwise makes reference to accredited status by a specific, recognized AB) with an indication of the type of entity that is accredited.

5.5.4.3 An estimate of uncertainty for the measurements made.

Note: While many reports contain a "best" uncertainty capability for calibrations performed under ideal conditions in the lab [a Calibration and Measurement Capability (CMC)], this does not meet the requirement of uncertainty of measurement for the specific measurements being reported.

5.5.5 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.

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.

As noted above, all maintenance shall be recorded in the Equipment Maintenance Log.

5.5.6 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.

5.5.6.1 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).

5.5.6.2 Storage

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

5.5.7 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.

For laboratories maintaining ISO 17025 accreditation: Outside calibrations must be performed to ISO 17025 standards by an ISO 17025 accredited calibration laboratory. The certificate of calibration must indicate the calibration had been performed following the ISO standards.

5.5.8 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 for the test method while the approval for an acetone vaporizer or water bath may be done verbally.

5.5.9 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.

5.5.10 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 affected any reported analytical results.

5.6 Measurement traceability

5.6.1 General

According to the International Vocabulary of Basic and General Terms in Metrology (VIM), traceability is the "property of the results of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparison, all having stated uncertainties". Any material used for calibration purposes in the laboratory must have its value traceable to NIST, if possible. Procedures have been developed following AIHA-LAP's *Guidelines for Traceability*.

EMSL is committed to ensuring the 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. Certificates of analysis for SRMs must be on file in the laboratory before using the material.
- Calibration of instrumentation against NIST-traceable standards. Wherever possible, reference materials used in the calibration and verification of instruments shall be obtained from a recognized National Metrology Institute (NMI) (e.g., NIST), or a producer accredited to ISO Guide 34 in combination with ISO 17025 calibration. For labs

accredited to ISO 17025 by A2LA or AIHA-LAP, the 17025 accrediting body of the producer shall also be an APLAC signatory (e.g., A2LA, ACLASS, and NVLAP).
- Analysis of consensus standards or proficiency testing samples where a qualified NIST-traceable reference material is not available.
- Ensuring results are traceable to lots of consumables used in the prep and analysis of samples.

5.6.2 Reference standards and reference materials

EMSL strives for all reference materials used by the laboratory to be traceable to certified reference materials or other well-categorized reference materials, where applicable. Reference materials shall be obtained from a vendor with a certificate of analysis which identifies the lot number. When selecting sources for reference material, sources should be from a national metrology institute or an accredited reference material provider (RMP) that conforms with ISO Guide 34 in combination with ISO/IEC 17025, or *ILAC Guidelines for the Competence of Reference Material Producers, ILAC G12*. For laboratories accredited by AIHA-LAP or A2LA, reference material providers must be selected which hold accreditations by accrediting bodies recognized directly or indirectly by ILAC. The two major North American accreditors of RMPs are A2LA and ACLASS. Accredited RMP lists can be found on their websites.

Reference standards shall be NIST-traceable where applicable, and include a 17025 calibration certificate showing traceability and uncertainty of measurement in compliance with the requirements in § 5.5.4 above. Reference standards of measurement (e.g., NIST traceable Thermometer, calibrated weights) maintained by the laboratory should only be used for calibrations, when possible.

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.

As with equipment, specific procedures for which reference standards and reference materials are required are detailed in the QMS Manual program-specific modules and analytical procedures.

Reference materials shall be stored according to manufacturer recommendations. If no expiration date is included on the material then a date shall be assigned that is appropriate for the material.

Common measurement standards and general policy requirements for calibration/recertification are listed below:

5.6.2.1 Reference Weights/Working Weights:
Reference weights are distinguished from working weights by their intended use. Reference weights are weight standards used only to annually verify the set(s) of working weights used during routine operations in the laboratory (i.e., verifying balances). Only laboratories with the capability of carrying out the procedures in the *EMSL Working Weight Verification SOP* will have a dedicated set of reference weights. At least every five (5) years reference weights shall be calibrated by an ISO 17025-accredited calibration service issuing a certificate meeting the "Requirements for Calibration Certificates from External Calibration Services" section above.

Working weights must be verified annually. If a lab does not have the capability, or does not own a set of reference weights, calibration shall be performed by an ISO 17025-accredited calibration service as above.

5.6.2.2 Reference Thermometer/Thermocouple:
Annually, the laboratory shall send at least one thermometer to an outside ISO 17025-accredited calibration service for calibration. This thermometer shall have readability (e.g., the smallest division which can be distinguished) at least as precise as the most precise temperature measuring instrument in the laboratory. Each temperature measuring instrument shall be calibrated to this Reference Thermometer at least every 12 months. See *EMSL Thermometer Calibration.Verification SOP* for additional requirements.

5.6.2.3 Stage Micrometers
Stage micrometers used in calibration of microscopes as per the program specific QMS Manual modules and technical SOPs shall be calibrated prior to first use and if damaged by an ISO 17025-accredited calibration service. The calibration certificate shall meet the requirements of § 5.5.4 above. If a laboratory does not own its own calibrated Stage Micrometer, one can be loaned from the corporate QA Department upon request.

5.7 Sampling

EMSL does not ordinarily conduct sampling for its customers. Sampling guides are available from the EMSL website for tests conducted by EMSL. 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 as applicable.

As EMSL is not present at the time of sampling, we take no responsibility for the quality of the sampling performed or information provided (e.g., sampling method, identity of sampler, locations, times or volumes.) EMSL procedures cover only the analysis of the samples submitted. Any specific comments about sampling that the customer wishes to add to the

report should be communicated on the chain of custody form, or in written correspondence to the lab.

Compliance samples may be rejected if it is determined they have been inappropriately sampled (e.g., improper volumes, containers, preservation, holding times). The customer is notified immediately if it is clear that sampling has been performed incorrectly in such a manner as it may affect the analysis. Reports may contain disclaimers if the sampling may affect the analysis.

5.8 Handling of test and calibration items

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*.

5.8.1 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.

5.8.2 Sample Receipt

Upon receipt of samples, the administrative coordinator will check for obvious signs that the sample integrity has not been compromised. Any problems with the samples will be reported to the customer immediately. The customer chain of custody will be signed indicating samples have been received by the laboratory.

5.8.3 Sample Acceptance

Samples are not accepted for analysis until they have been received and reviewed by the analyst or preparatory personnel. This review includes verification of receipt of all samples against the customer chain or custody. 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.

5.8.4 Log-in and 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.

5.8.5 Archival and Disposal of Samples

Once the analysis is complete and the analytical worksheet is signed, the analyst stores any remaining portion of the sample in an 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.

Any specific storage requirements are documented in the analytical SOPs or in the QMS Manual program-specific modules.

Upon request, samples will be returned to the customer.

5.9 Assuring the quality of test and calibration results

Laboratory performance will be determined by use of results from the following sources:

- 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.

5.9.1 Quality control program and review

The overall quality control program is established and overseen by the corporate QA manager and National Directors in order to ensure that each EMSL laboratory produces quality data. Each branch laboratory's QA program is implemented and managed by the quality assurance coordinator for that location. 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 QMS Manual 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 control coordinator 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 statistically derived 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 "Control of non-conforming work" and "Corrective action" sections 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 capability. 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.

5.9.2 Quarterly report

The person responsible for overseeing the QA in the lab (i.e., the lab quality assurance coordinator 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 national director or corporate QA manager. These reports are designed to express concerns, address needs and report any major changes to management. They are ultimately submitted to the corporate QA department for review.

Format shall include the following topics:

- Summary of quality control data (e.g., QC reanalysis that may have been out of control limits and the corrective action)
- Uncertainty Measurements – Sr for Micro; CV for PCM asbestos
- Summary of the number of corrective actions initiated and closed along with detail on any major issues
- Summary of preventative actions
- Calibration/Instrument Maintenance: dates of any Quarterly, semi-Annual or Annual equipment calibrations and any non-routine maintenance performed.
- Equipment Issues: summary of any outstanding equipment issues
- Summary of quarterly contamination monitoring
- Customer Problems
- Safety issues and results of safety audits
- Report of findings from any internal audits or external audits conducted during quarter
- Results of proficiency testing and/or round robin analysis
- Summary of staffing issues or changes
- Misc.

5.9.3 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 proficiency samples.

PT programs in which EMSL Analytical Laboratories participate include, but are not limited to:

- NVLAP – for PLM bulk and TEM airborne asbestos analysis
- AIHA-PAT – for environmental microbiology, environmental lead, organics, metals, silica, asbestos
- New York State ELAP – for asbestos in air, bulk and water; water microbiology; non-potable water chemistry
- RTC – for asbestos in drinking water
- ERA – for microbiology and TO-15
- WASP – for formaldehyde
- 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. Copies of confirmation of "data sent and received" are placed 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 for trends and evaluated against acceptance limits.

Whenever a laboratory reports an outlier on a proficiency testing round, a Corrective Action shall be initiated to review the root cause of the outlier. As this is equivalent to reporting incorrect results to a customer, a PT outlier should be treated accordingly. This process shall be completed within thirty (30) days of receipt of results.

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 lab manager and/or 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 for review. The plan will include all actions that will be taken (along with a timetable) to bring the quality of data to an acceptable level. Once the plan is acceptable, this should be forwarded to the Corporate Quality Assurance Manager for review and approval.

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 (See *EMSL Policy on Testing Results Reporting* for current requirements).

Several accreditation bodies (AB's) require that, as a condition of accreditation, results from proficiency testing (PT) programs used as a demonstration of competency for methods for which the laboratory is accredited be reported to the AB on a regular basis.

The following is a list of AB's that require PT results be forwarded on receipt:

AB Name	Programs to Report	Report to:
A2LA*	AIHA ELPAT results (Lead labs) AIHA EMPAT results (Micro labs)	Accreditation Specialist
AIHA	3rd party PTs not offered by AIHA (e.g., Pharma RR, AOAC Food, API Food)	Accreditation Specialist
Hawaii	Asbestos in Water PT results	Accreditation Officer
Louisiana**	AIHA IHPAT results (IH labs) AIHA ELPAT results (Lead Labs) NVLAP results – PLM & TEM	Accreditation Officer
Massachusetts	Asbestos in Water PT results	Accreditation Specialist
Ohio	AIHA ELPAT results (Lead Labs)	Accreditation Specialist
S. Carolina***	Asbestos in Water PT results	Accreditation Specialist

* Data to be reported using A2LA Form F104 – PROFICIENCY TESTING DATA SUBMISSION FORM. Corrective actions required for any outlying results within thirty (30) days of receipt of results.

** Requires submission of CAR for round failures only within thirty (30) days of receipt of results.

*** Requires data to be submitted directly from PT provider. NY ELAP contacted by QA Dept. to send results.

The EMSL corporate Quality Assurance Department maintains responsibility for reporting results of external proficiency testing (PT) results to accrediting authorities whom require results be submitted as a condition of accreditation. For PT tests which use online reporting options (e.g., AIHA EMPAT Direct, ELPAT, IHPAT, NVLAP), the QA Department logs onto the reporting website once final results have been posted and downloads a copy of the results which are then forwarded to the appropriate AB(s) according to their result submission requirements. For all other programs, laboratories forward results to the QA department when received and copies are prepared for submission to accrediting authorities. Generally, results are forwarded within 30 days of receipt.

5.9.4 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 submit results of all analysts who participated in the round to the Quality Assurance Department, where all results will be scored and graphed using standard deviation statistics.

The laboratory manager is responsible for ensuring that any results falling outside of the control limits be investigated and a corrective action report are completed.

5.10 Reporting the results

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.

5.10.1 Test reports

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)
- Any applicable disclaimers and statements (See specific SOPs)
- Notification of any deviations from the test method
- An estimation of uncertainty when requested by customer, required in the analytical SOP, or when necessary for the interpretation of data.
- 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.

When by written agreement any of these items are excluded from the final report, a copy of the written agreement shall be maintained in the laboratory and all information not reported shall be readily available upon request. Where requests to remove required disclaimers are received, the laboratory should consult with the QA department or national directors prior to proceeding since these are in many cases designed to protect EMSL by qualifying results.

5.10.1.1 Use of Significant Figures

Where stated, results are to be reported to the amount of significant figures prescribed by the analytical method. In the absence of a method requirement for significant

figures, the number of significant figures reported is equal to the number of significant figures present in the analytical measurement with the least precision.

5.10.1.2 Reference to Accreditation

Each accreditation agency sets its own requirements for use of its logo on customer reports. Likewise, additional requirements may be set for references made to accreditation. The specific policies set forth by the accrediting agencies can be found in an Appendix to this manual. In addition, EMSL's general policies can be found in § 5.11 below.

5.10.1.3 Listing of Accreditation/Required Statements (See also § 5.11 below)

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) or via the use of approved accredited laboratory logo.

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.

5.10.1.4 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.

5.10.1.5 Statement on Quality Control Results – ELLAP AIHA-LAP requirement
For those laboratories, which maintain the ELLAP AIHA-LAP 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-LAP, unless specifically indicated otherwise."

5.10.1.6 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

In addition, at the discretion of the laboratory manager, national director and QA Department samples may be subcontracted to a laboratory with equivalent accreditations.

In the case of AIHA-LAP ELLAP matrix suspensions, the laboratory shall inform AIHA-LAP in writing within ten (10) business days, of procedures for any samples that are received by the laboratory for analysis in the suspended FoT(s) until accreditation is restored.

5.10.1.7 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.

5.10.2 Final Report Approval

Final customer reports are released only after the data has been reviewed by an approved reviewer. In almost all cases the review is independent and performed by a qualified individual other than the analyst (some exceptions are listed below). This review is documented with the initials of the reviewer on the "Screened" line on the Internal Chain of Custody form. This review includes:

Quality Control Review
Quality control analysis performed for that specific batch of customer sample (see note), 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 quality 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

- Raw data (e.g., from bench sheets, prep logs, printouts from instrumentation) and the information on the chain of custody are reviewed for correctness and compared against the typed information on the final report to check for any transcription errors.
- Date derived from calculations will be reviewed to ensure that they appear correct based on the recorded data (this may be a brief overview).
- Where appropriate, correlations between data will be reviewed to ensure the sensibility of the data.

Appropriate Methodology

The review also verifies that the correct methodology was performed on the samples. This is done by checking on the customer's request as documented on the chain of custody, as well as any supplemental conversations with customer as recorded in laboratory records (if any).

5.10.2.1 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 ability 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*.)

5.10.2.2 Exceptions to Peer Review Requirement

5.10.2.2.1 All AIHA-LAP accredited analysis must be independently reviewed before it is released to the customer. No exceptions can be applied to work done under the AIHA-LAP accreditation. If work must be released prior to independent review, it must be marked "Preliminary" as per § 5.10.7 below.

5.10.2.2.2 For non-AIHA-LAP work, an independent review shall always be performed except under the specific circumstances identified below. In all other cases, work being reported prior to customers prior to independent review must be marked as "Preliminary" as per § 5.10.7 below.

5.10.2.2.3 Only in the following circumstances can a report be issued as Final without a second independent review being performed. In these circumstances, the report shall be reviewed by the original analyst prior to release. Whenever an exception is being applied, the number of the exception which appears below shall be documented next to the "Screened" line of the Internal Chain of Custody to document the circumstances.

(1) Non-AIHA-LAP analysis performed outside of a laboratory's regular business hours (i.e., 8-5 M-F) when a reviewer is not available to review work before the TAT.
(2) Non-AIHA-LAP analysis performed during a laboratory's regular business hours when a reviewer is not available to review work before the TAT due to extended leave.

5.10.3 Opinions and interpretations

EMSL generally discourages statements of opinions and interpretations on reports; however, a specialized report which contains results and interpretations as to whether the results are in or outside criteria is available.

5.10.4 Testing obtained from subcontractors

When a test report contains results obtained from a subcontractor, these will be clearly identified. See the *EMSL Subcontract SOP* for detailed procedures.

5.10.5 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. – *"This information may contain privileged and confidential information and is solely for the use of the sender's intended recipient(s). If you receive this information in error, please notify the sender and delete all copies."*

2) Email through Sample Master – The confidentiality statement is (automatically) included in the body of the e-mail – *"This email may contain privileged and confidential information and is solely for the use of the sender's intended recipient(s). If you received this email in error, please notify the sender by reply email and delete all copies and attachments. Thank you"*

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 - *"This information may contain privileged and confidential information and is solely for the use of the sender's intended recipient(s). If you receive this information in error, please notify the sender and delete all copies."* 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 insure 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.*" The user is prompted to check *"I accept the legal conditions above" or "I do not accept the legal conditions above"*

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".*

5.10.6 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/or the customer communication log).

5.10.7 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 § 5.10.2.2 above.

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. Verbal notifications must be recorded in writing on the internal chain of custody and/or in the customer correspondence log.

5.10.8 Exported Data

Exported data is provided in a variety of formats, (generally PDF format) 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. Final, signed customer reports are to be submitted in addition to delivery by email or CD. Electronically delivered data is not intended to replace hard copy results unless otherwise requested by a customer. In this way, exported data can be verified. Electronically transmitted results meet the requirements of the QA policies as documented in this manual.

5.10.9 Amendments to test 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

5.11 Use of Accreditation Logos and/or References to Accreditation in Advertising and Customer Reports

EMSL has defined the requirements for referencing accreditation in reports, advertising and promotional materials in the *EMSL Referencing Accreditation – Advertising Policy SOP*. This procedure has been developed based on the requirements *of ISO/IEC 17025:2005, A2LA – P101* and *NVLAP HB 150-Annex A*.

REVISION HISTORY

Previous revision histories are available from the QA department on request.

Revision	Date	Changes
16	5/30/13	Changed QAM to QMS Manual. Changed Client to Customer. Removed contents of Section 5.11 and following subsections and referenced the appropriate SOP. 5.2.1.10 – Updated title to Quality Systems Manager from Quality Programs Manager 5.2.1.11 – List of authorized tasks added from previous amendment, last paragraph added

		5.4.6 – Last paragraph added from previous amendment. 5.4.7 – Note moved from 5.4.7.2.1 5.4.7.1.1. – Deleted 2nd paragraph regarding remote log-in. 5.5.3 – 1st paragraph, deleted last sentence. 2nd paragraph regarding specific requirements deleted. Look to SOP for requirements. Last sentence added referring back to SOPs. 5.5.3.1-3 – Overhauled to remove requirements and reference SOPs as appropriate. 5.5.3.3. – Added note on recording CF. 5.6.1 – Clarified 2nd bullet & 4th bullet. Deleted last paragraph Removed prior section 5.6.2 and moved info into 5.5.3 and 5.6.2. 5.6.2.1-5.6.2.3 – Revised to remove details and refer back to SOPs. 5.8.4 – Removed 2nd paragraph regarding remote log-in 5.10.1 – Removed 4th paragraph. 5.10.3 – Removed last 3 paragraphs and replaced with second half of sentence. 5.11 – Removed section and replaced with reference to Advertising SOP and outside requirements.
15	9/16/11	5.6.1 – Added example of APLAC signatories. Added reference to Policy on Traceability. 5.6.2 – Expanded section to cover requirements for calibration of support equipment AND Standards. 5.6.2.1 – 5.6.2.1.3 – Added requirements for calibration certs from outside agencies. 5.6.3 – Added note that reference materials MUST be obtained from accredited reference material providers (when possible) and added reference to A2LA and ACLASS. 5.9.3 – Added TO-15 to list of programs provided by ERA. 5.9.3 – Added requirement that whenever an outlier is reported on PT a corrective action is required. Added requirement that corrective actions on PT outliers must be forwarded to corporate QA department. Added information regarding reporting of PT results to accrediting agencies (this supersedes the PT Reporting Policy). 5.11.3 – Expanded section 5.11.3 to also refer to references to accreditation on reports and not just use of logos. 5.11.3.3 – Modified requirement to ensure that WHENEVER both accredited and non-accredited results are reported together that non-accredited results are clearly indicated. Previously, this was only necessary if accreditation was referenced.
14	7/1/11	5.2.1.6 – Clarified that if TM or TD will be absent for more than 30 days, this must be reported to accrediting agencies. 5.2.2.1 – Clarified requirement that all employees (FT/PT, perm/temp) must read QAM and SOPs related to their work. 5.2.2.4.1 – Added instruction for conducting initial DOC where checklists are not available. 5.2.2.4.2 – New section clarifying frequency of Initial DOCs. Must be conducted where method has not been used for 12 months. 5.2.2.5.3 – Clarifies that lab management that conducts analysis cannot sign their own DOC recertifications. 5.2.2.8 – Note changed to allow raw data supporting DOCs to be referenced in personnel folders instead of being included within. 5.4.5 – Clarified that TNI requires a new Initial DOC be conducted when method has not been used in 12 months. Adds language noting TNI exception for methods used for at least one year prior to applying for TNI accreditation. 5.4.7.1.2 – Section change to correctly require the customer chain of custody be initialed by the prep person/analyst prior to beginning work on samples. 5.5.3 – Added 2nd paragraph w/ requirements for calibration certs received from outside accrediting bodies. 5.6.1 – Added addl language to 2nd bullet point requiring reference materials be obtained

		from NMI, or producer accredited to ISO 34 & 17025, A2LA and AIHA accredited labs must also use a producer recognized by APLAC. 5.6.2.1 – Modified language for balance calibrations to state they must be done onsite by a 17025 accredited calibration provider. 5.6.3 – Added requirement that AIHA or A2LA accredited labs must obtain reference materials from providers recognized directly or indirectly by ILAC. 5.10.1 – Removed requirement that date of issue appear on report. No longer a TNI requirement. 5.10.1.4 – Previous section on "Certification of Test Results for NELAC labs" removed as it is no longer a TNI requirement. 5.11.1.3 – Clarified that accreditation symbols may not be used prior to receiving accreditation. 5.11.3.3 – Added last sentence with specific NVLAP requirement.

APPENDIX A: Glossary

ACS – American Chemical Society

Accuracy – The closeness of a measured result to a known, theoretical or target value. This should be distinguished from "Precision" below.

AHERA – Asbestos Hazard Emergency Response Act

AIHA-LAP – American Industrial Hygiene Association Laboratory Accreditation Program

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 200 Route 130 North, Cinnaminson, NJ 08077

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. EMSL's chemical hygiene plan also includes its Biosafety Guide.

Coefficient of Variation (CV) - Standard deviation divided by the mean. Note: The Relative Standard Deviation (RSD) is the absolute value of the coefficient of variation.

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

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

Culturable - Capable of, or fit for, being cultivated. (antonym: non-culturable).
Note: Prior to Revision 10 of this document 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.

Document (*noun*): A written policy, procedure, instruction, form, template, etc. which is revision sensitive. If an outdated revision is used it could cause the wrong process to be followed (e.g., not all required information is included on a previous revision of a form template). Contrast with "Record" below.

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

Measurand – The quantity intended to be measured. In determining measurement uncertainty, this is usually defined in terms of the analyte being measured, on a specific sampling matrix, prepared and measured by a specific method.

Measurement Uncertainty – The uncertainty (or range of dispersion) of a measurement resulting from random and systematic errors in each step of the measurement process. Where a systematic bias exists and is not corrected for, then it should be reported separately.

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.

Method Validation – See *Validation, Methods*

NIST – National Institute of Standards and Technology

NLLAP — National Lead Laboratory Accreditation Program

NMI – National Metrology/Measurement Institute (e.g., NIST)

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

Non-Standard Method – An analytical procedure which is developed in-house or a significant modification to a published procedure which requires validation prior to being introduced into the laboratory. See also *Standard Method*.

NVLAP – National Voluntary Laboratory Accreditation Program

NYS ELAP – New York State Environmental Laboratory Approval Program

Precision– Closeness of repeated measurements to one another. This should be distinguished from "Accuracy" above.

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 this QMS Manual which address analytical method specific requirements (e.g., 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.

QAM – Quality Assurance Manager. **Note:** Prior to revision 16 of this document, also an acronym for "Quality Assurance Manual" which has been renamed to Quality Management System (QMS) Manual.

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.

Quality Management System (QMS) Manual – This manual and related program modules. Previously named "Quality Assurance Manual" or "QAM" prior to Revision 16. All old references in other management system documents to the "Quality Assurance Manual" or "QAM" refer to this document.

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).

Record (noun): A written record of events which are not revision sensitive. Data records related to analytical activities should form an unbroken trail between sample receipt and reporting including records of custody, prep and analytical steps, customer correspondence, equipment used, calibration

records of that instrument, etc. Records are controlled as per the *EMSL Control of Records SOP*. Contrast with a "Document" defined above. A form template is a document (revision sensitive), once information is entered on the form, the completed form is considered a record (cannot be revised only corrected as per SOP.

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

Reference Material Provider (RMP) –.EMSL requires that for tests accredited by AIHA-LAP or A2LA that all reference materials purchased after January 1, 2013 be purchased from ISO G34 accredited RMPs. A2LA and ACLASS both accredit to the G34 guideline.

Relative Standard Deviation (Sr or $\mathbf{S_r}$ or **RSD)**– See "Coefficient of Variation" above.

Reference Weights: Set of weights which are used only to calibrate working weights in the laboratory. They may also be used for periodic calibrations of other equipment, but not on a routine basis (e.g. for daily balance verifications). Reference weights shall be calibrated at least every five (5) years. Extra care shall be taken to maintain the integrity of the standard.

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 = $\frac{|R1 - R2|}{R} \times 100$

Where: R1-R2 = 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. If a method is significantly modified (e.g., changes to the method which may affect the principle of analysis), it shall no longer be considered Standard and shall be validated as a non-standard method.

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 (Cinnaminson, NJ). It receives technical direction and quality management from the Main Facility.

Traceability - A process whereby the result from a measuring instrument (or a material measure) can be compared, in one or more stages, with a national or international standard for the measurand in question.

Validation, Method – Planned process which must be completed prior to adoption of a new method by which the method's performance criteria are determined and documented. Performance criteria may include accuracy, precision, linearity, LOQ, LOD, and/or ruggedness.

Verification, Equipment – Process whereby equipment is checked against acceptance criteria to ensure that it is operating properly. Generally, a routine scheduled check performed by the laboratory.

Verification, Methods – A process whereby a laboratory verifies that it can perform a standard method or previously validated method within acceptable criteria at the location and with analysts and equipment at the location at which verification is performed.

Working Weights - A set of weights which are used during routine measurements and verifications in the laboratory. Working weights shall be calibrated annually in-house using a set of reference weights as defined above, or by an outside vendor if lab does not have a set of in-house reference weights.

REVISION HISTORY

Previous revision histories are available from the QA department on request.

Revision	Date	Changes
16	5/30/13	Added: - Accuracy - Document (noun) - Method Validation - Precision - QAM (Quality Assurance Manager) - QMS Manual - Record (noun) - Reference Material Provider (RMP) - Reference Weights - Validation, Method - Verification, Equipment - Verification, Methods - Working Weights Edited: - Branch Lab: Removed Haddon Ave address. - Non-conformance changed to non-conformity. - Non-Standard Method: Revised language. - Relative Standard Deviation: Clarified.

		-Standard Methods: Last sentence added.
15	9/16/11	Chemical Hygiene Plan – Added note that this includes Biosafety Guide. Coefficient of Variation – Added note referring to RSD Measurand – New definition Measurement Uncertainty – New Definition Relative Standard Deviation – New Definition RMP – New Definition Traceability – New Definition
14	7/1/11	No Changes.

MODULE A

Asbestos Analysis

POLARIZED LIGHT MICROSCOPY

PHASE CONTRAST MICROSCOPY

TRANSMISSION ELECTRON MICROSCOPY

Module A – Asbestos – PLM, PCM and TEM

Table of Contents

Module A – Asbestos – PCM, PLM and TEM

A.1.0 Scope

This module defines the policies and procedures specific for laboratories performing analysis for asbestos samples under AIHA-LAP, A2LA, NVLAP or State Accreditation requirements or for laboratories conducting this analysis without accreditation. The requirements documented in this module are supplemental to the policies and procedures documented in the main section of the Quality Management System (QMS) Manual. This Module maintains the same format as the main QMS Manual for easy reference of additional requirements.

REVISION HISTORY

Previous revision histories are available from the QA department on request.

Revision	Date	Changes
16	5/30/13	References to QAM changed to QMS.
15	9/16/11	No Changes.
14	7/1/11	Modified scope to differentiate between GMP and non-GMP requirements.

A.2.0 Normative references

- AIHA-LAP, LLC – Accreditation Policy Modules – September 2011.
- ISO/IEC 17025:2005.
- TNI Standards – July 1, 2011.
- NIST Handbook 150:2006.
- NIST Handbook 150-3:2006.
- NIST Handbook 150-13:2006.

REVISION HISTORY

Previous revision histories are available from the QA department on request.

Revision	Date	Changes
16	5/30/13	Updated 150-3 to 2009.
15	9/16/11	Updated reference to new AIHA-LAP standard
14	7/1/11	Updated reference to new TNI standard

A.3.0 Terms and definitions

See QMS Manual, Appendix A – Glossary. This section reserved for use.

REVISION HISTORY

Previous revision histories are available from the QA department on request.

Revision	Date	Changes
16	5/30/13	References to QAM changed to QMS.
15	9/16/11	Added reference to Appendix A.
14	7/1/11	No Changes.

A.4.0 Management requirements

A.4.1 Organization

A.4.1.1 NVLAP Sub-Facilities

A.4.1.1.1 Relationship with Main Facility

Following the NVLAP requirements, sub-facilities are to be supported by the main facility. The EMSL main facility includes the corporate Quality Assurance Department, Vice President, Asbestos Division, National Asbestos Manager as well as the corporate laboratory facility. The Quality Assurance Department, Vice President, National Manager and Regional Manager provide support to the sub-facilities including:

- Developing, implementing and maintaining quality assurance procedures and policies
- Standardizing reporting policies and standard operating procedures
- Implementing and enforcing the quality control program
- Providing monthly review of quality control data (including calibrations, reanalysis data, standards, contamination data, etc.)
- Completing annual reports to upper management on laboratory quality activities
- Providing technical direction and support
- Distribution of proficiency testing samples
- Selection of supplies and equipment

A.4.1.1.2 Sub-facility Internal Audits

The internal audit procedures for the sub-facility follow those policies written in the EMSL Internal Audit SOP.

A.4.1.1.3 Sub-facility Proficiency Testing

Regional Managers ensure that the NVLAP sub-facilities receive and analyze all NVLAP proficiency testing rounds. All active analysts participate in the testing when possible following the requirements of the NVLAP program.

The National Asbestos Manager later forwards a copy of the scored results to the sub-facilities. If necessary, the laboratory manager initiates corrective action procedures. A copy of these results is maintained at the sub-facility and is made available for analysts to review.

Results of the proficiency analysis of the sub-facility laboratories are not submitted to NVLAP.

A.4.2 Management system
No additional requirements. See § 4.2 of QMS Manual.

A.4.3 Document control
No additional requirements. See § 4.3 of QMS Manual.

A.4.4 Review of requests, tenders and contracts
No additional requirements. See § 4.4 of QMS Manual.

A.4.5 Subcontracting of tests and calibrations
Laboratories that choose to subcontract any sample analysis to an outside laboratory shall ensure that the subcontract laboratory maintains the same relevant accreditations as that of the contracting laboratory. The qualifications of EMSL laboratories are maintained on the *EMSL Subcontracting Qualifications Record* available on E-link. Use of non-EMSL subcontract laboratories must be approved by the National Director for Asbestos.

NOTE: EMSL laboratories are considered independent facilities following NVLAP and AIHA-LAP policy, therefore, subcontracting policies apply. See *EMSL Subcontracting SOP* and § 4.5 of QMS Manual for additional detail.

A.4.6 Purchasing services and supplies
Supplies including microscope slides, sample preparation tools, acetone, triacetin, copper specimen grids, filters, acids and dispersion oils are to be ordered through the corporate purchasing department as per § 4.6 of this QMS Manual and the *EMSL Purchasing SOP*. This allows for company-wide control and standardization of consumable supplies.

A.4.7 Service to the customer
No additional requirements. See § 4.7 of QMS Manual.

A.4.8 Complaints
No additional requirements. See § 4.8 of QMS Manual.

A.4.9 Control of nonconforming testing
No additional requirements. See § 4.9 of QMS Manual.

A.4.10 Improvement
No additional requirements. See § 4.10 of QMS Manual.

A.4.11 Corrective action
No additional requirements. See § 4.11 of QMS Manual.

A.4.12 Preventive action
No additional requirements. See § 4.12 of QMS Manual.

A.4.13 Control of records
No additional requirements. See § 4.13 of QMS Manual.

A.4.14 Internal audits
No additional requirements. See § 4.14 of QMS Manual.

A.4.15 Management reviews
No additional requirements. See § 4.15 of QMS Manual.

REVISION HISTORY

Previous revision histories are available from the QA department on request.

Revision	Date	Changes
16	5/30/13	References to QAM changed to QMS. "Client" changed to "Customer" to align with 17025. A.4.1.1.1 – Added reference to Regional Manager. A.4.1.1.3 – Changed responsibility for Sub-Facility PT to Regional Managers.
15	9/16/11	Removed reference to NVLAP subfacilities from NOTE to clarify requirements for subcontracting.
14	7/1/11	References to AIHA changed to AIHA-LAP. Minor editorial changes throughout. A.4.1.1.1 – Added references to National Asbestos Mgr. A.4.1.1.3 – Reference to Westmont changed to Cinnaminson. Removed statement that samples always ship from Cinnaminson.

A.5.0 Technical requirements

A.5.1 General

No additional requirements. See § 5.0 of QMS Manual.

A.5.2 Personnel

A.5.2.1 Additional PCM Training and Qualification Requirements

New analysts must complete the EMSL 'on the job' training program in asbestos PCM analysis in order to perform such analysis independently. EMSL also offers a more formal course – *Sampling and Analysis of Airborne Asbestos Dust.* The contents of this course have been evaluated by AIHA and found to meet their requirements as a substitute for the NIOSH 582 course. This course is provided following specific policies as described below.

A.5.2.1.1 Training Program – PCM

The laboratory manager or designee (i.e., sr. analyst) is responsible for ensuring all PCM analysts receive proper training. The lab manager will draw on the candidate's previous training, if any. The candidate will receive sufficient in-house training following EMSL's PCM Training Checklist to demonstrate proficiency and understanding in all related topics to the laboratory manager's satisfaction. This training program must include:

Theoretical

Trainees must read and understand the methods, procedures and policies related to the analysis. These include:

- NIOSH 7400 Method
- EMSL standard operating procedure for the analysis of fibers via PCM analysis
- Quality Management System (QMS) Manual

Demonstration

Working with the trainer, trainees must perform all steps involved with preparation and analysis. The hands on tasks must include:

- Preparation of the sample
- Calibration of the microscope
- Analysis of sample
- Calculation of result

Skills

An analyst-in-training must demonstrate proficiency in a number of ways. These include:

- Demonstration of accurate inter-analyst QC analysis on 95% of 50 real-time samples (see QC program for acceptance criteria - use QC report for PCM analysis)

- Generation of personal relative standard deviations (S_r) by the completion of 120 analyses on laboratory reference slides (20 analyses per slide, 40 analyses per range).
- Demonstration of accurate analysis on 80% of 10 past proficiency samples and succeed in generating data within the acceptable range as established by the agency(ies) statistical analysis.

All records pertaining to the analyst's training including the PCM training checklist, individual training records, bench sheets, etc. are maintained in the analyst's individual training binder. When all areas are signed off, and a DOC is issued from corporate QA department, the candidate may perform analysis.

A.5.2.1.2 Training Course: *Sampling and Analysis of Airborne Asbestos Dust – A NIOSH 582 Equivalent*

This course is provided at the discretion of corporate management, which may be based on regulatory requirements, project or customer's specific need, or general quality requisites.

Topics to be covered include:

- Introduction to asbestos & the asbestos industry
- Regulatory agencies/standards and compliance
- Sampling (including types of cassettes, pumps, calibrations, strategies, safety)
- PCM Microscopy (including optics, scope, alignment, calibration, maintenance)
- NIOSH Method 7400 (overview, history, calculations, etc.)
- Sample receiving, handling and preparation
- Sample analysis and reporting
- Quality control (incl. Intro to statistics, ISO 17025 and counting statistics, proficiency programs)
- Hands-on with PCM scope alignments/calibrations and fiber counting.
- Filter analysis practical and written exam

A.5.2.1.3 Qualifications Checklist – PCM

Training is documented with a qualifications checklist. This checklist is completed by the trainer, then dated and initialed by both trainer and trainee. The checklist includes a general section and method specific section.

A.5.2.1.4 Qualifying an Analyst – PCM

All analysts must complete the training program (even if they have previously completed a NIOSH 582 equivalent training course).

Training checklists are maintained, recording all tasks that are completed. Demonstration of Capability (DOC) certifications are issued by the Quality

Assurance Department once the training checklists are complete. Analysts are qualified to perform independent analysis when all requirements of the training checklist and the probationary periods (if applicable) are met.

A.5.2.1.5 Ongoing Training – PCM

Analyst performance and qualifications are reviewed annually. Recertification is completed when analysts have demonstrated continuing capability as discussed in the general section of this manual.

Also, if there are any updates to methodology or regulatory requirements, these are introduced at laboratory meetings or training sessions. During this meeting, the laboratory manager may review certain topics in PCM such as practical aspects of analyzing difficult samples, etc.

A record of this and other training will be documented on EMSL's Training Record forms and kept on file.

A.5.2.2 TEM Training and Qualification Requirements

New analysts must complete the EMSL training program in TEM asbestos analysis in order to perform the analysis independently. Training includes:

- Understanding of asbestos regulations/aspects of the industry.
- TEM theory, operation and calibration, including all support equipment.
- Method review (AHERA, NIOSH 7402, etc.)
- Proficiency analysis.
- Quality control reanalysis.
- Completion of a TEM asbestos portfolio demonstrating morphology, chemistry (EDXA) and diffraction (SAED.)

In all cases, previous training and experience is factored into this program. Completion of each phase of training is defined by the ability to demonstrate skills and knowledge to the satisfaction of the lab manager and QA manager. Each approved task is checked off on the analyst training log checklist. These training logs must be maintained even for those who have received prior training unless equivalent training records are transferred with the analyst.

A.5.2.2.1 TEM Theory

The lab manager or national asbestos management will draw on the candidate's previous training, if any. If not, the candidate will receive sufficient in-house training to demonstrate proficiency in these topics. Included are theories underlining selected area electron diffraction, energy dispersive X-ray analysis, crystallography and TEM operation, and calibration.

A.5.2.2.2 Hands-on Practices – TEM

When the candidate has received sufficient training to analyze samples, he/she will work in the laboratory alongside an experienced analyst. The candidate in training will be deemed proficient when at least 95% of 20 inter-analyst real-

time QC analyses are accepted using the criteria established by the QC program. In addition, for AIHA-LAP accredited labs the 20 day probation period must also be met (see A.5.2.4.5.3.)

A.5.2.2.3 Proficiency Analysis – TEM

Additionally, the trainee must perform analysis on one round of past proficiency samples and succeed in generating data within the acceptable range as established by the agency(ies) statistical analysis.

A.5.2.2.4 Qualifications Checklist – TEM

Training is documented with a qualifications checklist. This checklist is completed by the trainer. The checklist is separated into a general section and the method specific training.

A.5.2.2.5 Qualifying an Analyst – TEM

All analysts must have completed the entire TEM training program.

Training checklists, training records, analytical bench sheets, etc. are maintained to document each step of the training process. Demonstration of Capability (DOC) certifications are issued by the Quality Assurance Department once the training checklists are complete. Analysts are qualified to perform independent analysis when all requirements of the training checklist and the probationary periods are met.

A.5.2.2.6 Ongoing Training – TEM

Analyst performance and qualifications are reviewed annually. Recertification is completed when analysts have demonstrated continuing capability as discussed in the general section of this manual.

Also, if there are any updates to methodology or regulatory requirements, these are introduced at laboratory meetings or training sessions. During this meeting, the laboratory manager may review certain topics in TEM such as practical aspects of analyzing difficult samples, etc.

A record of this and other training will be documented on EMSL's Training Record forms and kept on file.

A.5.2.3 PLM Training and Qualification Requirements

Analysts must complete the EMSL training program in PLM asbestos analysis in order to perform analysis independently. The level of training may be adjusted according to the candidate's work experience, academic background and prior training. Training consists of four phases:

1) Theory and operation of polarized light microscopy technique and asbestos identification (understanding of method and standard operating procedures)
2) Practical application of microscopy and analysis of samples

3) Proficiency analysis
4) Quality control

A.5.2.3.1 Theory – PLM

A basic understanding of the asbestos industry, microscopy and the crystallography of asbestos is the preliminary part of the training program. Areas covered include:

- Health effects/regulatory issues of asbestos.
- Crystallography.
- The polarized light microscope.

A.5.2.3.2 Practical Factors – PLM

The trainee will work with an experienced analyst on polarized light microscopy techniques, sample preparation methods, the identification and quantitation of asbestos and non- asbestos materials found in bulk samples.

The trainee will analyze at least 50 field samples with an acceptable performance of accurate analysis on 94% of 50 real time samples (using the PLM QC program to determine acceptability)

A.5.2.3.3 Proficiency Analysis – PLM

Demonstration of accurate analysis on 80% of 10 past proficiency samples and succeeding in generating data within the acceptable range established by the PT providers' statistical analysis.

A.5.2.3.4 Qualifications Checklist – PLM

Training is documented with a qualifications checklist. This checklist is completed by the trainer. The checklist is separated into a general section and the method specific training.

A.5.2.3.5 Qualifying an Analyst – PLM

All analysts must have completed the PLM training program.

Training checklists are maintained, recording all tasks that are completed. Demonstration of Capability (DOC) certifications are issued by the QA department once the training checklists are complete. Analysts are qualified to perform independent analysis when all requirements of the training checklist and are met. In AIHA accredited laboratories, the 20 day probationary period requirement shall also be met (see Mod A § A.5.2.4.3).

A.5.2.3.6 Ongoing Training – PLM

Analyst performance and qualifications are reviewed annually. Recertification is completed when analysts have demonstrated continuing capability as discussed in the general section of this manual.

Also, if there are any updates to methodology or regulatory requirements, these are introduced at laboratory meetings or training sessions. During this meeting, the laboratory manager may review certain topics in PLM such as practical aspects of analyzing difficult samples, etc.

A record of this and other training will be documented on EMSL's Training Record forms and kept on file.

A.5.2.4 Additional Personnel Requirements for Accredited Laboratories

Summarized below are additional personnel requirements as established by AIHA-LAP and NYS ELAP. In addition, please see **Module A, Attachment 2** at the end of this Module for additional personnel education and experience requirements by other accrediting authorities.

A.5.2.4.1 AIHA-LAP - Technical Manager

- Employee of laboratory with authority to provide day to day supervision of technical operations with responsibility for ensuring that accredited analysis are performed by qualified, trained personnel that are adequately supervised.
- Bachelor's degree in an applicable physical or biological science (inorganic chemistry, environmental sciences, etc.)
- Present onsite at least 20 hours a week or 50% of operating hours (whichever is less) to address technical issues.
- Three (3) years of nonacademic analytical experience, of which at least two (2) years shall be in industrial hygiene analysis relevant to scope of AIHA-LAP accreditation.
- A relevant post-graduate degree (MS or PhD) shall be considered equivalent to one (1) year of work experience. Academic experience and post-graduate degrees may not be substituted for the two (2) years industrial hygiene experience.

A.5.2.4.2 AIHA-LAP –Quality Manager

- BS degree in an applicable basic or applied science AND one year nonacademic analytical experience or quality control experience appropriate to the analysis performed by the
- OR, In lieu of a BS, four years of nonacademic analytical or quality control experience
- Documented training in statistics or laboratory quality assurance/quality control.

Note: Appropriate documentation of training in statistics or laboratory quality assurance/quality control shall include at least one of the following: 1) College level course in statistics; 2) Continuing education in laboratory quality assurance/quality control (e.g., AIHA-LAP or equivalent course); or 3) Relevant

experience – documented examples of the level of quality assurance/quality control used in applicable work experience.

A.5.2.4.3 AIHA-LAP – Analysts for accredited tests

- Minimum of twenty (20) business days of hands-on experience conducting analyses in an industrial hygiene laboratory before initiation of independent work on customer samples. Until this time all analyses must be reviewed by the laboratory manager or senior analyst.
- For PCM analysts: Successful completion of the EMSL or other NIOSH 582 equivalent course. **Note:** EMSL's 582 course has now been reviewed by AIHA and found to be equivalent with the NIOSH course.
- Demonstrated ability to produce reliable results through accurate analysis of certified reference materials (CRMs), proficiency testing samples, or in-house quality control samples. This demonstration shall be done at a minimum of every six (6) months and documented.

A.5.2.4.4 NVLAP – TEM Technical Supervisor

The TEM technical supervisor(s) shall be qualified to conduct AEM studies, apply AEM to crystalline materials and shall be proficient in the field of asbestos analysis including procedures for sample handling, preparation, analysis, storage, disposal, and contamination monitoring.

A.5.2.4.5 NYS ELAP – Technical Director – PLM

- Associates Degree or 2 years equivalent college study.
- Specialized course in PLM analysis.
- 1 year experience under the supervision of an experienced analyst.

A.5.2.4.6 NYS ELAP – Technical Director – PCM

- Associates Degree or 2 years equivalent college study.
- Formal course work in PCM analysis.
- 1 year experience under the supervision of an experienced analyst.

A.5.2.4.7 NYS ELAP – Technical Director – TEM

- Bachelor's Degree.
- Specialized course in TEM analysis.
- 1 year experience under supervision of an experienced analyst.

A.5.3 Accommodation and environmental conditions

A.5.3.1 Laboratory conditions

A.5.3.1.1 Temperature

The rooms where analysis is performed should be held at normal temperature ranges. All reagents used in the analysis (refractive index oils, triacetin, etc.) shall not be kept in below freezing temperatures. Temperatures are recorded at the time of analysis when analyzing PLM samples due to the effect temperature has on the RI oils. Temperatures are recorded on the worksheet.

A.5.3.1.2 Lighting

Direct sunlight should be avoided when using the optical microscopes. Room lighting shall be provided which provides comfortable reading/writing conditions for the analysts. TEM analysis is performed in darkened conditions to provide ease while viewing the fluorescent screen.

A.5.3.1.3 Ventilation

Room ventilation must be provided so as to provide safe and comfortable conditions for the analyst.

A.5.3.1.4 Location

Air samples (PCM and TEM analysis) are not prepared in the same room where bulk sample preparation is performed.

A.5.3.2 Contamination

A.5.3.2.1 Contamination Management

In addition to the procedures and policies discussed in the main section of this manual, specific steps to avoid contamination in the asbestos laboratory include:

- Bulk sample containers are opened and samples examined using the stereo microscope only in the hood.
- Only small numbers of active samples are kept near the hood. The sample containers are kept closed at all times. Inactive samples are stored in a suitable, out of the way area.
- Target containers - samples, mounting reagents, microscope slides, and cover glasses are opened one at a time as practical.
- Prepared slides are stored in a protected manner.
- Prepared TEM samples are stored in an indexed grid box.
- Surfaces are frequently wiped clean with moistened wipes.

A.5.3.2.2 Ambient Air Monitoring

On a quarterly schedule, air monitoring is performed in the laboratory. Ambient air samples shall be collected from each work area as well as other common areas such as log in.

Sampling and analysis is performed according to the following requirements:

- Collection on 0.45 micron MCE filters (at least 1200 liters collected at no greater than 10 lpm).
- Collection during normal working hours to best monitor worker exposure.
- Analysis is performed via TEM AHERA protocol.
- The action level is considered exceeded if any asbestos is detected.

If any asbestos is detected, a PCM analysis is performed (to coincide the data with health and safety (OSHA) limits) and the event is documented on a corrective action (CAR) form. The area is cleaned and additional samples are collected and analyzed by TEM AHERA to ensure the area is free of contamination. Cleaning and sampling is to continue until the sample results are negative for asbestos. Additional monitoring in addition to the regular quarterly samples may be needed to ensure corrective actions were effective.

A.5.3.2.3 Resolution of Contamination in Lab Blanks

If analyses of the blank samples indicate the possibility of contamination, the customer sample analysis is immediately halted. The area and tools are cleaned and another blank sample prepared and analyzed. If this second sample shows contamination, a complete investigation is conducted to determine the contamination source (acetone, triacetin, dispersion oils, preparation containers, etc.). A detailed flow chart for resolution of PLM and TEM contamination can be found in the appropriate SOP's.

A.5.4 Test and calibration methods and method validation

A.5.4.1 List of Asbestos Specific SOPs

The scopes of accreditation differ between branch labs. The *EMSL List of Accredited Methods* is a compilation of all accredited test methods at each location. An up-to-date list can be found on E-link with the current revision of the QAM.

A.5.4.2 Estimation of uncertainty of measurement

EMSL has established and applies procedures for the determination and reporting of uncertainty to customers. These procedures are summarized in the "Uncertainty Worksheet – Asbestos" and detailed in EMSL's PLM SOP, NIOSH 7400 SOP, and TEM AHERA SOP.

A.5.4.3 Control of data

A.5.4.3.1 Data Review

As documented in the main QMS Manual § 5.4.3, data review is performed continuously by the laboratory management for irregularities or questionable results. Criteria for judging a result questionable will include deviation from prior data from the same sample, from another sample collected within the same homogenous area, etc. Any questionable result will be rechecked with other quality control samples.

A.5.4.3.2 Data Recording for TEM

EMSL is in the process of converting all worksheets to direct entry into our iL@b LIMS system. There are very specific requirements for the recording of information for the TEM analysis. Data recording should be done in a manner conducive to good record keeping. If data cannot be entered directly into the iL@b LIMS system, data should be recorded using either black or blue indelible ink on an original analytical worksheet. Data should not be recorded in lab notebooks or scrap paper and then transposed to the analytical worksheet. If

any correction on the data form needs to be made it should be done using a dated and initialed single-line strikeout and then the new data recorded next to the old data. The use of correction fluid is not permitted.

A.5.4.3.2.1 Sample Preparation Data

Sample preparation data is recorded on the internal chain of custody, the analytical worksheet, or directly into the LIMS system. The data recorded includes the following:

- Project identification number.
- Sample identification number.
- Customer identification.
- Sample description.
- Preparation date and analyst's ID.
- Grid box identification.
- Location of grid preparations in the grid box.
- Effective filtration area and volume filtered (applicable for water, Chatfield, etc.)

Specific procedures for each sample type and criteria for acceptable final preparations can be found in the applicable Standard Operating Procedures for the method.

A.5.4.3.2.2 Structure/Fiber Identification & Sizing (where applicable)

The analytical worksheet or direct data entry system will contain at a minimum:

- SAED identification and negative number, if applicable.
- EDXA spectra identification and printout or computer file ID, if applicable.
- Structure's mineralogical identification (i.e., chrysotile, amphibole or non-asbestos.)
- Structure classification (i.e., fiber, bundle, cluster, matrix.)
- Structure size.
- Quantitative totals of all structures / fibers identified as both asbestos and non-asbestos particles.
- Analyst initials and date.
- Sketch, if applicable.

A.5.4.3.2.3 SAED Indexing

Images of SAED diffraction patterns are developed and measured to verify the pattern identity. Each analyst is required to have an on-screen identification accuracy of at least 80% as determined by indexing the negative. If any analyst falls below 80% the analyst must not analyze customer samples until the laboratory manager has reviewed his/her data and determine the cause of the problems involved. Corrective actions will then be documented.

Chrysotile:
Suspected chrysotile diffraction patterns are examined for a 5.3 Å layer-line (row) spacing and for the correct orientation and d-spacings. If results differ by more than 5% of accepted values, identification of chrysotile is suspect.

Amphibole:
Suspected amphibole patterns are examined for a 5.3 Å layer-line spacing (if the pattern is of random orientation) or for Zone-Axis measurements if a zone axis pattern was obtained. If results differ by more than 5% of accepted values, identification is suspect, particularly for amphiboles.

A.5.4.3.2.4 EDXA Spectra Evaluation
EDXA spectra can be evaluated either qualitatively, by comparing the sample spectra to spectra obtained from asbestos standards, or quantitatively by calculating elemental concentrations using K-Factors obtained during EDXA calibration.

A.5.5 Equipment

A.5.5.1 Equipment List
Each EMSL asbestos laboratory maintains a variety of equipment suitable to their size and workload. Specific equipment requirements can be found in the analytical SOPs. Each lab maintains an inventory of equipment onsite which provides specific of their particular equipment. This list is available for review upon request.

A.5.5.2 PCM Calibrations & Verifications

A.5.5.2.1 Stage Micrometer
See § 5.6 of main QMS Manual.

A.5.5.2.2 Microscope Alignments and Calibration
Daily (Each analyst to perform daily or prior to analysis):

- Phase Ring Alignment - adjust to concentric.
- Contamination control - clean microscope and work area.

Weekly (Each analyst to perform weekly)

- HSE/NPL Test Slide – block 3 must be visible, 4-5 at least partially visible, 6-7 invisible.
- Due to the current unavailability of HSE/NPL test slides, some labs use the HSE/UPO slides. These slides are available in different resolutions and acceptable line visibility is as follow:
  HSE/ULO Red - Lines 1- 3,must be visible, 4- 5 partially visible, lines 6-7 invisible.
  HSE/ULO Green - Lines 1-4 visible, 5-6 partially visible, line 7 invisible.

Monthly

- Measurement of Walton-Beckett Graticule - diameter must be 100 µm.

NOTE: For labs complying with the TNI (NELAC) Standard this must be checked and recalculated once per day by each analyst using the scope.

First time use (New, newly received or repaired microscope)

- Phase Ring Alignment - adjust to concentric
- Contamination control - clean microscope and work area
- HSE/NPL or HSE/UPO acceptability as listed above.
- Walton Beckett Graticule -diameter must be 100 µm.

A.5.5.2.3 Analyst Calibration

Daily (Each analyst, each day prior to performing PCM analysis):

- Standard reference slide (past proficiency test slide or other well characterized real world samples with targets and acceptance limits.)

A.5.5.2.4 Hood Check

Quarterly, measure and record flow rate of PCM hoods with anenometer following the *EMSL Hood Maintenance and Calibration SOP* for acceptance criteria.

A.5.5.3 TEM Calibrations and Verifications

A.5.5.3.1 Alignment

Proper alignment of a transmission electron microscope is imperative in order to provide quality data. Each microscope will be checked for alignment daily, before first use and thereafter during the day as the analyst deems necessary or due to deteriorating conditions during analysis. If the microscope cannot be brought into alignment, the microscope should be serviced. The microscope is then realigned for use. Any service performed on the microscope is recorded in the equipment maintenance log.

A.5.5.3.2 Magnification

It is imperative to know accurate image magnifications for the sizing of asbestos both on the TEM phosphor screen and negative. In order to achieve this, the magnification will be calibrated monthly, both on phosphor screen and negative, using a carbon replica standard of 2,160 lines/mm at both 20,000 X and 10,000 X nominal magnifications. If the calibrated magnifications do not fall within acceptable limits of 2SD < 5% cumulative mean, the calibration should be checked for accuracy.

If the calculated magnification differs significantly from the target magnification and no other sources of error can be found (e.g., calculation errors, non-eucentricity), the microscope should be serviced and realigned and magnification recalibrated.

Magnifications will be charted over time to indicate any trends or problems. The variation of calibration data points, (defined as 2 X the standard deviation of the past measurements to date) must be <5% of the mean. This data is tracked and managed in the EMSL QC program.

Any service is documented in the equipment maintenance log.

A.5.5.3.3 Calibration of Measuring Aids

It is important to determine the exact size of the 0.5 and 5 micron measuring aids on the phosphor screen (either circles or two perpendicular lines depending on manufacturer). This is easily measured but requires a one-time procedure of removing the viewing glass and measuring directly on the phosphor screen with a fine ruler. Be careful not to scratch the phosphor coating. Armed with these measurements and the most current magnification calibration results one can calculate their exact size at the magnification used for analysis. (These markings need to be recalibrated every time the phosphor screen is recoated.)

For asbestos in water analysis, additional calibration of 1.0 and 10 µm aids at 10,000x is also required.

A.5.5.3.4 Camera Constant

In order to index or measure selected area electron diffraction (SAED) patterns an accurate camera constant must be obtained. For this purpose the on screen and on negative camera constants will be calculated monthly (provided measurements have been stable over time - see Note below) using a gold-coated TEM grid. Camera constants shall not fall outside 2xSD<5% cumulative mean (the average calibrated camera constant to date). In the event the camera constant measurement indicates change outside these limits, sources of variability should be investigated and the calibration frequency should be increased to weekly for a period of four weeks.

If all sources of error have been investigated but the measured result differs significantly from the target value, the microscope should be serviced and realigned and the camera constant recalculated. Any service is documented in the equipment maintenance log.

Camera constant calibrations will be charted over time to indicate any trends or problems. The variation of calibration data points, (defined as 2X the standard deviation of the past measurements to date) must be <5% of the mean. This data is tracked and managed in the EMSL QC program.

If sufficient data has been collected which indicates confidence in the stability of measurements, frequency of camera constant calibration can be adjusted to monthly (see NOTE). If values fall outside the acceptance range based on statistical evaluation, frequency is increased to weekly for approximately four

weeks time until stability of measurements is obtained again. Stability is determined by evaluating the data collected from weekly measurements over a period of 6 months (24 data points) and using the above mentioned criteria.

NOTE: For those instruments utilized for water calibration, frequency must be maintained at a weekly rate during the period of time analysis is performed.

A.5.5.3.5 Chrysotile Beam Dose

Low beam dose verifies the TEM can generate SAED diffraction patterns obtained from single chrysotile fibrils without damaging the fibril. Low beam dose must be demonstrated quarterly with 9 of 10 SAED patterns obtained from NIST traceable chrysotile fibrils. A fibril having a diameter greater than or equal to 1 µm in length must be visible for a minimum of 15 seconds. The electron micrograph of both the chrysotile fibril image and the SAED pattern obtained from that fibril must be maintained.

When proper dose levels are achieved, the parameters of the microscope settings are documented and known by each operator. These settings include:

- Condenser aperture.
- Spot size.
- Accelerated voltage.
- Beam current.

A.5.5.3.6 Spot Diameter

The beam size (at crossover) normally used for EDXA elemental analysis is calibrated quarterly to verify a spot diameter of less than 250 nm. An electron micrograph verifying this calibration must be recorded quarterly.

Diameter measurements will be charted over time to indicate any trends or problems. The variation of spot diameters, defined as 2 × the standard deviation of the past measurements to date, must be <25% of the mean. This data is tracked and managed in the EMSL QC program.

A.5.5.3.7 Mapping Areas with Abnormal Spectra

The sections of the grid specimen holder, which may produce abnormal spectra, must be known to all analysts. Using a known standard reference material, such as NIST 2063a or 1866 Amosite, the areas producing abnormal spectra are recorded. This way determination can be made as to the regions that should be avoided in routine analysis.

A.5.5.3.8 EDXA Detector

The following lists the proper calibration and monitoring of performance for the EDXA detector.

The TEM's Energy Dispersive X-Ray Analyzer (EDXA) is checked daily at the Al and Cu peak center line measuring, 1.48 keV and 8.04 keV respectively, within +/-0.02 keV.

To assure low energy detection of the EDXA system, a resolvable Na kα peak must be measured using the NIST SRM 1866 crocidolite standard. These measurements must meet the criteria:

$I_B > 3(2I_B^b)^{1/2}$ where:
I_B = Integrated peak intensity, background subtracted
I_B^b = Integrated background intensity

Print a hard copy of the spectrum, sign, date, and file. It is strongly recommended to save spectrum on the hard drive. This must be done quarterly.

Using a single fibril of chrysotile from NIST SRM 1866, 1876a, or 1876b, the detector must be capable of clearly resolving the Mg and Si peaks. Hard copies of the spectrum are printed, signed, dated, and filed. This must be done quarterly.

The detector resolution is measured using a Mn source to verify the Mn kα peak has a resolution of less than or equal to 175 eV at full width half maximum. Resolution measurements are tracked over time to indicate any trends or problems. The value of the sum measurements and the variation (defined as 2X the standard deviation of the past measurements to date) must not exceed 180 eV. Print a hard copy of the spectrum, sign, date, and file. This must be done on a semi-annual basis.

For labs complying with the TNI (NELAC) standard, this frequency shall be quarterly.

Elemental K-Factors for Mg, Ca, and Fe relative to Si are calculated using NIST SRM 2063a or equivalent as a standard. The Mg to Fe ratio is also calculated using NIST SRM 2063a or equivalent as a standard. Elemental K-Factors for Na and Al to relative to Si are calculated from an Albite standard. These two sets of standards for K-Factor determination should be done at the same time (preferably the same day.) The following are some of the pass-fail criteria (see *Asbestos QC SOP* for complete listing):

Mg:Si – 1.0 - 2.0
Ca:Si – 1.0 - 1.75
Fe:Si – 1.0 - 2.0
Mg:Fe – 1.5 or less
Na:Si – 1.0 – 4.0
Al:Si – 1.0 – 1.75

Print a hard copy of the spectrum, sign, date, and file. It is strongly recommended to save spectrum on the hard drive. This must be done on a semi-annual basis.

A.5.5.3.9 Plasma Asher

Although the AHERA method specifies 10% ashing, it allows for etching less than this amount if 10% generates a texture that negatively affects structure counting. EMSL has evaluated the ashing procedures and found that in most cases 5% removal produces better preparations with lower fiber loss and better intact carbon films.

The low temperature plasma asher is calibrated quarterly to provide the calculated time needed to remove 5% of the collapsed mixed cellulose ester filter. This is performed gravimetrically and is charted against time.

Any service is documented in the equipment maintenance log.

A.5.5.3.10 Grid Opening Measurement

TEM 200 mesh locator grids are to be measured using light microscopy. Upon the receipt of each batch (10 vials of 100 grids), 2 grids per vial are removed and measured at the rate of 20 grid openings per grid for a total of 400 grid openings measured. A total of 2% of the grid lot is measured to determine the average grid opening area in mm^2.

Precision of the measuring system itself is tracked and documented.

See also *EMSL Grid Measurement SOP*.

A.5.5.3.11 Muffle Furnace

The high temperature muffle furnace is verified quarterly at three different temperatures in the temperature range of 450° to 500° C. A high temperature thermometer should be immersed in a sand bath for temperature readings. Actual temperature recorded should be within ± 5% of target temperature. Record date, target temperature, measured temperature and initials of technician. Any service performed is recorded in the equipment maintenance log.

A.5.5.3.12 Effective Filtration Area

An accurate result in any procedure requiring filtration depends upon an accurate measurement of the effective filter area (EFA). Prior to use on actual samples, the EFA of all filter funnel apparatus should be determined and documented. The EFA of disposable filter funnels needs to be documented using the “Effective Filtration Area Log” form at a rate of 2 per lot. This information should be stored in the laboratory files for future reference.

A.5.5.3.13 Analytical Balance & Weights
See §§s 5.5.3 & 5.6.2 of main QMS Manual.

A.5.5.4 PLM Calibrations and Verifications

Calibration procedures must be followed prior to the analysis of samples to ensure that results of analysis reflect true and accurate data. The following summarizes the type and frequency of calibration required. Details on the performance of these functions are found in the PLM SOP.

A.5.5.4.1 Microscope Calibration

Daily (Each analyst to perform daily, prior to analysis):

- Center stage or objective & center and align condenser lens.
- Align polars (full extinction.)
- Crosshair alignment fixed in polarizer's privileged direction.

A.5.5.4.2 Analyst Calibration

Daily

- Standard reference sample (may be actual sample material or pre-mounted slides from old proficiencies that are mounted in the proper RI medium that allow the recording of all the optical properties including the refractive index of the asbestos fiber.)
- Contamination check with fine grained, reagent grade salt.

Monthly

- Check standard Amosite mount for proper dispersion color / wavelengths.

A.5.5.4.3 Balance Calibration & Verification
See § 5.5.3 of main QMS Manual.

A.5.5.4.4 RI Oil Calibration

All RI oils are calibrated every time a new bottle is open.
If the date of last calibration on the bottle is greater than three months, then the oil needs to be calibrated before use.

For NIOSH 9002 samples, RI Oils must be calibrated weekly or on next use.

See *EMSL RI Calibration SOP*.

A.5.5.4.5 Muffle Furnace Calibration

Calibrate muffle furnace temperature quarterly at three different temperatures in the temperature range of 450° to 500°C.

A.5.6 Measurement traceability

The results of analytical measurements are traceable to recognized standards. These standards include:

- SRM 1876b (or equivalent, i.e., NVLAP PT round.)
  NOTE: NVLAP no longer recognizes NYS ELAP samples as NIST traceable.
- SRM 1867 or 1867a.
- SRM 2063a.
- SRM 1866 (a or b.)
- Calibration using NIST certified or NIST traceable support equipment (thermometers, balance weights, stage micrometer, etc.)
- Consensus standards such as past proficiency testing samples.

A.5.7 Sampling

For purposes of this manual, sampling is defined as the procedures involved with the splitting of samples for distribution to other laboratories and the preparation of samples for analysis (sub-sample preparation).

Samples are not split prior to shipment to another laboratory for regular customer analysis (as in sub-contracting). Where samples are shipped for quality control purposes, the originating laboratory may choose to retain a portion of the sample for internal quality control purposes. Care must be taken when splitting the sample to ensure the sample is split as evenly as possible.

Note*:* The splitting of samples for QC is optional and at the discretion of the laboratory manager*.*

Sub-sample preparation procedures are detailed in the *EMSL PLM SOP*.

A.5.8 Handling of test and calibration items

A.5.8.1 Sample Acceptance Criteria: General

Whenever samples fail to meet sample acceptance criteria, the chain of custody and/or other project records shall be appropriately commented and the customer shall be contacted immediately. If the customer requests the analysis to continue, the laboratory shall ensure that all correspondence is clearly documented. Sample acceptance criteria include, but are not limited to, the lists included in the following sections.

A.5.8.2 Sample Acceptance Criteria: PCM

Samples accepted for PCM analysis must comply with a number of specific conditions. Examples of situations where samples might be judged unacceptable include:

- Bulk samples packaged with the PCM cassettes.
- Cassettes packaged with Styrofoam 'peanuts.'
- Tops missing from the cassette (or disassembled.)
- Wet filter.

See also *EMSL PCM NIOSH 7400 SOP* for additional criteria (if any.)

A.5.8.3 Sample Acceptance Criteria: TEM

Samples accepted for TEM analysis must comply with a number of conditions. Samples are judged unacceptable under any of the following circumstances:

- Air cassettes submitted with bulk samples.

- Air cassettes packaged with Styrofoam 'peanuts.'
- Air cassettes submitted with missing tops (or disassembled.)
- Air cassettes submitted with wet filters.
- Water samples submitted with preservative added.
- Insufficient amount of sample submitted.
- More than one non-layered sample in container ('baggie'.)

See also *EMSL PLM SOP* for additional criteria (if any.)

A.5.8.4 Sample Acceptance Criteria: PLM

Samples accepted for PLM analysis must comply with a number of conditions. Samples are judged unacceptable under any of the following circumstances:

- Insufficient amount of sample submitted.
- Sample containers open.
- Sample numbers on the COC don't match sample numbers on the sample, or are otherwise unidentifiable.
- Samples submitted in damaged sample containers
- Evidence of cross contamination.

See also specific EMSL TEM SOPs for additional criteria (if any.)

A.5.8.5 Sample Storage & Disposal

Sample Type	Standard Retention Time	Storage Conditions
Bulk and Air Asbestos	60 days	Stored in ziplock bags Air & Bulk not stored together
TEM Grids (AHERA)	3 Years	
TEM Grids (NYS NOBs)	3 Years	
Water grids (filtrate of water sample/ petri dishes may optionally be stored as well)	3 Year	If Stored on filters used for Prep in individual 50 mm Petri dishes
Micro vac & wipe Petri dishes and grids	1 Year	Stored on filters used for prep in individual 50 mm Petri dishes

Following analysis, all bulk and air samples are placed in ziplock bags and held for at least 60 days from the final report date unless otherwise requested by the customer. All TEM grids analyzed for AHERA compliance are held for three (3) years. Grids for micro vac and wipes are held for only one (1) year. Samples containing ≥1% asbestos are discarded through a licensed hazardous waste removal company. A copy of the waste manifest is stored in the laboratory files.

Air samples shall not be stored with bulk samples, containers must be secure, and storage boxes should be placed in an area void of any possibility of damage.

After analysis is complete, the filtrate of water samples may optionally be stored on the filters used for preparation in individual 50 mm petri dishes. The prepared grids are stored in grid boxes assigned specifically to be stored for 3 years.

The petri dishes and grids are stored for three (3) years from the date of the final report.

If requested, samples will be returned to the customer.

A.5.9 Assuring the quality of test and calibration results

A.5.9.1 Monthly QC Data Report to Management

In addition to the Quarterly Report required by all departments, the lead quality control coordinator or quality assurance coordinator (or lab manager) shall compile a monthly report of quality control data by the 15th of each month for submission to the corporate QA department.

The laboratory manager will prepare the monthly report highlighting the following:

- Summary of all QC activities.
- Results of investigations of any QC outlier results.
- Report of any problems, discrepancies encountered,

A.5.9.2 Trend Analysis of QC Data – PLM, TEM, PCM

As discussed below, QC data for the asbestos department will be charted over time in order to evaluate analyst and laboratory performance. This data shall be reviewed by the laboratory's quality control and/or quality assurance coordinator or department manager. Statistically relevant trends should trigger an evaluation.

Examples of a significant trend include:

- Seven (7) consecutive data points on either side of the mean.
- For any group of (3) data points, two data points outside the warning limits.
- For any group of (5) data points, four data points outside the warning limits.

Trend analysis shall be documented along with conclusions. If any actions are taken as a result, these may be documented as preventive actions. Trend evaluations shall be included in quality reports submitted to the laboratory manager and corporate quality assurance department.

A.5.9.3 Selection of Quality Control Samples

The selection of samples for reanalysis is as random as possible while meeting the requirement that 30% of QC samples fall between 1%-10%. Original (first) results should not be known when the second analysis is performed.

Samples chosen are typically random however, samples may be selectively chosen if there is a problematic or unique sample where a reanalysis may provide important information about that sample.

A.5.9.4 Single Analyst Laboratories

Laboratories that have a single analyst will be unable to perform in-house, inter-analyst QC analysis. Therefore the percentage of intra-analyst QC analysis as well as inter-lab QC analysis should be increased to maintain the overall 10% QC requirement.

A.5.9.5 PCM Quality Control

The laboratory manager will determine how QC testing is implemented; either on a frequency basis (e.g., after the analyses of every ten samples) or a percentage of sample volume.

The Quality Assurance Department will inspect the results of QC testing on a regular basis and provide the necessary support and directives to the laboratory manager to ensure the QC program is properly executed.

The laboratory manager (or manager's designee) of each laboratory is responsible for implementing the day-to-day QC testing and ensuring the correct types of testing occur at the appropriate frequencies. The laboratory manager is also responsible for ensuring complete records of QC testing are maintained.

A.5.9.5.1 Intra-Analyst – PCM

The original analyst reanalyzes the same sample. An attempt should be made to perform the analysis as 'blindly' as possible. Data is evaluated using the PCM QC program spreadsheet.

A.5.9.5.2 Reference Samples – PCM

Known standards are analyzed as if they were actual customer samples.

At the start of each day, the analyst will be given a standard reference slide at random for analysis. Results of this count are then compared to the standard reference value calculated by the proficiency program which will determine whether the results are within accepted limits. Slides are rotated to ensure all slides are analyzed at approximately the same frequency over a period of time.

Note: The analyst may not analyze customer samples until she/he has counted a reference slide (i.e. past PAT sample). Results must be with in acceptance criteria before analysis of customer samples can begin.

A.5.9.5.3 Statistical Analysis of PCM QC Data

Copies of data produced in intra-analyst testing will be submitted to the laboratory quality assurance or quality control coordinator or laboratory manager. The quality assurance or quality control coordinator or lab manager then carries out statistical analysis, using the EMSL monthly quality control report Excel spreadsheet. Procedures for this analysis, data collection, and data evaluation are described below. This program covers the QC requirements for airborne fiber counting. It addresses the requirements as defined in NIOSH Method 7400.

The principle objectives of the QC program are as follows:

- To determine analyst CV values over the ranges of fiber concentrations to assist in identifying random intra-analyst errors.
- To verify that results of analysis are precise within the 95% confidence level as measured using the determined analyst CV.
- To verify that an analyst's results are accurate as measured against a general consensus result (past PAT samples and well characterized customer samples).

The program has three principle methods used to satisfy our objectives. These include:

1) Intra-analyst re-analysis of 10% of the samples
2) Routine re-analysis of Standard Reference slides
3) Inter-laboratory round robins

Data collected from the analysis of the same reference sample (from past PAT rounds) will be used to calculate analyst CV values, from all 3 required ranges (5-20, >20-50, >50-100 fibers in 100 fields). The CV is updated as data is collected from daily reference slide analysis. Calculations are updated as 20 data points are collected.

The system will use these CV values to determine the acceptance of each set of sample replicates that are run daily. The system uses statistical calculations following those referenced in the NIOSH 7400 Method, Issue 2 dated August 1994 and is based on paired difference statistic. When a re-analysis does not agree with the original all other samples in that set are to be reanalyzed. Test the new analysis with the original analysis for the entire batch and discard any failed data. Report results from those sample sets that fall within the control limits only.

A.5.9.5.3.1 Calculations

Standard Deviation:

A standard deviation is calculated for each set of data (minimum 20 data points/range) generated for each applicable range of fiber concentration using the formula:

$$\sigma = \sqrt{\frac{\sum\left(x - \overline{x}\right)^2}{n}}$$

Where: $\sigma =$ standard deviation

$x =$ Data point (f/mm^2)

$\overline{x} =$ Average of data points (f/mm^2)

$n =$ Number of data points

Coefficient of Variation (also referred to as relative standard deviation S_r)
With the standard deviation calculated,

$$CV = \frac{\sigma}{\overline{x}}$$

Paired Difference analysis (for pass / fail):
Each pair of replicate counts is compared using the paired difference quality test as follows:

$$\left|\sqrt{x_1} - \sqrt{x_2}\right| > 2.8 \times mean \times (.5 \times CV)$$

Where:

X_1 = Original fiber count (f/mm^2)
X_2 = Replicate (f/mm^2)
Mean = Average of the square roots of the two fiber counts (f/mm^2)
CV = Coefficient of variation (as established for each analyst, each fiber range)

NOTE: This calculation represents the rejection/ acceptance criteria for replicate data.

A.5.9.5.3.2 Control Charts

The replicate data is plotted on a control chart as a graphic tool designed to monitor the analyst's precision performance. It graphs the comparison with the difference of the square roots of the paired data with the acceptable limit calculated using the quality test explained above. The program normalizes these numbers to 1 and uses the following control limits.

- 1 = UCL (upper control limit) - 0.65 = UWL (upper warning limit)
- -1 = LCL (lower control limit) - 0.65 = LWL (lower warning limit)

Data is generated and charted to monitor and measure both individual analysts and overall laboratory performance. It measures trends in the analytical processes, which may affect the quality of data. These control charts contribute to the criteria for determining validity of the data and monitors any bias that an analyst and/or laboratory may be experiencing.

A.5.9.6 TEM Quality Control

The following section describes the type and frequency of quality control analysis performed by the TEM laboratory. The frequency and type of quality control analyses are dictated by the analytical procedures and regulatory agencies.

Quality control data is tracked and managed in the EMSL quality control program.

The laboratory enters QC data into Excel worksheets, which then provides information including:

- Acceptance/rejection of replicate and duplicate data.
- Performance trends.
- Upper and lower control limits.
- Acceptance/rejection of calibration measurements.
- Record of QC and calibration measurements and frequencies.
- Contamination events.
- Corrective actions.
- Control charts.

A.5.9.6.1 Standards Analysis

SRM 1876b or equivalent must be analyzed once each year per analyst.

The laboratory and analysts must obtain mean analytical results on SRM 1876b (or equivalent) so that trimmed mean values fall within 80% of the lower limit and 110% of the upper limit as published on the certificate.

Where the SRM 1876b is unavailable (note: as of the date of this revision of the QMS Manual, NIST has chosen to discontinue this SRM), EMSL will use NVLAP past proficiency testing samples as the reference standard. The results are evaluated using the criteria established by the PT provider.

NOTE1: NVLAP no longer recognizes NYS ELAP proficiency samples as NIST-traceable. These should no longer be used as a substitute for SRM 1876b.
NOTE2: Standard analysis of NIST 1876 or substitute is not applicable for TEM Bulk (NOB) samples, they have their own standards detailed in section A.5.9.6.4.3

A.5.9.6.2 AHERA, EPA Level I, II & III

A.5.9.6.2.1 Intra-Analyst Same Grid Opening Reanalysis

At least 2% (1/50 samples analyzed) of analyses are reanalyzed by the same analyst counting the same grid openings. QC samples are to be analyzed without prior knowledge of results where possible.

The measure of variance is calculated using the formula:
R = |(A-B)/((A+B)/2)|

Where:

R = the measure of variance for the analysis
A = the value of the first analysis in structures
B = the value of the second analysis in structures

Measures of variance (R) are recorded and plotted over time to determine trends and problems in analyses.

The Pass/Fail criteria for the QC analyses are as follows:

- < 5 structures = +/- 1 structure
- 5-20 structures = +/- 2 structures
- >20 structures = +/- 3 structures

A failure based on the above criteria will result in a verified analysis in order to determine the cause of the problem. A cumulative record of False Positives, False Negatives, and True Positives based on the verified analysis are kept for each analyst.

A.5.9.6.2.2 Inter-Analyst Same Grid Opening Reanalysis

At least 4% (1/25) of analyses are reanalyzed by a different analyst counting the same grid openings. (Single analyst labs must perform 1/10.) QC samples are to be analyzed without prior knowledge of results where possible.

The measure of variance is calculated using the formula

R = (A-B)/((A+B)/2)

Where:

R = the measure of variance for the analysis
A = the value of the first analysis in structures
B = the value of the second analysis in structures

Measures of variance (R) are recorded and plotted over time to determine trends and problems in analysis.

The Pass/Fail criteria for the QC analyses are as follows:

- < 5 structures = +/- 1 structure
- 5-20 structures = +/- 2 structures
- 20 structures = +/- 3 structures

A failure based on the above criteria will result in a verified analysis in order to determine the cause of the problem. A cumulative record of False Positives, False Negatives, and True Positives based on the verified analysis are kept for each analyst.

A.5.9.6.2.3 Same Prep Different Grid Opening Analysis

Sample reanalysis of different grid openings is performed to monitor and evaluate the method in regard to loading deposition uniformity on the filter. Re-analyses are analyzed at a frequency of 1 in 100, samples QC analyses should be split relatively evenly between intra-and inter-analyst analyses.

Poissonian statistics are applied to re-analysis data. QC samples are to be analyzed without prior knowledge of results where possible. The analysis is accepted when:

$$|(A-B)| \leq 1.5 \times ((A+B)/2)^{1/2}$$

Where:

A = the value of the first analysis in structures
B = the value of the second analysis in structures

A.5.9.6.2.4 Sample Re-preparations

Same sample re-preparations are performed to monitor any possible discrepancies that may occur in the implementation of the overall method. This includes sampling, preparation and analysis. Re-preparations are analyzed at a frequency of 1 in 100 samples and should be split relatively evenly between intra- and inter-analyst analyses.

Poissonian statistics are applied to re-preparation data. QC samples are to be analyzed without prior knowledge of results where possible. The analysis is accepted when:

$$|(A-B)| \leq 2.0 \times ((A+B)/2)^{1/2}$$

Where:

A = the value of the first analysis in structures
B = the value of the second analysis in structures

A.5.9.6.2.5 Verified Analysis

At least 1/100-grid openings analyzed are reanalyzed by at least one other analyst using a verified analysis technique. Structures within a grid opening are either sketched or plotted and their locations are verified. 20% of the samples used for verified analysis must contain between 6-40 structures/grid opening (approximately 1,000 – 5,000 asbestos structures per $mm^{2)}$, with the exception of verified analysis used to resolve discrepancies.

Analysts-in-training are required to perform a greater amount of verified analysis as seen fit by the laboratory manager and as dictated by the analyst's QC results.

A.5.9.6.2.6 Laboratory Blank Sample Analysis

Prep one blank per batch or 10% of the daily total (whichever is greater) and after cleaning or servicing the preparation area. Analyze 1 per 100 filter analyses for MCE (mixed cellulose ester) filters, and 1 per 25 filter analyses for PC (polycarbonate) filters. Store all prepared grids (even if

not analyzed) and record blank data on appropriate forms. Blank QC analysis is made part of the overall 10% quality assurance analysis.

For Labs complying with the TNI (NELAC) standard, Lab blanks must be analyzed at a rate of 1 per 20 samples analyzed.

Criteria for the maximum allowable contamination levels for laboratory blanks are:

MCE Filters:

- cumulative average of < 5 structures/mm^2 , AND
- a single preparation level of < 15 structures/mm^2.

PC Filters:

- cumulative average of 18 structures/mm^2, AND
- any single preparation level of 53 structures/mm^2.

A.5.9.6.3 ASTM Dust Microvac and Wipe Sample Analysis

Quality control for this method specifies 10% of total analyses (excluding blanks) and requires following the QC procedures as recommended by NVLAP/NIST and ASTM. The re-analysis must be performed on second grid preparations from the final filter.

A.5.9.6.3.1 Intra-Analyst Reanalysis

At least 3% of analyses are reanalyzed by the same analyst on different grid openings of different preparations. QC samples are to be analyzed without prior knowledge of results where possible.

The analysis is accepted when:

$$|(A-B)| \leq 1.5 \times ((A+B)/2)^{1/2}$$

Where:

A = the value of the first analysis in structures
B = the value of the second analysis in structures

For any failure of the above criteria, re-analysis is required in order to determine the cause of the problem.

A.5.9.6.3.2 Inter-Analyst Reanalysis

At least 7% of analyses are reanalyzed by a different analyst on different grid openings of different preparations. QC samples are to be analyzed without prior knowledge of results where possible.

The analysis is accepted when:

$$|(A-B)| \leq 2.0 \times ((A+B)/2)^{1/2}$$

Where:

A = the value of the first analysis in structures
B = the value of the second analysis in structures

For any failure of the above criteria, re-analysis is required in order to determine the cause of the problem.

A.5.9.6.3.3 Process Blanks

1 process blank is prepped and analyzed along with each sample set.

A.5.9.6.4 TEM NOB (ELAP 198.4) & Chatfield VAT

A.5.9.6.4.1 Intra-Analyst Reanalysis

At least 2% of analyses are reanalyzed by the same analyst. QC samples are to be analyzed without prior knowledge of results where possible.

Measures of variance are calculated using the formula:

$$R = |(A-B)/((A+B)/2)|$$

Where:

R = the measure of variance for the analysis
A = the value of the first analysis in % asbestos
B = the value of the second analysis in % asbestos

Measures of variance are recorded and plotted over time to determine trends and problems in analyses.

The Pass/Fail criteria for the QC analyses are as follows:

- $R \leq 1$ – PASS.
- $R > 1$ – FAIL.
- Incorrect Asbestos ID – FAIL.
- Asbestos missed during analysis (false negative) – FAIL.
- Asbestos incorrectly identified to be present in a negative sample (false positive) – FAIL.

A failure based on the above criteria will result in reanalysis to determine the cause of the problem. If this should fail to resolve the problem, the sample will be reprepped (a complete gravimetric reduction) and again reanalyzed by the initial analyst.

R values are maintained and R control charts updated monthly along with results for and resolutions of failures.

A.5.9.6.4.2 Inter-Analyst Reanalysis

At least 7% of analyses are reanalyzed by a different analyst; the sample is re-prepped including ashing and acid dissolution. QC samples are to be analyzed without prior knowledge of results where possible.

Measures of variance are calculated using the formula:

R = (A-B)/((A+B)/2)

Where:

R = the measure of variance for the analysis
A = the value of the first analysis in % asbestos
B = the value of the second analysis in % asbestos

R-values are recorded and plotted over time to determine trends and problems in analyses.

The Pass/Fail criteria for the QC analyses are as follows:

- R > 1 or R< -1 – FAIL.
- Incorrect Asbestos ID – FAIL.
- Asbestos missed during analysis (false negative) – FAIL.
- Asbestos incorrectly identified to be present in a negative sample (false positive) – FAIL.

A failure based on the above criteria will result in reanalysis to determine the cause of the discrepancy. If this should fail to resolve the problem, the sample will be re-prepped (complete gravimetric reduction) and again reanalyzed by the initial analyst.

R values are maintained and R control charts updated monthly, along with reasons for and resolutions of failures.

A.5.9.6.4.3 *Standard Analysis*

At least 1% of analyses are prepared of reference standards or consensus standards. Results are charted to determine analyst as well as laboratory precision and accuracy.

A.5.9.6.4.4 *Blank Analysis*

At 5% (1/20) of sample volume, a known negative floor tile is prepped and analyzed for % weight recovery and contamination. Residue weights must be within 10% of the average recovery weight. If asbestos is detected, the source of contamination must be traced and problem resolved.

A.5.9.6.5 EPA 100.2

Quality control follows TNI guidelines:

- Total number of QA samples and blanks must be at least 10% of total sample workload.
- There are no inherent inter- or intra-analyst QC requirements but good practice would include both.

A.5.9.6.5.1 *Verified QC Analysis*

At least 5% of samples must be analyzed by the analysis of the same grid openings in a verified format, including sketches and verification of all discrepancies. Verified QC is evaluated by NISTIR 5351, and analysts must maintain at least ≥ 80% True Positives, ≤ 10% False Positives and ≤ 20% False Negatives for cumulative verified analysis from analysis of verified samples and standards.

A.5.9.6.5.2 *Verified Standard Analysis*

Standard samples are analyzed at a rate of 1% of total analyses. Standard samples must be created from all six NIST (NIST 1866 & 1867) standard asbestos types with final preparations containing 1-20 asbestos fibers (>10µm long) per grid opening.

Standards should be reanalyzed using verified analysis of the same grid openings, including sketches and verification of all discrepancies. Verified QC is evaluated by NISTIR 5351, and analysts must maintain at least ≥ 80% True Positives, ≤ 10% False Positives and ≤ 20% False Negatives for cumulative verified analysis from analysis of verified samples and standards.

A.5.9.6.5.3 *Replicate QC*

At least 1% of samples should be reanalyzed by the analysis of different grid openings of the same preparation used for analysis.

The analysis is accepted when;

$$|(A-B)| \leq 1.5 \times ((A+B)/2)^{1/2}$$

Where:

A = the value of the first analysis in structures
B = the value of the second analysis in structures

For any failure of the above criteria reanalysis is required in order to determine the cause of the problem.

Note: Definition for Replicate QC above is specific to water methodologies.

A.5.9.6.5.4 *Duplicate QC*

At least 1% of samples should be reanalyzed by re-preparing the sample by; re-filtration, re-preparation and reanalysis of the same volume aliquot as used for the original analysis.

For the analysis of different preparations, the analysis is accepted when:

$$|(A-B)| \leq 2.0 \times ((A+B)/2)^{1/2}$$

Where:

A = the value of the first analysis in structures
B = the value of the second analysis in structures

For any failure of the above criteria reanalysis is required in order to determine the cause of the problem.

Note: Definition for Duplicate QC above is specific to water methodologies.

A.5.9.6.5.5 Blanks

A process blank is filtered, prepared and analyzed before each batch of samples. The process blank must meet a contamination level of ≤ 0.01MFL for fibers > 10µm long.

A.5.9.7 PLM Quality Control

A.5.9.7.1 Intra-Analyst Reanalysis – PLM

A.5.9.7.1.1 Frequency

At least 2% of analyses are re-prepared and reanalyzed by the same analyst. A full analysis is performed (re-prepared, optical properties recorded, etc.).

A.5.9.7.1.2 Statistical Analysis

Measures of variance are calculated using the formula

$$R = |(A-B)/((A+B)/2)|$$

Where :

R = the measure of variance for the analysis
A = the value of the first analysis in %
B = the value of the second analysis in %

Measures of variance are recorded and plotted over time to determine trends and problems in analyses.

The Pass/Fail criteria for the QC analyses are as follows:

- $R \leq 1$ – PASS.
- $R > 1$ – FAIL.

- Incorrect Asbestos ID – FAIL.
- Asbestos missed during analysis (false negative) – FAIL.
- Asbestos incorrectly identified to be present in a negative sample (False positive) – FAIL.

For any failure of the above criteria the cause of the failure is identified and corrected.

A.5.9.7.2 Inter-Analyst Reanalysis – PLM

A.5.9.7.2.1 Frequency

At least 7% of analyses are reanalyzed by a different analyst; the sample is re-prepped from the original sample.

A.5.9.7.2.2 Statistical Analysis

Measures of variance are calculated using the formula

R = (A-B)/((A+B)/2)

Where:

R = the measure of variance for the analysis
A = the value of the first analysis in %
B = the value of the second analysis in %

R-values are recorded and plotted over time to determine trends and problems in analyses.

The Pass/Fail criteria for the QC analyses are as follows:

- $-1 \leq R \leq 1$ – PASS.
- R > 1 and R< -1 – FAIL.
- Incorrect Asbestos ID – FAIL.
- Asbestos missed during analysis (false negative) – FAIL.
- Asbestos incorrectly identified to be present in a negative sample (False positive) –FAIL.

For any failure of the above criteria the cause of the failure is identified and corrected.

A.5.9.7.3 Reference Samples – PLM

A.5.9.7.3.1 Frequency

Past proficiencies and known standards made with SRM 1866 and 1867 are analyzed. These standards are used to both calibrate evaluate the performance of the analyst.

The standards are used to:

- Calibrate analyst visual estimation technique

- Verify the analyst's ability to correctly measure optical properties. Optical properties recorded must be within the acceptance criteria established by NIST.

At least 1% of analyses are to be quantitative standards repeatedly submitted and quantified.

A.5.9.7.3.2 Statistical Analysis

Results are quantified and charted to determine analyst, as well as laboratory precision and accuracy, using the following formula for percent recovery.

%R = (A/F) x 100

Where:

%R = percent recovery
A = the analytical result
F = the formulated standard weight

A.5.9.7.4 EMSL PLM Consensus Program

In addition to the EMSL standard quality control program, a separate quality analysis program is used which provides for an additional check on analyst performance.

Following the sampling strategies documented in the AHERA regulations, sample batches are generally submitted to our laboratories in sets collected from homogenous areas. Samples are typically collected in sets of 2, 3, 5 or 7 depending on the total area sampled. These sets should contain samples of identical type.

Collection of samples in this way helps to minimize the chance for false negative results whether the source is from sampling error, non-homogeneity or lab error.

The homogeneous make up of these sets provides the lab with an opportunity to provide an extra layer of quality control. If the analysis of each homogenous group is split between two different analysts, a check on each analysis is achieved without any additional analytical effort.

See *EMSL PLM Consensus Analysis Program SOP* for additional information and procedure.

A.5.9.7.5 Blanks

For Friable samples at least one blank should be processed daily, this should entail the preparation of a known negative material to slide using all tools and oils to be used for analysis that day.

For NOB samples a known negative floor tile is prepped and analyzed for % weight recovery and contamination. Residue weights must be within 10% of the average recovery weight.

For Labs complying with the TNI (NELAC) Standard a similar check is made with every 20 uses of a piece of homogenization equipment.

For all blanks, if asbestos is detected, the source of contamination must be traced and problem resolved.

A.5.9.8 Proficiency Testing

A.5.9.8.1 General

In addition to the policies and procedures mentioned in the general section of this manual, results are reported by each active analyst following the requirements of the proficiency testing (PT) program and must ensure:

- Analyses are not contracted out to another laboratory.
- The laboratory keeps and uses proficiency testing materials as in-house instructional materials, unless otherwise directed.
- All analysts (full and part time) participate in proficiency testing rounds (all analysts need not participate in proficiency testing prior to returning the results to the PT provider, but all analysts shall participate without prior knowledge of the testing results at a later date- where applicable.)
- Each analyst should analyze and record sample results independently as part of the lab's internal QC system.
- A single result is reported back to the PT provider by the laboratory unless otherwise specified in the PT instructions.
- Procedures and calculations (if any) are documented as to how a single result is determined.
- Results from multiple analyses are not averaged.
- Test results are used for inter-analyst comparisons.
- Corrective actions are taken and documented for problems indicated by proficiency testing.
- Test results, when applicable, are used in determining accuracy and precision for each analyst.

A.5.9.8.2 PCM Proficiency Testing

EMSL laboratories will participate in proficiency testing programs where accredited.

EMSL asbestos laboratories participate in the following programs at the discretion of the QA manager:

- AIHA-PAT Programs Industrial Hygiene Proficiency Analytical Testing program (IHPAT)

- Mandatory proficiency testing administered by State agencies as applicable
- AIHA Registry Programs Asbestos Analyst Registry (AAR)

Proficiency samples from these programs are to be run as normal laboratory samples, except where agency policy dictates additional requirements.

A.5.9.8.3 TEM Proficiency Testing

EMSL TEM asbestos laboratories participate in the following programs:

- Mandatory proficiency testing administered by the NYS ELAP.
- The mandatory testing administered by the NIST (National Institute for Standards and Technology) National Voluntary Laboratory Approval Program (NVLAP).

Proficiency samples are to be run as normal laboratory samples, except where Agency policy dictates additional requirements.

All analysts, including those analyzing in a NVLAP sub-facility participate in the analysis of the NVLAP proficiency samples.

A.5.9.8.4 PLM Proficiency Testing

EMSL PLM asbestos laboratories participate in the following programs:

- Mandatory proficiency testing administered by the NYS ELAP.
- The mandatory testing administered by the NIST (National Institute for Standards and Technology) National Voluntary Laboratory Approval Program (NVLAP).

Proficiency samples are to be run as normal laboratory samples, except where Agency policy dictates additional requirements.

All analysts, including those analyzing in a NVLAP sub-facility participate in the analysis of the NVLAP proficiency samples.

A.5.9.9 Round Robin Program

In addition to the intra-laboratory QC, laboratories participate in an inter-lab exchange among other EMSL laboratories and select laboratories outside of the EMSL network. The TEM, PLM and PCM programs are managed by the corporate Quality Assurance department.

The EMSL asbestos Inter-laboratory program is documented in the *EMSL Inter-Laboratory Sample Exchange – Asbestos – SOP*.

The compiled results of the most recent inter-lab exchange shall remain posted in the laboratory for review by analysts.

A.5.10 Reporting the results

A.5.10.1 Reference to NVLAP Accreditation

A.5.10.1.1 Reports with NVLAP accredited and non-accredited data

Whenever a report contains data covered by NVLAP accreditation and data not covered by NVLAP accreditation, the report must prominently display the following statement at the beginning of the report: "This report contains data that are not covered by the NVLAP accreditation."

A.5.10.1.2 Use of NVLAP Logo

EMSL does not generally display the logos from accreditation agencies on the final report. Logos are commonly used on mailing envelopes and marketing materials. The NVLAP logo is displayed in compliance with the following procedures:

- Logo must be accompanied by the NVLAP Code and approved (by NVLAP) caption. The caption shall appear below and in close proximity to the logo.
- Logo must stand by itself and shall not be combined with any other logo, symbol or graphic.
- The aspect ratio shall be 1 to 2.25.
- The logo and caption shall be of a size that allows the caption to be easily read. The size of the caption shall not exceed the size of the logo itself.
- The logo shall appear in black, blue or other color approved by NVLAP and may be filled or unfilled. In the case of a filled logo, the same color shall be used for the outline and the fill.
- If the NVLAP term or logo is used in a contract or proposal, the term and logo is to be accompanied by a description of the laboratory's scope of accreditation and current accreditation status.

A.5.10.1.3 Use of NVLAP term

Whenever the term NVLAP is used to reference accredited status, it shall be accompanied by the NVLAP Lab Code. *For example: NVLAP Lab Code XXXXXX-X.*

REVISION HISTORY

Previous revision histories are available from the QA department on request.

Revision	Date	Changes
16	5/30/13	References to QAM changed to QMS. "Client" changed to "Customer" to align with 17025. A.5.2.1 – Revised language on our course to clarify extent of AIHA endorsement. A.5.2.3.1 – Removed references to "chemistry" of asbestos in favor of crystallography. A.5.2.3.4 – Updated to remove requirement for probationary period for non-AIHA accredited labs. A.5.4.3.2.2 – Header change to include "Structure". A.5.5.2.1 – language removed in favor of reference back to main QAM A.5.5.2.2 – Acceptable range removed for W-B Graticule. Must measure 100 microns. A.5.5.2.4 – Removed acceptance criteria from Hood check and referred back to SOP.

		A.5.5.3.8 – Clarified NIST SRM 1866 A.5.5.3.13 - language removed in favor of reference back to main QAM A.5.5.4.1 – clarified requirement for condenser A.5.5.4.2 – Revised salt requirement from table salt to reagent grade salt. A.5.5.4.3 - language removed in favor of reference back to main QAM. A.5.6, A.5.9.6.1 – added note that NYS ELAP samples are no longer considered NIST traceable & added reference to 1867a. A.5.8.1 – New section but no new requirements. Moved from next section for clarity. A.5.8.2, A.5.8.3 – Added reference to SOP. A.5.8.4 – Added additional criteria and reference to SOP. A.5.9.3 – clarified "random" Attachments 1 & 2: Updated to reflect changes above where necessary.
15	9/16/11	A.5.2.1.1 – "On-the-Job" - Added reference to PCM Training Checklist. A.5.2.1.1 – "Skills" – Added requirement for generation of personal relative standard deviation to demonstration of proficiency. Clarified language on analyst training records. A.5.2.2.1 – Modified to allow national asbestos management to evaluate previous training. A.5.2.2.5 & 6– Clarified language. No new requirements. A.5.2.3.2 – Added the word "light." A.5.2.4.3 – Added note regarding status of EMSL's 582 course as AIHA approved. A.5.3.2.2 – Added requirement that common areas (e.g., log-in) shall also have ambient air monitoring. A.5.3.2.3 – Clarified that section applies to Lab blanks only. A.5.4.3.2.3 – Clarifies that if an analyst falls below 80% they cannot analyze customer samples until the lab manager has reviewed data and taken corrective action. A.5.5.2.2 – Added reference to use of HSE/UPO slides when HSE/NPL slide is not available. A.5.5.2.2 - Walton-Beckett measurements in TNI/NELAC labs must be conducted daily by each analyst using the scope. A.5.5.2.2 – Clarified that first-time use refers to after microscope repair. A.5.5.3.8 – Added requirement that for TNI/NELAP labs, detector resolution must be measured quarterly instead of annually. A.5.5.3.8 - Added requirement that K-Factors for Na and Al from Albite shall be performed at the same time (same day). A.5.5.4.2 – Removed "refractive index" from Monthly requirements. A.5.6 – Added NVLAP PT rounds as an equivalent where SRM 1876b is not available. A.5.8.4 – Modified requirements for Water Grids to make retention of petri dishes optional. Retention of filtrate is still required even if grids are not kept. A.5.8.4 – Corrected definition of ACM for waste removal > 1% instead of >=1. A.5.9.6.2.6 – Added requirement that TNI/NELAP labs must analyze Lab blanks at rate of 1 per 20 samples analyzed. A.5.9.6.5.5 – Clarified blanks should be analyzed BEFORE each batch of samples. A.5.9.7.5 – New Section "Blanks" Revised Attachments to reflect TNI/NELAP frequency changes.
14	7/1/11	References to AIHA changed to AIHA-LAP. References to NELAC changed to TNI. Minor editorial changes throughout. A.5.2.1 & A.5.2.1.2 – Title of course changed to match current title A.5.2.1.2 – Summary of topics updated A.5.2.1.3 – clarified that training checklist must be signed by both trainer and trainee A.5.2.1.4 & A.5.2.2.5– clarified that DOC certs come from QA Dept. A.5.2.4.4 – Section added on NVLAP TEM Supervisor requirements.

		A.5.3.2.1 – Added last bullet (frequent surface wiping)_ A.5.3.2.2 – Added 2nd bullet (collection during normal working hours) A.5.5.2 – Clarified that weekly HSE checks need to be done by each analyst. A.5.5.3.4 – Clarified requirements when camera constants fall outside 2xSD<5% acceptance criterion. A.5.5.3.10 – Clarified requirement. A.5.5.4.5 – Range of muffle furnace calibrations modified for consistency. A.5.8.4 – Added retention requirements for NYS NOB grids, microvac & wipe grids. A.5.9.5.3 – Clarified that QC program checks analyst results against a consensus standard, not necessarily a reference sample. Also added round robins as a method for meeting these objectives. A.5.9.6.2.1&2 – Clarified QC analysis types as Same Grid Opening Reanalysis A.5.9.6.2.3 – First paragraph added and changed title to Same Prep Different Grid Opening Analysis A.5.9.6.2.4 – Clarified requirement that sample repreps should be split relatively evenly between inter- and intra-analyst analyses. A.5.9.6.2.5 – Moved requirement for higher rates of verified analysis for analysts-in-training to this section. A.5.10.1.1 – New section added on referencing NVLAP where reports contain both accredited and non-accredited data.

Module A
Attachment 1: QC Frequencies

POLARIZED LIGHT MICROSCOPY
PHASE CONTRAST MICROSCOPY
TRANSMISSION ELECTRON MICROSCOPY

PLM CALIBRATION FREQUENCIES

DAILY

PLM SCOPE ALIGNMENT
Record date, check off for rotation centering, condenser & objective alignment, axial illumination full extinction and crosshair alignment fixed in polarizer's privileged direction.

CONTAMINATION CHECK
Clean microscope and work area daily and all equipment after each use.
Prep and analyze a fine grained reagent grade salt sample as a check for asbestos contamination.

EACH DAY OF USE

ANALYTICAL BALANCE VERIFICATION
Analytical balance should be checked as per the *Balance Calibration.Verification SOP*.

MONTHLY

AMOSITE DISPERSION COLORS
Check Amosite Standard for proper dispersion color wavelengths. Record DS color wavelengths, date and the analyst performing the calibration.

QUARTERLY

RI OILS
RI oil calibration to +/- 0.004 using certified refractive index solids. Record date, nominal refractive index, measured refractive index, temperature and analyst's initials. All RI oils are calibrated when bottle is opened for first use. In addition, calibrate on next use if an oil has not been used in 3 months.

MUFFLE FURNACE TEMPERATURE CHECK
Muffle furnace should be verified using three-point calibration covering 450, 480 and 500 degrees Celsius. Thermometer should be immersed in sand bath. Record date, target temperatures, measured temperatures, and analyst's initials.

AIR MONITORING
Ambient air samples should be collected (0.45 micron MCE cassettes, at least 1200 liters collected at not greater than 10 lpm) from each work area and analyzed by TEM using AHERA rules.

HOOD CALIBRATION
Measure and record flow rate of hoods with Anenometer as per the *EMSL Hood Maintenance and Calibration SOP*.

ANNUALLY

THERMOMETERS

Thermometers used for measurement of ambient air temperature shall be verified annually as per § 5.6.2 of the main QMS Manual and the *EMSL Thermometer Calibration.Verification SOP*.

ANALYTICAL BALANCE

The analytical balance shall be calibrated annually by an outside calibration firm accredited to ISO 17025.

WORKING WEIGHTS

Weights used for routine measurements in the lab shall be verified annually as per § 5.6.2 of the main QMS Manual and the *EMSL Working Weight Verification SOP*.

5 YEARS

REFERENCE WEIGHTS

Weights (used only for calibration of working weights) must be calibrated by an ISO 17025 accredited calibration service to NIST-traceable source every 5 years as per § 5.6.2 of main QMS Manual.

PLM FRIABLE QC ANALYSIS FREQUENCIES

STANDARD REFERENCE SAMPLE ANALYSIS (Daily)
One standard reference sample (known percentages) should be analyzed daily to determine precision and accuracy. Record date, analyst, type and percentage of asbestos present as determined by calibrated visual estimation. A full analysis documented completely on a standard PLM benchsheet is required for each sample for each analyst.

INTER-ANALYST REANALYSIS (1/15 Friable Samples and 1/15 Non Friable Samples)
1/15 samples should be analyzed by different analyst (inter analyst) and R-values calculated R = {(A-B)/((A+B)/2)}. Analysis fails if R > 1 or < -1, misidentification of Asbestos occurs, or ACM vs. Non ACM. A full analysis documented completely on a standard PLM bench sheet is required for each sample for each analyst.

INTRA-ANALYST REANALYSIS (1/50 Friable and 1/50 Non Friable Samples)
1/50 samples should be re-analyzed by the same analyst (intra-analyst) and R-values calculated R = {(A-B)/((A+B)/2)}. Analysis fails if R > 1 or < -1, misidentification of Asbestos occurs, or ACM vs. Non ACM. A full analysis documented completely on a standard PLM bench sheet is required for each sample for each analyst.

ROUND ROBIN (2 times/year)
All analysts should participate. Record dates of analysis, in-house analyst signatures, all results, reasons for and resolution of disagreements.
A full analysis documented completely on a standard PLM bench sheet is required for each sample for each analyst.

PLM NOB QC ANALYSIS FREQUENCIES

STANDARD REFERENCE SAMPLE (1/100 Samples)
At least 1 out of 100 samples shall be a verified quantitative standard that has been routinely resubmitted to determine analyst's precision and accuracy.

INTER-ANALYST REANALYSIS (1/15 Non Friable Samples)
1/15 samples should be analyzed by different analyst (inter analyst) and R-values calculated R = {(A-B)/(A+B)/2}. Analysis fails if R > 1 or < -1, misidentification of Asbestos occurs, or ACM vs. Non ACM. A full analysis documented completely on a standard PLM bench sheet is required for each sample for each analyst.

INTRA-ANALYST REANALYSIS (1/50 Non Friable Samples)
1/50 samples should be re-analyzed by the same analyst (intra-analyst) and R-values calculated R = {(A-B)/(A+B)/2}. Analysis fails if R > 1 or < -1, misidentification of Asbestos occurs, or ACM vs. Non ACM. A full analysis documented completely on a standard PLM bench sheet is required for each sample for each analyst.

NOB PREPARATION CHECK (1/20 NOB Samples)
A known negative floor tile is routinely re-submitted. These samples must go through the full preparation and analysis regimen and then be analyzed for asbestos contamination and residue recovery (% wt). NOB residue weights must be within 10% of the average recovery weight to be acceptable (PASS). If asbestos is detected, the source of contamination must be traced and problem resolved to prevent recurrence.

ROUND ROBIN (2 times/year)
All analysts should participate. Record dates of analysis, in-house analyst signatures, all results, reasons for and resolution of disagreements.
A full analysis documented completely on a standard PLM bench sheet is required for each sample for each analyst.

PCM CALIBRATION FREQUENCIES

DAILY

ALIGNMENT
Check alignment (phase rings) and illumination. Record date and analyst's initials.

CONTAMINATION CONTROL
Clean microscope and work area daily and all equipment after each use.

MICROSCOPE FIELD AREA MEASUREMENT (For TNI/NELAC labs)
Once per day, each analyst using the scope shall check the diameter of the Walton-Beckett Graticule. Measurement must equal 100 microns. Record diameter, PASS / FAIL, corrective action if necessary, date and the analyst's initials.

Other labs shall complete this Monthly.

WEEKLY

PHASE SHIFT DETECTION
The HSE / NPL Slide contains 7 blocks of grooves. Blocks 4 and 5 must be at least partially visible. Record the highest block visible, PASS / FAIL, corrective action if necessary, date and the analyst's initials.

For HSE/UPO Slides if used:

HSE/ULO Red - The microscope should be able to completely resolve the first 3 sets of lines (1-3), the next two sets of lines (4- 5) should be partially visible. The microscope should not be able to see the last two sets (6-7) of lines at all, they should be invisible.

HSE/ULO Green - The microscope should be able to completely resolve the first 4 sets of lines (1-4), the next two sets of lines (5-6) should be partially visible. The microscope should not be able to see the last set (7) of lines at all, they should be invisible.

MONTHLY

MICROSCOPE FIELD AREA MEASUREMENT
Check the diameter of the Walton-Beckett Graticule. It must equal 100 microns. Record diameter, PASS / FAIL, corrective action if necessary, date and the analyst's initials.

For Labs complying w/ TNI (NELAC) Standard this should be increased to each time a difference analyst uses the scope.

MECHANICAL COUNTER

Mechanical counter accuracy is documented by counting to 100 while clicking the counter with each count. The clicker must read 100 on the 100th count. Record date, PASS/FAIL and analyst's initials.

QUARTERLY

AIR MONITORING

Ambient air samples should be collected from each work area. The samples should be collected on 0.45 micron MCE filters (at least 1200 liters collected at no greater than 10 lpm) and analyzed by TEM using AHERA rules.

HOOD CALIBRATION

Measure and record flow rate of PCM hoods with anemometer as per the *EMSL Hood Maintenance and Calibration SOP*. Record date, flow rate and the analyst's initials. See SOP for acceptance criteria.

PRIOR TO FIRST USE

STAGE MICROMETER

The stage micrometer in use at laboratory should be calibrated to ISO 17025 standards initially prior to first use, and if damaged as per § 5.6.2 of the main QMS Manual.

PCM QC ANALYSIS FREQUENCIES

DAILY REFERENCE SLIDE
Each Analyst should analyze at least one Reference Slide daily (taken from low, medium and high fiber count pool randomly) in order to generate a CV for each analyst and for the lab. Record fiber counts and date for each analyst.

INTRA-ANALYST REANALYSIS (1/10 Samples)
Perform blind intra-analyst recounts on 10% of filters counted. Record analyst, date, Reference #, Sample #, initial and QC fiber counts, density, PASS / FAIL, comments / corrective actions.

ROUND ROBIN (2 times/year)
All analysts should participate. Record dates of analysis, in-house analyst signatures, all results, reasons for and resolution of disagreements.
A full analysis documented completely on a standard PCM bench sheet is required for each sample for each analyst.
Samples are chosen from previously analyzed customer samples or past proficiency testing samples.

TEM CALIBRATION FREQUENCIES

DAILY

Al, Cu CALIBRATION
Collect spectrum on Al, Cu grid. Peaks should be centered at 1.48 and 8.04 both to within +/- 0.02 keV. If not then calibration of the instrument is necessary. Record date, analyst & results. It is strongly recommended to save spectrum on the hard drive.

MICROSCOPE ALIGNMENT
Check off after each step. Record date and analyst's initials.

CONTAMINATION CONTROL
Clean work area and equipment after each sample.

SAED (as needed)
Indexing of diffraction patterns to verify a cumulative 80% accuracy rating for each analyst.

EACH DAY OF USE

ANALYTICAL BALANCE
Analytical balance should be checked in all applicable ranges as per § 5.5.3.1 of main QMS Manual and *EMSL Balance Calibration.Verification SOP*. See SOP for acceptance criteria.

WEEKLY

CAMERA CONSTANT
Record camera length and camera constant as per the *TEM CAL Worksheet*. Produce negative, measurement results from photo and screen (+/- 5% change acceptable), and screen diameter that corresponds to 5.3 Angstroms.
Note: If sufficient data has been collected which indicates confidence in the stability of measurements, frequency of camera constant calibration can be adjusted to monthly.
Note: For those instruments utilized for water calibration frequency must be maintained at a weekly rate during the period of time analysis is performed.

MONTHLY

MAGNIFICATION CALIBRATION
Calibration of screen and negative (+/- 5% change acceptable). Produce negative, calculations and results and conversion factors for the small and large circles on the phosphor screen.

QUARTERLY

BEAM DOSE
ED patterns of 9 out of 10 NIST SRM chrysotile fibrils (max. diameter 0.05 microns) must remain visible for 15 seconds. Record one fibril image and one photo of ED pattern.

ASHER CALIBRATION
Determine ash time to etch 10% of collapsed filter. Chart ash time versus date.
NOTE: If during TEM analysis it is observed that a 10% ash results in over etching of the filter, the lab should switch to 5% as its target for calibration.

SPOT SIZE MEASUREMENT
Crossovers at spot size 3 take picture and record actual diameter

Na SENSITIVITY
Resolvable (statistically significant) Na K alpha peaks from NIST SRM 1866 crocidolite. Produce calculations, dated and signed spectra AND photo of fibril. It is strongly recommended to save spectrum on the hard drive..

CHRYSOTILE FIBRIL SENSITIVITY
Check for resolvable Mg and Si peaks from single fibril from either NIST SRM 1866 or 1876b chrysotile. Produce dated and signed spectra. It is strongly recommended to save spectrum on the hard drive.

AIR MONITORING
Ambient air samples should be collected from each work area on 0.45 micron MCE filters and analyzed by TEM AHERA.

X-RAY DETECTOR RESOLUTION (For TNI/NELAP labs)
FWHM of Mn peak. Collect 2000 FS counts in the Mn peak (or more, but be consistent each time). Resolution must be <175 eV. Produce dated and signed spectra. It is strongly recommended to save spectrum on the hard drive.
NOTE: Other labs this must be done semi-annually.

SEMI - ANNUALLY

X-RAY DETECTOR RESOLUTION
FWHM of Mn peak. Collect 2000 FS counts in the Mn peak (or more, but be consistent each time). Resolution must be <175 eV. Produce dated and signed spectra. It is strongly recommended to save spectrum on the hard drive.
NOTE: For labs complying with the TNI (NELAC) Standard this frequency must be quarterly.

K FACTORS:
USING SRM 2063 and Albite: Collect 10,000 integral or 2000 FS counts in the Si peak (or more, but be consistent each time). The various sensitivity factors must be calculated each with their own PASS/FAIL criteria. 10 runs. Produce dated & signed hard copy of spectrum. It is strongly recommended to save spectrum on the hard drive.

GRID OPENING AREA: Twenty grid opening areas from twenty grids (400 total) must be calculated for **each lot of 1,000** grids. Record date, lot number, analyst and average GSO.

ANNUALLY

ANALYTICAL BALANCE

The analytical balance shall be calibrated by an external calibration service accredited to ISO 17025 annually as per § 5.5.3 of the main QMS Manual and *EMSL Balance Calibration.Verification SOP*..

WORKING WEIGHTS

Weights used for routine measurements in the lab shall be verified annually as per § 5.6.2 of the main QMS Manual and the *EMSL Working Weight Verification SOP*.

5 YEARS

REFERENCE WEIGHTS

Weights (used only for calibration of working weights) must be calibrated by an ISO 17025 accredited calibration service to NIST-traceable source every 5 years as per § 5.6.2 of main QMS Manual.

TEM AIR QC ANALYSIS FREQUENCIES

INTRA-ANALYST SAME GRID OPENING REANALYSES (1/50 Air Samples)
This reanalysis used to determine the analyst's precision. Calculate R values where R=[(A-B)/(A+B)/2]. Chart R values and PASS/FAIL results for each analyst and for lab in the following four ranges of asbestos structures only:

RANGE of MEAN of RECOUNT	PASS/FAIL CRITERIA
<5 Structures	±1 Structure
5-20 Structures	±2 Structures
>20 Structures	±3 Structures

Verified analysis is required to resolve Failures. Record sample, grid(s) and grid opening(s) analyzed date(s) of analyses, analyst's signature, both results, R-value reasons for and resolutions of disagreements. A cumulative record of true positives, false positives, and false negatives, is maintained for each analyst.

INTER-ANALYST SAME GRID OPENING REANALYSES (1/25 AIR Samples)
This reanalysis of the same grid openings is used to determine both the laboratory's overall precision and to detect bias of the various analysts. Calculate R values where R=[(A-B)/(A+B)/2]. Chart R values and PASS/FAIL results for each analyst and for lab in the following four ranges of asbestos structures only:

RANGE of MEAN of RECOUNT	PASS/FAIL CRITERIA
<5 Structures	±1 Structure
5-20 Structures	±2 Structures
>20 Structures	±3 Structures

For any failures, verified analysis is required. Record sample, grid(s) and grid openings) analyzed date(s) of analysis, signatures, both results, R-value, reason(s) for analysts and resolution(s) of disagreement(s). A cumulative record of true positives, false positive and false negatives is maintained for each analyst.

SAME GRID/DIFFERENT OPENING REANALYSIS (1/100)
Inter-analyst analysis – 0.5 in 100 samples
Intra-analyst analysis – 0.5 in 100 samples

SAME SAMPLE REPREPARATIONS (1/100)
Inter-analyst analysis – 0.5 in 100 samples
Intra-analyst analysis – 0.5 in 100 samples

VERIFIED ANALYSES (1/100 Grid Openings Analyzed)
20% of the samples used must contain between 6-40 structures/grid opening (approximately 1,000-5,000 asbestos structures/mm^2. Previous customer samples, NYS ELAP proficiency samples, NVLAP proficiency samples and NIST SRM 1876b samples may be used.) Record results from each analyst, date(s) of analysis, acceptability (within appropriate guidelines), reason(s) for

and resolution(s) of disagreements, analyst's signature(s). A cumulative record of true positives, false positives and false negatives is maintained for each analyst. Maintain a separate record for NIST SRM 1876b or equivalent analysis.

INTER-LAB ROUND ROBIN ANALYSES (1/200 G.O.) (2 times/year)
Use asbestos samples that cover a range from less than 100 to more than 2,000 structures/sq. mm. This re-analysis of the same grid opening must be by VERIFIED ANALYSIS. Record sample, grid and grid opening identification, date(s) of analysis, in-house analyst's signature, all results reasons for and resolutions of disagreements. Analysts must attain an average accuracy of $\geq$ 80% True Positives, $\leq$ 20% False Negatives and $\leq$10% False Positives to maintain verified status.

LABORATORY BLANK (AIR Samples)
Prep 1 blank per series or 10% of daily total; Analyze 1 per 100 filter analyses for MCE (mixed cellulose ester) filters, and 1 per 25 filter analyses for PC (polycarbonate) filters as measure of cleanliness.

TEM NOB QC ANALYSIS FREQUENCIES

INTRA ANALYST - NEW PREP (1/50 NOB Samples Re-analyzed by Same analyst)
This reanalysis is used to determine the analyst's precision and check the laboratory's preparation technique. Calculate R-values for each pair. R= |(A-B)/[(A+B)/2]| Analysis fails if R >1, misidentification of Asbestos occurs, or ACM vs. Non ACM. Record sample, dates of analyses, analyst's initials, both results, R-values, causes and corrective actions for failures. R Control charts updated monthly for each analyst's precision. Also check recovery (% Wt) of both sample preparations. Re-prep weight must be within 10% of initial prep weight to pass. Failure requires a third prep be made (all steps checked by lab supervisor) to determine correct recovery. Record dates of all preparations, weights, technician initials, reasons for and resolutions of failures.

INTER ANALYST - NEW PREP (1/15 NOB Samples Re-analyzed by different analyst)
This reanalysis is used to determine laboratory precision and to check the laboratory's preparation technique. Calculate R-values for each pair of analyses. R= (A-B)/[(A+B)/2]. Analysis fails if R >1 or < -1, misidentification of Asbestos occurs, of ACM vs. Non ACM. Record sample, dates of analysis, analyst's initial, both results, R-values, reasons for and resolutions for failures. R Control charts updated for each analyst's precision.

Also check residue recovery (% Wt) of both sample preparations. Re-prep weight must be within 10% of initial prep weight to pass. In case of failure, request a third prep be made (all steps checked by lab supervisor) to determine correct recovery. Record dates of all preparations, weights, technician initials, reasons for and resolutions of failures.

INTER-LAB ANALYSIS (2 times/year) ROUND ROBIN
Samples analyzed for asbestos contents and residue recovery (% Wt). Record asbestos type(s), percentage(s), analyst(s), and dates of analyses. Track misclassifications (false positive, false negative) and misidentification of asbestos types and residue recovery (% Wt.)

NOB PREPARATION CHECK (1/20 NOB Samples)
A known negative floor tile sample is prepped and analyzed for asbestos contamination and residue recovery (%Wt). These samples must go through the full preparation and analysis regimen. NOB residue weights must be within 10% of the average recovery weight to be acceptable (PASS). Track PASS/FAIL % monthly and cumulatively for each year. If asbestos is detected, the source of contamination must be traced and problem resolved to prevent recurrence.

STANDARD REFERENCE SAMPLE (1/100 Samples)
At least 1 out of 100 samples shall be a verified quantitative standard that has been routinely resubmitted to determine analyst's precision and accuracy.

Module A
Attachment 2: Additional Qualification Requirements

Additional Qualification Requirements by Accrediting Authorities for ASBESTOS

Accred. Agency	Lab Manager		QA Manager		Analyst	
	Required Degree	Required Lab Exp	Required Degree	Required Lab Exp	Required Degree	Required Lab Exp
AIHA-LAP	**(Tech. Manager)** B.S. – applicable physical or biological science	**(Tech. Manager)** - 3 years of relevant non-academic analytical experience. A minimum of 2 years in IH within the Scope of Accreditation and 1 year from other lab analytical procedures. - M.S. or Ph.D. is equivalent to 1 year of work experience.	**(Quality Manager)** B.S. – applicable basic or applied science	**(Quality Manager)** 1 year of non-academic analytical or QC experience appropriate to types of analysis performed. Or in lieu of a degree – 4 years of non-academic analytical or QC experience. - Documented training in statistics or laboratory quality assurance/quality control.	**(Analyst)** B.S. in chemistry or related science **(Technician)** No degree is necessary	- Both Analysts and Technicians shall complete a training course (in-house is acceptable) for applicable analysis. - Both Analysts and Technicians need to demonstrate capability through SRMs, PT or QC samples. Re-certification every 6 months - Both Analysts and Technicians shall have 20 business days of hands-on experience before independent analysis on customer samples.
NYS ELAP TNI standard (July 2011)	**(Tech. Director) TEM** B.S. degree and specialized courses in use of instrument **PLM** A.S. degree and specialized courses in use of instrument or 2 years of equiv. college study or formal coursework **PCM** A.S. degree or 2 years of equiv. college study or formal coursework	**(Tech. Director) TEM** 1 year experience under supervision in use of instrument **PLM** 1 year experience under supervision in use of instrument **PCM** 1 year experience under supervision in use of instrument				
CA ELAP	**(Lab Director)** B.S. degree in applicable science	(**Lab Director)** 3 years experience M.S. substituted for 1 year of exp. Ph.D. substituted for 2 years of exp.	**(Principal Analyst)** B.S. – applicable basic or applied science	**(Principal Analyst)** 6 months experience in analysis. Completion of training course		

Accred. Agency	Lab Manager		QA Manager		Analyst	
	Required Degree	Required Lab Exp	Required Degree	Required Lab Exp	Required Degree	Required Lab Exp
FL DOH TNI standard (July 2011)	**(Tech. Director) TEM** B.S. degree and specialized courses in use of instrument **PLM** A.S. degree and specialized courses in use of instrument or 2 years of equiv. college study or formal coursework **PCM** A.S. degree or 2 years of equiv. college study or formal coursework	**(Tech. Director) TEM** 1 year experience under supervision in use of instrument **PLM** 1 year experience under supervision in use of instrument **PCM** 1 year experience under supervision in use of instrument				
NJ DEP	**(Lab Manager)** B.S. degree or A.A. degree or No degree	**(Lab Manager)** B.S. – 1 year experience A.A. – 3 years experience None – 5 years experience	**(QA Officer)** B.S. degree or A.A. degree or No degree	**QA Officer)** B.S. – 1 year experience A.A. – 3 years experience None – 5 years experience	**(Operators)** B.S. degree or A.A. degree or No degree	**(Operators)** B.S. – 1 year experience A.A. – 3 years experience None – 5 years experience **TEM** Completion of formal training course
Louisiana LADEQ	**(Lab Tech Director)** B.S. degree in science or 4 years equiv. experience	**(Lab Tech Director)** Minimum of 2 years in environmental analysis.	**(QA Manager)** B.S. degree in science or 4 years equiv. experience	**(QA Manager)** Minimum of 2 years in environmental analysis.	**(Supervisors)** B.S. degree or 4 years experience **(Instrument Operators)** H.S. diploma and completion of in-house training course	**(Supervisors)** Minimum of 1 year experience **(Instrument Operators)** 6 months experience and passing PT results.
Pennsylvania DEP TNI Standard (July 2011)	**(Lab Supervisor) TEM** B.S. degree and specialized courses in use of instrument **PLM** A.S. degree and specialized courses in use of instrument or 2 years of equiv. college study or formal coursework **PCM** A.S. degree or 2 years of equiv. college study or formal coursework	**(Lab Supervisor) TEM** 1 year experience under supervision in use of instrument **PLM** 1 year experience under supervision in use of instrument **PCM** 1 year experience under supervision in use of instrument				

Accred. Agency	Lab Manager		QA Manager		Analyst	
	Required Degree	Required Lab Exp	Required Degree	Required Lab Exp	Required Degree	Required Lab Exp
Texas TCEQ TNI standard (July 2011)	**(Tech. Director) TEM** B.S. degree and specialized courses in use of instrument **PLM** A.S. degree and specialized courses in use of instrument or 2 years of equiv. college study or formal coursework **PCM** A.S. degree or 2 years of equiv. college study or formal coursework	**(Tech. Director) TEM** 1 year experience under supervision in use of instrument **PLM** 1 year experience under supervision in use of instrument **PCM** 1 year experience under supervision in use of instrument				

Addendum/Amendment Form

Approvals:

Laboratory Manager — Date:

Joy E. Dell'Aringa — 7/29/13

Corporate Approval — Date:

Laboratory: All laboratories participating in Food Testing

Original Document: EMSL QMS Manual, Mod G

Current Revision #: Rev. 16 Original Rev. 0 Addendum

Effective Date: 6/14/13 Original 7/29/2013 Addendum

Addendum or Amendment:

Section G.5.9.3 shall be marked as obsolete and greyed out in the online QMS Manual R16.

As a result of QMS.Manual_ModG_Amendment_2013_07_22 which affected G.5.9.2.3, Section G.5.9.3 is now repetitive and unnecessary. As a result, this section will be marked as obsolete and greyed out. The change will be officially adopted into QMS Manual Rev. 17.

Note: Please mark all copies of original document where changs are considered. An asterisk with a note to see the addendum would be sufficient. Addendum is not considered official without a signature from the corporate level. Once approved, addendum should be added to the Local Document Control List, and an approved copy attached to any printed SOP. Ensure staff knows where to check for addendums.

END OF AMENDMENT/ADDENDUM LANGUAGE
(remaining pages are acknowledgement)

Addendum Acknowledgement Form

Original Document: EMSL QMS Manual, Mod G Addend Rev. Rev. 0
Original Rev. Rev. 16 Addend. Date: 7/29/2013

Signature below indicates review and understanding of the addendum referenced above. It is understood these are modifications of the original document and supersede the original document as noted above.

Signature	Date