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McCAMPBELL ANALYTICAL INC.
LABORATORY QUALITY ASSURANCE MANUAL

When Quality Counts

McCampbell Analytical, Inc.
1534 Willow Pass Road
Pittsburg, CA
94565-1701
Revision 4

Responsible Parties

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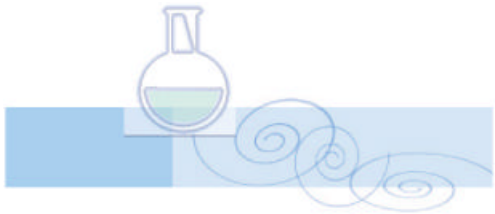

ACKNOWLEDGEMENTS

McCampbell Analytical is indebted to dozens of hard-working employee's who collectively contributed to the development of this environmental laboratory *Quality Manual*. Any effective quality assurance/quality control program depends on the entire organization, including management and every individual on the staff. Without their time, effort, and expertise this manual would never have been realized.

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APPENDICES

SECTION 3 – INTRODUCTION AND SCOPE

The purpose of this *Quality Manual* is to outline the quality system for the laboratory. This *Quality Manual* defines the policies, procedures, and documentation that assure analytical services continually meet a defined standard of quality that is designed to provide clients with data of known and documented quality and, where applicable, demonstrate regulatory compliance.
McCampbell Analytical, Inc. (MAI) was founded in 1991, and through excellence in quality and service has grown to over 60 employees and 40 major pieces of instrumentation situated in 32,000 square feet of work space. McCampbell Analytical, Inc. is independently owned and operated and is located in the San Francisco Bay Area. McCampbell Analytical tests drinking water, effluent, soils, solids, hazardous waste, air, industrial materials and food for a wide variety of chemical compounds including organic, inorganic and metallic contaminants.

POLICY
This Quality Manual sets the standard under which all laboratory operations are performed including the laboratory's organization, objectives, and operating philosophy. A well conceived QA program provides a sound framework for the generation of laboratory data that is scientifically valid, representative and legally defensible. The validity and reliability of the data generated by the Laboratory are assured by adherence to rigorous quality assurance/quality control (QA/QC) protocols. The application of sound QA/QC principles, beginning with initial planning and continuing through all field and laboratory activities, including the final report, are designed to meet that goal. The fundamental elements of the Laboratory Section's QA program include Standard Operating Procedures (SOPs), quality control practices, performance testing samples, internal audits, external audits and an ethics policy. This manual and the quality control procedures described within are not to be viewed as complete. Rather, they serve as a basic foundation on which to build a stronger, more viable Quality Assurance Management Plan (QAMP). Other documents that may detail or affect the quality management program include the Chemical Hygiene Plan (CHP), quality guidance documents, memoranda, work instructions, standard operating procedures and periodic reports. These documents may further define or guide the implementation of quality standards within the Laboratory, but shall not conflict with the QAMP or diminish the effectiveness of the program. Adherence to the practices described in this manual is required of all employees. **Employees are required to familiarize themselves with the sections of this manual that pertain to their operations and are encouraged to comment on its contents and make recommendations for more efficient procedures.**

Following is a list of documents used to develop the Laboratory's QAM.
• Interim Draft EPA Requirements for Quality Management Plans, U.S. Environmental Protection Agency, EPA QA/R-2, July 1993 et seq.
• EPA Requirements for Quality Assurance Project Plans, EPA QA/R-5 et seq.
• Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs, American Society for Quality Control, Energy and Environmental Quality Division, Environmental Issues Group, ANSI/ASQC E4-1994 (Formerly EQA-1), January 1994 et seq.
• Quality Management and Quality System Elements for Laboratories - Guidelines, American National Standard, American Society for Quality Control, ANSI/ASQC Q2-1991 et seq.
• International Standard ISO/IEC Guide 17025 – 1999 et seq.
• NELAC standards, Chapter 5, Quality Systems

3.1 Scope of Testing

The laboratory scope of analytical testing services includes but is not limited those listed.

A. HYDROCARBONS

B. VOLATILE ORGANIC COMPOUNDS (VOCs) BY GC-MS & GC-FID/PID

C. SEMIVOLATILE ORGANIC COMPOUNDS (SVOCs) BY GC-MS

D. POLYNUCLEAR AROMATIC HYDROCARBONS

E. PESTICIDES

1. NITROGEN & PHOSPHOROUS PESTICIDES
2. CHLORINATED PESTICIDES
3. ACIDIC HERBICIDES
4. OTHER PESTICIDES

F. DIOXINS & DIBENZOFURANS

G. MISCELLANEOUS ORGANICS BY HPLC

H. WATER TREATMENT PARAMETERS

I. METALS

J. ANIONS

K. WET CHEMISTRY

L. *AIR MATRIX*

M. BACTERIOLOGICAL TESTING

N. MISCELLANEOUS TESTING

A full list of environmental testing method for which the laboratory is accredited can be found on the certificate in the QA/QC's office.

3.2 Table of Contents and References

The table of contents is in Section 2 of this Manual. This *Quality Manual* uses the references from the 2003 NELAC Standard, Chapter 5, Appendix A. McCampbell core competency is in environmental methodologies. However, we have an extensive library of analytical methods that takes us beyond the environmental field, such as:

- **E**nvironmental **P**rotection **A**gency (EPA)
- **A**merican **P**ublic **H**ealth **A**ssociation - Standard Methods (APHA)

- **A**ssociation of **O**fficial **A**nalytical **C**hemists (AOAC)
- **A**merican **S**ociety for **T**esting and **M**aterials (ASTM)
- **C**alifornia **D**epartment of **F**ood and **A**griculture (CDFA)
- **S**oil **S**cience **S**ociety of **A**merica (SSSA)
- **N**ational **I**nstitute for **O**ccupational **S**afety & **H**ealth - Manual of Analytical Methods (NIOSH)
- **P**esticides **A**nalytical **M**ethods (PAM)
- **O**ccupational **S**afety and **H**ealth **A**dministration (OSHA)
- **B**acterial **A**nalytical **M**anual (BAM)
- **B**ay **A**rea **A**ir **Q**uality **M**anagement **D**istrict (BAAQMD)
- **U**nited **S**tates **G**eological **S**urvey (USGS)
- **A**merican **A**ssociation of **C**ereal **C**hemists (AACC)
- **F**ood & **D**rug **A**dministration – Food Additives Analytical Manual (FDA)

3.3 Glossary and Acronyms Used

Quality control terms are generally defined within the section that describes the activity.

Glossary

Accuracy: The degree of agreement between a measurement and true or expected value, or between the average of a number of measurements and the true or expected value.

Batch: Environmental samples, which are prepared and/or analyzed together with the same process, using the same lot(s) of reagents. A preparation batch is composed of one to 20 environmental samples of a similar matrix, meeting the above-mentioned criteria. Where no preparation method exists (example, volatile organics, water) the batch is defined as environmental samples that are analyzed together with the same process and personnel, using the same lots of reagents, not to exceed 20 environmental samples. An analytical batch is allowed to stay open for up to 5 days and is composed of prepared environmental samples, extracts, digestates, or concentrates that are analyzed together as a group.

Chain of Custody (COC): A system of documentation demonstrating the physical possession and traceability of samples.

Comprehensive Environmental Response, Compensation and Liability Act (CERCLA/Superfund): Legislation (42 U.S.C. 9601-9675 et seq., as amended by the Superfund Amendments and reauthorization Act of 1986 (SARA), 42 U.S.C. 9601et seq.

Compromised Sample: A sample received in a condition that jeopardizes the integrity of the results.

Confirmation: Verification of the presence of a component using an additional analytical technique. These may include second column confirmation, alternate wavelength, derivatization, mass spectral interpretation, alternative detectors, or additional cleanup procedures.

Corrective Action: Action taken to eliminate the causes of an existing non-conformance, defect or other undesirable situation in order to prevent recurrence.

Data Audit: A qualitative and quantitative evaluation of the documentation and procedures associated with environmental measurements to verify that the resulting data are of acceptable quality.

Demonstration of Capability (DOC): Procedure to establish the ability to generate acceptable accuracy and precision.

Equipment Blank: A portion of the final rinse water used after decontamination of field equipment; also referred to as Rinsate Blank and Equipment Rinsate.

Document Control: The act of ensuring that documents (electronic or hardcopy and revisions thereto) are proposed, reviewed for accuracy, approved for release by authorized personnel, distributed properly and controlled to ensure use of the correct version at the location where the prescribed activity is performed.

Federal Water Pollution Control Act (Clean Water Act, CWA): Legislation under 33 U.S.C. 1251 et seq., Public Law 9250086 Stat. 816.

Field Blank: A blank matrix brought to the field and exposed to field conditions.

Field of Testing (FOT): This term is based on NELAC's categorization of accreditation based on program, matrix, and analyte.

Good Laboratory Practices (GLP): Formal regulations for performing basic laboratory operations outlined in 40 CFR Part 160 and 40 CFR Part 729 and required for activities performed under FIFRA and TSCA.

Holding Time: The maximum time that a sample may be held before preparation and/or analysis as promulgated by regulation or as specified in a test method.

Instrument Blank: A blank matrix that is the same as the processed sample matrix (i.e.. extract, digestate, condensate) and introduced onto the instrument for analysis.

Internal Chain of Custody: An unbroken trail of accountability that ensures the physical security of samples, data and records. Internal Chain of Custody refers to additional documentation procedures implemented within the laboratory that includes special sample storage requirements, and documentation of all signatures and/or initials, dates, and times of personnel handling specific samples or sample aliquots. MAI identifies these types of samples as "evidentiary samples" and an internal COC is implemented. This is not the case with routine samples.

Instrument Detection Limit (IDL): The minimum amount of a substance that can be measured with a specified degree of confidence that the amount is greater than

zero using a specific instrument. The IDL is associated with the instrumental portion of a specific method, and sample preparation steps are not considered in its derivation. Typically it is equal to the lowest calibration point in the initial calibration.

Laboratory Control Sample (LCS): A blank matrix spiked with a known amount of analyte(s), processed simultaneously with, and under the same conditions as, samples through all steps of the analytical procedure.

Limit of Detection (LOD): The minimum amount of a substance that an analytical process can reliably detect. McCampbell refers to this as the *Method Detection Limit (MDL)*.

Matrix: The substrate of a test sample. Common matrix types include soil, water, air, non-aqueous liquids, but may also include more specialized matrices such as children's toys, pork liver, and soil gas.

Matrix Duplicate (MD): Duplicate aliquot of a sample processed and analyzed independently; under the same the laboratory conditions; also referred to as Sample Duplicate or the Laboratory Duplicate.

Matrix Spike (MS): Field sample to which a known amount of target analyte(s) is added.

Matrix Spike Duplicate (MSD): A replicate matrix spike.

Method Blank: A blank matrix processed simultaneously with, and under the same conditions as, samples through all steps of the analytical procedure.

Method Detection Limit (MDL): The minimum amount of a substance that can be measured with a specified degree of confidence that the amount is greater than zero using a specific measurement system. The MDL is a statistical estimation at a specified confidence interval of the concentration at which the relative uncertainty is +100%. The MDL represents a range where qualitative detection occurs using a specific method. Quantitative results are not produced in this range.

Non-conformance: An indication, judgment, or state of not having met the requirements of the relevant specifications, contract, or regulation.

Precision: An estimate of variability. It is an estimate of agreement among individual measurements of the same physical or chemical property, under prescribed similar conditions.

Preservation: Refrigeration and/or reagents added at the time of sample collection to maintain the chemical, physical and/or biological integrity of the sample.

Proficiency Testing: Determination of the laboratory calibration or testing performance by means of inter-Laboratory comparisons.

Proficiency Test (PT) Sample: A sample, the composition of which is unknown to the analyst that is provided to test whether the analyst/laboratory can produce analytical results within specified performance limits. Also referred to as a Performance Evaluation (PE) Sample.

Proprietary: Belonging to a private person or company. Confidential.

Quality Assurance (QA): An integrated system of activities involving planning, quality control, quality assessment, reporting and quality improvement to ensure that a product or service meets defined standards of quality with a stated level of confidence.

Quality Assurance Manual (QAM): A document stating the quality policy, quality system and quality practices of the laboratory. The QAM may include by reference other documentation relating to the laboratory's quality system.

Quality Assurance Project Plan (QAPP): A formal document describing the detailed quality control procedures by which the quality requirements defined for the data and decisions pertaining to a specific project are to be achieved.

Quality Control (QC): The overall system of technical activities, the purpose of which is to measure and control the quality of a product or service.

Quality Control Sample: A control sample, generated at the laboratory or in the field, or obtained from an independent source, used to monitor a specific element in the sampling and/or testing process.

Quality Management Plan (QMP): A formal document describing the management policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an agency, organization of the laboratory to ensure the quality of its product and the utility of the product to its users. Also known as the Quality Assurance Manual.

Quality System: A structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required QA/QC.

Quantitation Limit (QL): The minimum amount of a substance that can be quantitatively measured with a specified degree of confidence and within the accuracy and precision guidelines of a specific measurement system. The QL can be based on the MDL, and is generally calculated as 1-5 times the MDL; however, there are analytical techniques and methods where this relationship is not applicable. At McCampbell, the QL is referred to as the **Reporting Limit (RL)** or **Practical Quantitation Level (PQL)**, and may be referred to in other published documentation as the Estimated Quantitation Level (EQL).

Raw Data: Any original information from a measurement activity or study recorded in laboratory notebooks, worksheets, records, memoranda, notes, or exact copies thereof and that are necessary for the reconstruction and evaluation of the report of the activity or study. Raw data may include photography, microfilm or microfiche copies, computer printouts, magnetic/optical media, including dictated observations, and recorded data from automated instruments. Reports specifying inclusion of "raw data" do not need all of the above included, but sufficient information to create the

reported data.

Record Retention: The systematic collection, indexing and storing of documented information under secure conditions.

Reference Standard: A standard, generally of the highest metrological quality available at a given location, from which measurements made at that location are derived. *This definition is consistent with bodies such as NIST.*

Reporting Limit (RL): The level to which data is reported for a specific test method and/or sample. The RL is generally related to the QL and takes matrix interference effects into consideration when establishing how low an analyte can be detected. The RL must be minimally at or above the MDL, and is typically equivalent to the lowest calibration standard concentration in the initial calibration.

Resource Conservation and Recovery Act (RCRA): Legislation under 42 USC 321 et. Seq. (1976).

Safe Drinking Water Act (SDWA): Legislation under 42 USC 300f et seq. (1974), (Public Law 93-523).

Sampling and Analysis Plan (SAP): A formal document describing the detailed sampling and analysis procedures for a specific project.

Sensitivity: The difference in the amount or concentration of a substance that corresponds to the smallest difference in a response in a measurement system using a certain probability level.

Spike: A known amount of an analyte added to a blank, sample or sub-sample.

Standard Operating Procedure (SOP): A written document which 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.

Storage Blank: A blank matrix stored with field samples of a similar matrix.

Systems Audit: A thorough, systematic, on-site, qualitative review of the facilities, equipment, personnel, training, procedures, record keeping, data validation, data management, and reporting aspects of a total measurement system.

Traceability: The property of a result of a measurement that can be related to appropriate international or national standards through an unbroken chain of comparisons.

Trip Blank: A blank matrix placed in a sealed container at the laboratory that is shipped, held unopened in the field, and returned to the laboratory in the shipping container with the field samples.

Verification: Confirmation by examination and provision of evidence against specified standards.

Acronyms

A list of acronyms used in this document and their definitions are:

AA	–	Accrediting Authority
ANSI	–	American National Standards Institute
ASQC	–	American Society for Quality Control
ASTM	–	American Society for Testing and Materials
Blk	–	Blank
°C	–	degrees Celsius
cal	–	calibration
CAS	–	Chemical Abstract Service
CCV	–	Continuing calibration verification
COC	–	Chain of custody
DO	–	Dissolved oxygen
DOC	–	Demonstration of Capability
EPA	–	Environmental Protection Agency
g/L	–	grams per liter
GC/MS	–	gas chromatography/mass spectrometry
ICP-MS	–	inductively coupled plasma-mass spectrometry
ICV	–	Initial calibration verification
ISO/IEC	–	International Organization for Standardization/International Electrochemical Commission
lb/in^2	–	pound per square inch
LCS	–	Laboratory control sample
LFB	–	Laboratory fortified blank
MDL	–	method detection limit
mg/Kg	–	milligrams per kilogram
mg/L	–	milligrams per liter
MS	–	matrix spike
MSD	–	matrix spike duplicate
NELAC	–	National Environmental Laboratory Accreditation Conference
NELAP	–	National Environmental Laboratory Accreditation Program
NIST	–	National Institute of Standards and Technology
PT	–	Proficiency Test(ing)
PTOB	–	Proficiency Testing Oversight Body
PTPA	–	Proficiency Testing Provider Accreditor
QA	–	Quality Assurance
QC	–	Quality Control
QS	–	Quality System
QAM	–	Quality Assurance Manual
RL	–	Reporting Limit
RPD	–	Relative percent difference
RSD	–	Relative standard deviation
SOPs	–	Standard operating procedures
spk	–	spike
std	–	standard
TNI	-	The NELAC institute
µg/L	–	microgram per liter
UV	–	Ultraviolet

VOC – Volatile organic compound
WET – Whole effluent toxicity

3.4 Management of the Quality Manual

The Quality Manager is responsible for maintaining the currency of the Quality Manual.

The Quality Manual is reviewed by the Quality Manager and laboratory personnel to ensure it still reflects current practices and meets the requirements of any applicable regulations or client specifications. Sections of the manual are updated by making a change to the Section and then increasing the revision number by one. The cover sheet of the Quality Manual (Section 1) must be re-signed and the Table of Contents (Section 2) is updated whenever a Section is updated. The Quality Manual is considered confidential within McCampbell Analytical, Inc. and may not be altered in anyway except by approval of the Laboratory Director and Quality Manager. If it is distributed to external users, it is for the purpose of reviewing McCampbell Analytical Inc.'s, management system and may not be used for any other purpose without written permission.

SECTION 4 – ORGANIZATION

POLICY

The laboratory is a legally identifiable organization. The laboratory is responsible for carrying out testing activities that meet the requirements of ISO/IEC 17025:2005(E) and that meet the needs of the client. Through application of the policies and procedures outlined in this Section and throughout the Quality Manual:

- The laboratory assures that it is impartial and that personnel are free from undue commercial, financial, or other undue pressures that might influence their technical judgment.
- Management and technical personnel have the authority and resources to carry out their duties and have procedures to identify and correct departures from the laboratory's management system.
- Personnel understand the relevance and importance of their duties as related to the maintenance of the laboratory's management system.
- Ethics and data integrity procedures ensure personnel do not engage in activities that diminish confidence in the laboratory's capabilities.
- Confidentiality is maintained.

4.1 Laboratory Organization

Policy

The organizational structure indicated minimizes the potential for conflicting or undue interests that might influence the technical judgment of analytical personnel.

The laboratory is a commercial facility founded in 1991 with over 60 employees, over 40 major pieces of instrumentation, situated in 32,000 square feet of workspace. The tax ID number is available upon request, if applicable.

The laboratory operates in Pittsburg, California at 1534 Willow Pass Road. The analytical areas of the laboratory are separated into different sections encompassing Hydrocarbons, MBTEX, VOCs, SVOCs, Polynuclear Aromatic Hydrocarbons, Pesticides, Dioxins and Dibenzofurans, HPLC, Organics, Water Treatment Parameters, Metals, Anions, Wet Chemistry, Air Matrix, Bacteriological Testing and Fish Toxicity.
The laboratory has the resources and authority to operate a management system that is capable of identifying departures from that system and from procedures during testing, and initiates actions to minimize or prevent departures.

Appendix D is an example of the laboratory's organization chart. Additional information regarding responsibilities, authority and interrelationship of personnel who manage, perform or verify testing is included in Section 5 –"Management" and Section 20 – "Personnel". These Sections also include information on supervision, training, technical management, job descriptions, quality personnel, and appointment of deputies for key managerial personnel.

4.2 Conflict of Interest and Undue Pressure

The organizational structure minimizes the potential for conflicting or undue interests that might influence the technical judgment of analytical personnel. In addition, procedures are in place to prevent outside pressures or involvement in activities that may affect competence, impartiality, judgment, operational integrity, or the quality of the work performed at the laboratory.

SECTION 5 – MANAGEMENT

Policy
The Management Team has overall responsibility for the technical operations and authority needed to generate the required quality of laboratory operations.

Policy
The Management Team's commitment to quality and to the Quality System is stated in the Quality Policy, which is upheld through the application of related policies and procedures.

Policy
The Management Team ensures technical competence of personnel operating equipment, performing tests, evaluating results, or signing reports, and limits authority to perform laboratory functions to those appropriately trained and/or supervised.

5.1 Management Requirements

Top management includes the Laboratory Director, Laboratory Manager, Technical Manager, Supervisors and the Quality Manager. Management's commitment to good professional practice and to the quality of its products is defined in the Quality Policy statement, Section 5.3

Management has overall responsibility for the technical operations and the authority needed to generate the required quality of laboratory operations. Management ensures communication within the organization to maintain an effective management system and to communicate the importance of meeting customer, statutory, and regulatory requirements. Management assures that the system documentation is known and available so that appropriate personnel can implement their part. When changes to the management system occur or are planned, managers ensure that the integrity of the system is maintained.

Management is responsible for carrying out testing activities that meet the requirements of the TNI Standard, the ISO/IEC 17025 Standard, Alaska DOE and

that meet the needs of the client.

Managers implement, maintain, and improve the management system, and identify noncompliance with the management system of procedures. Managers initiate actions to prevent or minimize noncompliance.

Management ensures technical competence of personnel operating equipment, performing tests, evaluating results, or signing reports, and limits authority to perform laboratory functions to those appropriately trained and/or supervised. Management is responsible for defining the minimal level of education, qualifications, experience, and skills necessary for all positions in the laboratory and assuring that technical staff has demonstrated capabilities in their tasks.

Training is kept up to date by the Management Staff by periodic review of training records and through employee performance review. Management bears specific responsibility for maintenance of the management system. This includes defining roles and responsibilities to personnel, approving documents, providing required training, providing a procedure for confidential reporting of data integrity issues, and periodically reviewing data, procedures, and documentation. The assignment of responsibilities, authorities, and interrelationships of the personnel who manage, perform, or verify work affecting the quality of environmental tests is documented in Section 20.
Management ensures that audit findings and corrective actions are completed within required time frames.

Designated alternates are appointed by management during the absence of the Laboratory Director, Laboratory Manager, Technical Director/Lead Chemist or the Quality Manager, and always if the absence is more than 15 days. In the absence of the Laboratory Manager the Technical Director/Lead Chemist is the designated alternate. In the absence of the Technical Director/Lead Chemist the Laboratory Manager is the designated alternate. In the absence of the Quality Manager the QA/QC staff, Technical Director/Lead Chemist and the Laboratory Manager are the designated alternates. In the absence of the Laboratory Director, the Laboratory Manager is the designated alternate.

5.2 Management Roles and Responsibilities

Laboratory Director/President/CEO

The Laboratory Director/President/CEO (herein referred to as "Laboratory Director") of the laboratory has overall management responsibility and authority for budgeting, resource allocation, long term planning, sales, marketing, and final approval on all management and administrative policies and management plans. The Laboratory Director, with the assistance of the Management Team, authorizes the QAM and as such, sets the standards for the quality system. The Laboratory director ensures that

the Quality System complies with CA DPHS ELAP, NELAP, Alaska DOE and ISO/IEC 17025:2005(E).

Laboratory Manager

The Laboratory Manager is accountable to the Laboratory Director and oversees the daily operations of the laboratory. The Laboratory Manager is also responsible for the generation of reliable data, the allocation of personnel and resources, setting goals and objectives for the business and employees, achieving the financial, business and quality objectives of the laboratory. Furthermore, to see that all tasks performed in the laboratory are conducted according to the requirements of this QAM, the Project Technical Profile and/or the appropriate QAPP; and to assure that the quality of service provided complies with the project's requirements.

The Laboratory Manager has the authority to affect those policies and procedures to ensure that only data of the highest level of excellence are produced. As such, the laboratory manager supports a QA Department, which has responsibilities independent from sampling and analysis.

The Laboratory Manager, with the assistance of the Quality Assurance Manager and Technical Director, has the overall responsibility for establishing policies that ensure the quality of analytical services meet our client's expectations. These policies are defined in this QAM.

The Laboratory Manger ensures that the Quality System complies with CA DPHS ELAP, NELAP, Alaska DOE and ISO/IEC 17025:2005(E).

Quality Assurance Manager

The QA Manager is responsible for ensuring that the laboratory's quality system and Quality Assurance Manual (QAM) meet the requirements set forth in the QMP, providing quality systems training to all new personnel, maintaining the QAM, and performing or overseeing systems, data, internal and external audits. The QA Manager performs, or supervises: the maintenance of QA records, the maintenance of certifications and accreditations, and assists in reviewing new work as needed. The QA Manager is ensures that the Quality System complies with CA DPHS ELAP, NELAP, Alaska DOE and ISO/IEC 17025:2005(E). The Quality Manager does not report to the technical manager.

The Quality Assurance Manager has the full-time responsibility to evaluate the adherence to policies and to assure that systems are in place to produce the level of quality defined in this QAM. Specific responsibilities:

- Ensures IDL/MDL studies are completed and documented
- Ensures method validation studies are completed and documented
- Periodically performs data package inspections

- Assist in the preparation, compilation, and submittal of quality assurance project plans
- Reviews program plans for consistency with organizational and contractual requirements and advises appropriate personnel of deficiencies
- Maintains QA records
- Maintains certifications and accreditations
- Initiates and oversees both internal and external audits; documents root cause investigations for all noted deficiencies; and ensures timely audit closure
- Maintains a corrective action process for internally identified issues and ensures timely closure
- Manages the laboratory's PT Program and performs/documents root cause investigations for all failures
- Monitors to ensure the documentation of training and method demonstration are current
- Facilitates SOP development and document control

The QA Manager shall have the authority recommend that data be accepted or rejected, and recommend that work in progress be stopped in the event that procedures or practices compromise the validity and integrity of analytical data. The QA Manager is available to any employee at the facility to resolve data quality or ethical issues. The QA Manager shall be independent of laboratory operations.

Technical Director/Lead Chemist

The Technical Director/Lead Chemist reports directly to the Laboratory Director and Laboratory Manager. The Technical Director/Lead Chemist, with the assistance of the QA Manager, is responsible for maintenance of accurate Method SOPs and enforcement of the requirements of the Quality Assurance program with the supporting manual. The Technical Manager ensures that the Quality System complies with CA DPHS ELAP, NELAP, Alaska DOE and ISO/IEC 17025:2005(E). Responsibilities include:

- Responsible for the generation of reliable data
- Execute and supervise analytical procedures according to approved methodology.
- Manage Laboratory operations; work scheduling, sample tracking, prompt reporting of results
- Check calibrations and calculations as needed to assure compliant results.
- Supervise staff, set goals and objectives for employees, and guide the staff towards achieving the quality objectives of the laboratory.
- Monitor the validity of the analyses performed and data generated in the laboratory to assure its reliability.

- Determine qualifications needed for technical positions and evaluate job candidates against those requirements.
- Certify technical laboratory personnel based on education and background to ensure that staff has demonstrated capability in the activities for which they are responsible.
- Data investigation and direction sample preparation and processing.

Designated alternates are appointed by management during the absence of the Laboratory Director, Laboratory Manager, Technical Director/Lead Chemist or the Quality Manager, and always if the absence is more than 15 days. In the absence of the Laboratory Manager the Technical Director/Lead Chemist is the designated alternate. In the absence of the Technical Director/Lead Chemist the Laboratory Manager is the designated alternate. In the absence of the Quality Manager the QA/QC staff, Technical Director/Lead Chemist and the Laboratory Manager are the designated alternates. In the absence of the Laboratory Director, the Laboratory Manager is the designated alternate.

5.3 Quality Policy

Management's commitment to quality and to the management system is stated in the Quality Policy below, which is upheld through the application of related policies and procedures described in the laboratory's *Quality Manual*, SOPs and policies.

Quality Policy Statement

It is the mission of McCampbell Analytical Inc (MAI) to provide leadership, education and advocacy for the responsible stewardship of California's environment and natural resources. MAI Laboratory is committed to protecting California's environment and human health by providing the highest quality data obtainable with reasonable cost and effort and the best overall service in environmental testing. The Laboratory provides analytical and technical support to our clients and their programs to ensure that the results produced and reported meet the requirements of the data users and comply with state and federal regulations. A quality management system has been implemented that is clear, effective, well-communicated, and supported at all levels within MAI. The Quality Assurance Manual (QAM) details the quality assurance (QA) program in effect at MAI laboratory. The primary purpose of this document is to establish and maintain uniform operational and quality control procedures and to ensure data is of a known and documented quality.

A well conceived QA program provides a sound framework for the generation of laboratory data that is scientifically valid, representative and legally defensible. The validity and reliability of the data generated by the Laboratory are assured by adherence to rigorous quality assurance/quality control (QA/QC) protocols. The application of sound QA/QC principles, beginning with initial planning and continuing through all field and laboratory activities, including the final report, are designed to meet that goal. The fundamental elements of the Laboratory's QA program include Standard Operating Procedures (SOPs), quality control practices, performance testing samples, internal audits, external audits and an ethics policy.

This manual and the quality control procedures described within are not to be viewed as complete. Rather, they serve as a basic foundation on which to build a stronger, more viable Quality Assurance Management Plan (QAMP) within MAI. Other documents that may detail or affect the quality management program include the Contingency Plan, Employee

Safety Manual, quality guidance documents, memoranda, work instructions, standard operating procedures and periodic reports. These documents may further define or guide the implementation of quality standards within the Laboratory, but shall not conflict with the QAMP or diminish the effectiveness of the program. Adherence to the practices described in this manual is required of all employees. The laboratory ensures that personnel are free from any commercial, financial, and other undue pressures, which might adversely affect the quality of work. Laboratory employees are required to familiarize themselves with the quality documentation and to implement the policies and procedures in their work. All employees are trained annually on ethical principles and procedures surrounding the data that are generated. The laboratory maintains a strict policy of client confidentiality. This policy is implemented and enforced through the unequivocal commitment of management, at all levels, to the Quality Assurance (QA) principles and practices outlined in this manual, the NELAC Standard and ISO17025.

All employees are required to familiarize themselves with the sections of this manual that pertain to their operations and are encouraged to comment on its contents and make recommendations for more efficient procedures.

Following is a list of documents used to develop the Laboratory's QAM.
• Interim Draft EPA Requirements for Quality Management Plans, U.S. Environmental Protection Agency, EPA QA/R-2, July 1993 et seq.
• EPA Requirements for Quality Assurance Project Plans, EPA QA/R-5 et seq.
• Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs, American Society for Quality Control, Energy and Environmental Quality Division, Environmental Issues Group, ANSI/ASQC E4-1994 (Formerly EQA-1), January 1994 et seq.
• Quality Management and Quality System Elements for Laboratories - Guidelines, American National Standard, American Society for Quality Control, ANSI/ASQC Q2-1991 et seq.
• International Standard ISO/IEC Guide 17025 – 1999 et seq.
• NELAC Standards, Chapter 5, Quality Systems-July 2003.

5.4 Ethics and Data Integrity System

The laboratory has an Ethics and Data Integrity policy that is signed by all employees at the time of employment. It is included in appendix A. The laboratory's Ethics and Data Integrity program, training and investigations are discussed in section 19 "Data Integrity Investigations".

5.5 Documentation of Management/Quality System

The management system is defined through the policies and procedures provided in this *Quality Manual* and written laboratory Standard Operating Procedures (SOPs) and policies.

5.5.1 Quality Manual

Policy
The Quality Assurance Manager ensures that the laboratory's policies and objectives for quality are documented by reference or by inclusion in this Quality Assurance Manual, and that the Quality Assurance Manual is communicated to, understood by, and implemented by all personnel concerned, where appropriate.

Policy
Where the *Quality Assurance Manual* documents laboratory requirements, a separate SOP or policy is not required.

The Quality Manual contains the following required items:

5.5.1.1 document title;

5.5.1.2 laboratory's full name and address;

5.5.1.3 name, address (if different from above), and telephone number of individual(s) responsible for the laboratory;

5.5.1.4 identification of all major organizational units which are to be covered by this quality manual and the effective date of the version;

5.5.1.5 identification of the laboratory's approved signatories;

5.5.1.6 the signed and dated concurrence (with appropriate names and titles), of all responsible parties including the quality manager(s), technical manager(s), and the agent who is in charge of all laboratory activities, such as the laboratory director or laboratory manager;

5.5.1.7 the objectives of the management system and contain or reference the laboratory's policies and procedures;

5.5.1.8 the laboratory's official quality policy statement, which shall include management system objectives and management's commitment to ethical laboratory practices and to upholding the requirements of this Standard; and

5.5.1.9 a table of contents, and applicable lists of references, glossaries and appendices.

5.5.2 Standard Operating Procedures (SOPs)

Standard operating procedures (SOPs) represent all phases of current laboratory operations (they include an effective date, revision number, and signature of the approving authorities, at least two signatures are necessary from the Laboratory Director, Laboratory manager, Technical Director and Quality manager and are available to all personnel. They contain sufficient detail such that someone with similar qualifications could perform the procedures. There are two types of SOPs used in the laboratory: 1) test method SOPs, which have specific requirements as outlined below, and 2) general use SOPs which document general procedures. Each accredited analyte or method has an SOP. Sometimes an SOP is a copy of a method, and any additions are clearly described. The laboratory's test method SOPs include the following topics, where applicable.

i. identification of the method;
ii. applicable matrix or matrices;

iii. limits of detection and quantitation;
iv. scope and application, including parameters to be analyzed;
v. summary of the method;
vi. definitions;
vii. interferences;
viii. safety;
ix. equipment and supplies;
x. reagents and standards;
xi. sample collection, preservation, shipment and storage;
xii. quality control;
xiii. calibration and standardization;
xiv. procedure;
xv. data analysis and calculations;
xvi. method performance;
xvii. pollution prevention;
xviii. data assessment and acceptance criteria for quality control measures;
xix. corrective actions for out-of-control data;
xx. contingencies for handling out-of-control or unacceptable data;
xxi. waste management;
xxii. references; and
xxiii. any tables, diagrams, flowcharts and validation data.

5.5.3 Order of Precedence

In the event of a conflict or discrepancy between policies, the order of precedence is as follows unless otherwise noted:

Quality Manual
SOPs and Policies
Other (Work Instructions (WI), memos, flow charts, etc.)

SECTION 6 – DOCUMENT MANAGEMENT

This Section describes procedures for document management, which includes controlling, distributing, reviewing, and accepting modifications. The purpose of document management is to preclude the use of invalid and/or obsolete documents.

The laboratory manages three types of documents, 1) controlled, 2) approved, and 3) obsolete.

A CONTROLLED DOCUMENT is one that is uniquely identified, issued, tracked, and kept current as part of the quality system. Controlled documents may be internal documents or external documents.

APPROVED means reviewed, and either signed and dated, or acknowledged in writing or secure electronic means by the issuing authority(ies).

OBSOLETE DOCUMENTS are documents that have been superseded by more recent versions.

POLICY
All documents that affect the quality of laboratory data are managed appropriate to the scope and depth required.

6.1 Document Control

Policy
Documents will be reviewed and approved for use by either the laboratory manager or the quality assurance manager or designee prior to issue.

Documents are reviewed as needed to ensure their contents are suitable and in compliance with the current quality systems requirements, and accurately describe current operations.

Approved copies of documents are available to all personnel on the laboratory server.

Documents are stored electronically and analysts are able to view SOPs on computers at work stations. These documents are in PDF format and are maintained on the network that all computers have access to. There is a list of electronic documents and the analysts sign a distribution list, when documents are updated and replaced.

Controlled internal documents are uniquely identified with 1) date of issue, 2) revision identification, 3) page number, 4) the total number of pages (or a mark to indicate the end of the document), and 5) the signatures of the issuing authority (i.e. management).

A master list of controlled internal documents is maintained that includes distribution, location, and revision dates. The Quality Assurance Manager maintains the controlled document list.

6.1.1 Document Changes to Controlled Documents

6.1.1.1 Paper Document Changes

Policy
The original approving authority or designee approves document changes.

Policy
The document management process allows for handwritten modifications to documents.

All handwritten document changes must be marked, initialed and dated. All document changes must be approved by either the Laboratory Manager,

Quality Assurance Manager, Laboratory Director, or Technical Director. The modified document is copied and distributed as soon as practicable, and obsolete documents are removed.

Amendments to documents are incorporated into a new revision and stored electronically.

6.1.1.2 Electronic Document Changes

Suggested revisions to electronic documents are presented to "The Management Staff," for review and approval. Changes to electronic documents are approved either on an accompanying form or through electronic means (such as email, change tracking functions, or memoranda).

Where practicable, the altered text or new text in the draft is identified during the revision or review process to provide for easy identification of the modifications.

6.2 Obsolete Documents

Policy
All invalid or obsolete documents are removed from general distribution, or otherwise prevented from unintended use.

Obsolete documents retained for legal use or historical knowledge preservation are appropriately marked as "Obsolete Document" and retained in the QA/QC office with controlled access.

The "Management Team" identifies obsolete documents as being obsolete. All copies of the obsolete document are collected from employees according to the distribution log, and each obsolete document is clearly marked "Obsolete Document" on the front cover or destroyed. At least one copy of any obsolete document is kept in the QA Managers office or the laboratory Managers office as required by the regulations or client. Documents are kept for at least 5 years.

SECTION 7 – REVIEW OF REQUESTS, TENDERS AND CONTRACTS

POLICY
The review of all new work assures that oversight is provided so that requirements are clearly defined, the laboratory has adequate resources and capability, the health and safety of all involved is clearly defined, and the test method is applicable to the customer's needs. This process assures that all work will be given adequate attention without shortcuts that may compromise data quality.

Contracts for new work may be formal bids, signed documents, verbal, or electronic. The client's requirements, including the methods to be used, must be clearly defined, documented and understood. Requirements might include target analyte lists, project specific reporting limits (if any), project specific quality control requirements (if any), turnaround time, and requirements for data deliverables. The review must also cover any work that will be subcontracted by the laboratory.

7.1 Procedure for the Review of Work Requests

The Laboratory Manager, Technical Director and/or Sales Manager determines if the laboratory has the necessary accreditations, resources, including schedule, equipment, deliverables, and personnel to meet the work request.

The Laboratory Manager, Technical Director and/or Sales Manager informs the client of the results of the review if it indicates any potential conflict, deficiency, lack of accreditation, or inability of the lab to complete the work satisfactorily.

The client is informed of any deviation from the contract including the test method or sample handling processes. All differences between the request and the final contract are resolved and recorded before any work begins. It is necessary that the contract be acceptable to both the laboratory and the client.

The client repeats the review process when there are amendments to the original contract. The participating personnel are given copies of the amendments.

The managers will review the work request and confirm that the laboratory has any required certifications, that it can meet the client's data quality and reporting requirements, and that the lab has the capacity to meet the client's turn around needs.

Most communication will occur electronically and documentation stored at the managers computer.

Note: For repetitive routine tasks, the review may be made only at the initial inquiry stage or on granting of a contract for on-going routine work performed under a general agreement with the client, provided the client's requirements don't change.

For new, complex or large projects, the proposed work contract is given to the Laboratory Director.

- Sales Manager will in turn forward the work contract to the appropriate personnel to evaluate such items as:
- Contractual obligations, bonding issues and payment terms
- Method capabilities, analyte lists, reporting limits, and quality control limits
- Turnaround time feasibility

- QA/QC issues, including certification/accreditation
- Formal laboratory quote
- Final report formatting and electronic deliverable documents
- Time required to keep sample in house
- Final sample disposal requirements
- Review PT sample results

The Sales Manager submits the bid and formal quote to the client and maintains copies of all signed contracts.[44]

7.2 Documentation of Review

Records are maintained for every contract or work request, when appropriate. This includes pertinent discussions with a client relating to the client's requirements or the results of the work during the period of execution of the contract.

SECTION 8 – SUBCONTRACTING OF TESTS

A SUBCONTRACT LABORATORY is defined as a laboratory external to this laboratory, or at a different location than the address indicated on the front cover of this manual, that performs analyses for this laboratory.

POLICY
When subcontracting analytical services, the laboratory assures work requiring accreditation is placed with an appropriately accredited laboratory or one that meets applicable statutory and regulatory requirements for performing the tests.

8.1 Procedure

A list of subcontractors is maintained on the laboratory server in folder MAI MAIN.

A copy of the certificate and analyte list for subcontractors is maintained as evidence of compliance.

The sales and project management staff notify the client of the intent to subcontract the work in writing.
The laboratory must gain the approval of the client to subcontract their work prior to implementation.

The laboratory performing the subcontracted work is identified in the final report. The laboratory assumes responsibility to the client for the subcontractor's work, except in the case where a client or a regulating authority specified which subcontractor is to be used.

The Laboratory Manager may nominate a laboratory as a subcontractor based on need.

A listing of all approved subcontracting laboratories and supporting documentation is available from the Quality Assurance Manager or Laboratory Manager. At the discretion of the Management Team, a letter or e-mail may be sent to the subcontract lab requesting the following information: (typically, only certifications [#4] are requested)

1. Copy of Quality Assurance Manual. Ensure data quality limits for relevant methods are acceptable and that training procedures are adequate.

2. Method SOPs. Some labs may not submit copies due to internal policies. In these cases, a copy of the first page and signature page of the SOP is acceptable. A table of contents including effective dates may also be acceptable. The SOP can be examined if an on-site audit is performed.

3. The most recent sets of proficiency results and any associated corrective action.

4. Copy of necessary certifications verifying that the required approvals are current. Ensure that all needed analytes are included; some may not be accreditable (if so, document). Certificate and scope of International Standard accreditation are required, when applicable. The Management Team requests a copy of the current certification annually.

5. Example final report to confirm format is compliant and provides the necessary information.

6. Statement of Qualifications (SOQ) or Summary list of Technical Staff and Qualifications – position, education and years of experience.

7. USDA permit if soils less than three feet deep from New York, North Carolina, South Carolina, Georgia, Florida, Tennessee, Alabama, Mississippi, Louisiana, Arkansas, Texas, Oklahoma, New Mexico, Arizona, California, Hawaii, or outside the continental U.S. are to be analyzed. These samples require special shipping measures. It may be necessary to heat-treat the samples before shipping; however, some analytes/tests may be irrelevant after heat treatment.

8. State, ISO 17025, and/or NELAC Audit with Corrective Action Responses.

9. Description of Business Ethics and Data Integrity Plan.

SECTION 9 – PURCHASING SERVICES AND SUPPLIES

Note: When MAI refers to services, it means balance calibration, NIST thermometer calibration, Class 1 weight calibrations, or service contracts for instrumentation.

POLICY
The laboratory ensures that purchased supplies and services that affect the quality of environmental tests are of the required or specified quality by using approved suppliers and products.

POLICY
The laboratory has procedures for purchasing, receiving, and storage of supplies that affect the quality of environmental tests.

9.1 Procedure

The relevant staff member (Director, Manager, or Chemist) reviews and approves the supplier of services and supplies and approves technical content of purchasing documents prior to ordering.

Evaluation of suppliers is accomplished by ensuring the supplier ships the product or material ordered and that the material is of the appropriate quality by signing packing slips or other supply receipt documents. The purchasing documents contain the data that adequately describe the services and supplies ordered.

Receipt of Supplies

Supplies received are reconciled against the packing list and/or invoice and inspected for damage. Supplies, reagents and chemical standards are marked as received and inspected in LIMS and distributed to the appropriate individuals, departments or storage areas.

Storage of Supplies

Supplies received are stored according to manufacturer's instructions, laboratory SOP, and/or test method specifications.

9.2 Approval of Suppliers

A list of approved suppliers is kept on the LIMS.

SECTION 10 – SERVICE TO THE CLIENT

The laboratory collaborates with clients and/or their representatives in clarifying their requests and in monitoring of the laboratory performance related to their work. Each request is reviewed to determine the nature of the request and the laboratory's ability to comply with the request within the confines of prevailing statutes and/or regulations without risk to the confidentiality of other clients.

10.1 Client Confidentiality

Policy
The laboratory confidentiality policy is to not divulge or release any information to a third party without proper authorization, such as a legal court order.

Policy
All electronic data (storage or transmissions) are kept confidential, based on technology and laboratory limits, as required by client or regulation.

It is McCampbell Analytical, Inc. policy not to release any data to third parties without the client's authorization. When asked for data by a third party we must first obtain our client's permission, in writing, before releasing data. Data that are electronically transmitted by fax or email contains a confidentiality notice directing any unintended recipient to inform us of our error and destroy the received documents. Electronically stored data within the laboratory's computer network are protected by firewall security.

We will comply with any written request by a client or government agency to maintain strict confidentiality regarding any data or techniques that are proprietary or matters of national security. The agreement must be in writing and will be signed by all pertinent parties within the laboratory.

10.2 Client Support

Communication with the client, or their representative, is maintained to provide proper instruction and modification for testing. Technical staff is available to discuss any technical questions or concerns the client may have.

The client, or their representative, may be provided reasonable access to laboratory areas for witnessing testing.

Delays or major deviations to the testing are communicated to the client immediately by the laboratory director or project manager.

The laboratory will provide the client with all requested information pertaining to the analysis of their samples. An additional charge may apply for additional data/information that was not requested prior to the time of sample analysis or previously agreed upon.

10.3 Client Feedback

The laboratory seeks both negative and positive feedback following the completion of projects and periodically for ongoing projects. Feedback provides acknowledgement, corrective actions where necessary, and opportunities for continuous improvement.

Negative customer feedback is documented as a customer complaint (see Section 11 – "Complaints"). A survey has been compiled and is used periodically to assess client feedback.

SECTION 11 – COMPLAINTS

The purpose of this section is to assure that customer complaints are addressed and corrected. This includes requests to verify results or analytical data.

POLICY
At least one member of the Laboratory Management Team, or a deputy, reviews all complaints and determines appropriate action. The Laboratory Management Team includes the Laboratory Director, Laboratory Manager, QA Manager and the Technical Director.

PROCEDURE
All customer complaints are documented by the person receiving the complaint and addressed by the Management Team or appropriate deputy. If it is determined that a complaint is without merit, it is documented, and the client is contacted. If it is determined

that the complaint has merit and corrective action is required, a corrective action is initiated. See Section 13 for corrective action procedures.

SECTION 12 – CONTROL OF NON-CONFORMING WORK

NON-CONFORMING WORK is work that does not meet acceptance criteria or requirements. Non-conformances can include unacceptable quality control results or departures from standard operating procedures or test methods. Requests for departures from laboratory procedures can be approved by the Management Team and documented.

12.1 Exceptionally Permitting Departures from Documented Policies and Procedures

If a client requests a departure from laboratory procedures, the laboratory will not consider that departure as a non-conformance that requires corrective action. However, that non-conformance will be documented as a client specific requirement that was approved by management.

12.2 Non-Conforming Work

The policy for control of non-conforming work is to identify the non-conformance, determine if it will be permitted, and take appropriate action. All employees have the authority to stop work on samples and immediately consult the management team when they suspect the process does not conform to laboratory requirements.

The responsibilities and authorities for the management of non-conforming work are detailed in procedure MAI02-NC/CAR/PR, Nonconformance/Corrective Action Report (NC/CAR/PR). The procedure for investigating and taking associated corrective actions of non-conforming work are also described in MAI02-NC/CAR, Nonconformance/Corrective Action Report (NC/CAR/PR).

The Management Team evaluates the significance of the nonconforming work, and takes corrective action immediately. The client is notified immediately if their data has been impacted. The Management Team may authorize resumption of work after non-conformance.

A controlled copy of procedure MAI02-NC/CAR/PR Nonconformance/Corrective Action Report (NC/CAR/PR) and of all procedures can be found on the server.

12.3 Stop Work Procedures

All employees have the authority to stop work on samples and immediately consult the management team when any suspect the process does not conform to laboratory requirements.
When an investigation of nonconformance indicates that the cause of the nonconformance requires that a method be restricted or not used until modifications are implemented, the Laboratory Director and Technical Manager will immediately

notify all personnel of the suspension/restriction. The lab will hold all relevant reports to clients pending review. The Quality Manager must be involved in the resolution of the issue and must verify that the issue is resolved before work may resume. Personnel are notified by the Technical Manager when resumption of work is authorized. The Technical Manager and Quality Manager will document the issue, root cause and resolution using the corrective action procedures described in Section 14 – "Corrective Action".

SECTION 13 – IMPROVEMENT

Improvement in the overall effectiveness of the laboratory management system is a result of the implementation of the various aspects of the laboratory's management system: quality policy and objectives ; internal auditing practices; the review and analysis of data ; the corrective action and preventive action process; and the annual management review of the quality management system where the various aspects of the management/quality system are summarized, and evaluated and plans for improvement are developed.

SECTION 14 – CORRECTIVE ACTION

CORRECTIVE ACTION is the action taken to eliminate the causes of an existing nonconformity, defect, or other undesirable situation in order to prevent recurrence (NELAC, 2003).

POLICY
Deficiencies cited in external assessments, internal quality audits, data reviews, complaints, or managerial reviews are documented and require corrective action. Corrective actions taken are appropriate for the magnitude of the problem and the degree of risk.

14.1 General Procedure

The laboratory uses a corrective action procedure outlined in MAI02- NC/CAR/PR. All staff are responsible for initiating corrective action on routine data reviews. The Quality Assurance Officer is responsible for monitoring and recording corrective actions.

All deficiencies are investigated and a corrective action plan developed and implemented if determined necessary. The implementation is monitored for effectiveness as part of the internal audit program.

Specific corrective action protocols specified in test methods may over-ride general corrective action procedures specified in this manual.

All Corrective action reports are logged, numbered, and tracked in support of the management review process.

14.1.1 Cause Analysis

When failures due to systematic errors have been identified, the first step of the corrective action process starts with the initial investigation and determination of root cause(s) of the problem. Records are maintained in the corrective Action Folder

on server h. These are filed show that the root cause(s) was investigated, and includes the results of the investigation.

Where there may be non-systematic errors and as such the initial cause is readily identifiable or expected random failures (e.g. failed quality control), a formal root cause analysis is not performed and the process begins with selection and implementation of corrective action

14.1.2 Selection and Implementation of Corrective Actions

Where uncertainty arises regarding the best approach for analysis of the cause of exceedances that require corrective action, appropriate personnel will recommend corrective actions that are appropriate to the magnitude and risk of the problem and that will most likely eliminate the problem and prevent recurrence. The QA/QC Team ensures that corrective actions are discharged within the agreed upon time frame with support from the Management Team.

14.1.3 Monitoring of Corrective Action

The QA/QC Team will monitor implementation and documentation of the corrective action to assure that the corrective actions were effective.
Following procedures in MAI02- NC/CAR/PR.

14.2 Additional Audits

Where the identification of non-conformances or departures from normal lab procedures cast doubt on the laboratory's compliance with its own policies and procedures, or on its compliance with the TNI Standard, the laboratory ensures that the appropriate areas of activity are audited as soon as possible.

In many cases, the additional audits are follow-ups after the corrective action has been implemented to ensure it is effective. These are done when a serious issue or risk to the laboratory have been identified.

14.3 Technical Corrective Action

CAUSE ANALYSIS in corrective action investigates the root cause of the problem.

Policy
Sample data associated with a failed quality control are evaluated for the need to be reanalyzed or qualified.

Unacceptable quality control results and issues that affect the lab's performance are documented, and if the evaluation requires cause analysis, the cause and solution are recorded.

The analyst is responsible for initiating or recommending corrective actions and ensuring that exceedances of quality control acceptance criteria are documented.

Analysts routinely implement corrective actions for data with unacceptable QC measures. First level correction may include re-analysis without further assessment. If the test method SOPs addresses the specific actions to take, they are followed. Otherwise, corrective actions start with assessment of the cause of the problem.

The Management Team review corrective action reports and suggest improvements, alternative approaches, and procedures where needed. If the data reported are affected adversely by the nonconformance, the client is notified in writing.

The discovery of a non-conformance for results that have already been reported to the client must be immediately evaluated for significance of the non-conformance, its acceptability to the client, and determination of the appropriate corrective action.

SECTION 15 – PREVENTIVE ACTION

POLICY

PREVENTIVE ACTION, rather than corrective action, aims at minimizing or eliminating inferior data quality or other non-conformance.

PROCEDURE

Preventative action includes, but is not limited to, several components.

15.1 Regular routine maintenance of instrumentation and support equipment Section 20.2 and 20.3. At MAI there are three service and maintenance people on staff that assist analyst in the maintenance and servicing of analytical equipment.

15.2 The review of quality control data to distinguish trends.

15.3 MAI has a dual data review process. The analytical results are processed in two separate and different systems. The first is through the laboratory Information Management System (LIMS). The second is an excel spread sheet program that computes final results independently from LIMS. At the time of reporting the results are compared to each other and any discrepancies are investigated before reports are sent to the client.

15.4 The laboratory participates in performance testing samples for all tests for which these samples are available. These cover a range of selective matrixes. Which include Drinking Water, Waste Water, Hazardous waste, Underground storage and Industrial Hygiene samples. The laboratory makes every effort to acquire performance testing samples for any test it performs. The results of these blind samples give the laboratory some indication of the confidence in the analytical processes, and where actions need to be taken to prevent problems.

15.5 The laboratories non-conformance/corrective action program also includes preventative actions. Some incidents in the laboratory do not require corrective action responses, but the laboratory could possibly profit from action being taken to improve a system.

When improvement opportunities are identified or if preventive action is required, action plans are developed, implemented and monitored to reduce the likelihood of the occurrence of nonconformities.

Procedures for preventive actions include the initiation of such actions and subsequent monitoring to ensure that they are effective.

All personnel have the authority to offer suggestions for improvements and to recommend preventive actions, however management is responsible for implementing preventive action.

SECTION 16 – CONTROL OF RECORDS

POLICY
The laboratory maintains a record system appropriate to its needs, records all laboratory activities, and complies with applicable standards or regulations as required.

16.1 Records Maintenance

Records are a subset of documents, usually data recordings that include annotations, such as daily refrigerator temperatures recorded on a laboratory form, lists, spreadsheets, or analyst notes on a chromatogram. Records may be on any form of media, including electronic and/or hard copy. Records allow for the historical reconstruction of laboratory activities related to sample handling and analysis.

i) all raw data, whether hard copy or electronic, for calibrations, samples and quality control measures, including analysts' worksheets and data output records (chromatograms, strip charts, and other instrument response readout records)

ii) a written description or reference to the specific method(s) used, which includes a description of the specific computational steps used to translate parametric observations into a reportable analytical value (a copy of all pertinent Standard Operating Procedures);

iii) laboratory sample ID code;

iv) date of analysis;

v) time of analysis is required if the holding time is seventy-two (72) hours or less, or when time critical steps are included in the analysis (e.g., extractions and incubations);

vi) instrumentation identification and instrument operating conditions/parameters (or reference to such data);

vii) all manual calculations (including manual integrations);

viii) analyst's or operator's initials/signature or electronic identification;

ix) sample preparation, including cleanup, separation protocols, incubation periods or subculture, ID codes, volumes, weights, instrument printouts, meter readings, calculations, reagents;

x) test results (including a copy of the final report);

xi) standard and reagent origin, receipt, preparation, and use;

xii) calibration criteria, frequency and acceptance criteria;

xiii) data and statistical calculations, review, confirmation, interpretation, assessment and reporting conventions;

xiv) quality control protocols and assessment;

xv) electronic data security, software documentation and verification, software and hardware audits, backups, and records of any changes to automated data entries;

xvi) method performance criteria including expected quality control requirements;

xvii) proficiency test results;

xviii) records of demonstration of capability for each analyst;

xix) a record of names, initials, and signatures for all individuals who are responsible for signing or initialing any laboratory record;

xx) correspondence relating to laboratory activities for a specific project;

xxi) corrective action reports;

xxii) preventive action records;

xxiii) copies of internal and external audits including audit responses;

xxiv) copies of all current and historical laboratory SOPs, policies and *Quality Manual*s;

xxv) sample receiving records (including information on any interlaboratory transfers);

xxvi) sample storage records;

xxvii) data review and verification records;

xxviii) personnel qualification, experience and training records;

xxviv) archive records; and

xxviv) management reviews.

16.2 Records Management and Storage

Policy
Records, including electronic records, are easy to retrieve, legible, and protected from deterioration or damage; held secure and in confidence; and are available to accrediting authorities for a minimum of seven years.

Policy
The laboratory maintains a record management system for control of laboratory notebooks, instrument logbooks/Excel data sheets, standards logbooks, and records for data reduction, validation, storage, and reporting.

Policy
Archived information and access logs are protected against fire, theft, loss, environmental deterioration, vermin, and in the case of electronic records, electronic or magnetic sources.

Policy
In the event that the laboratory transfers ownership or goes out of business, records are maintained or transferred according to the clients' instructions.

Procedure
The laboratory maintains a record management system for control of laboratory notebooks, instrument logbooks, standards logbooks, and records for data reduction, validation, storage, and reporting. The QAO is responsible for the controlled documents. Where electronic notebooks and spreadsheets are used, the LIMS maintains all data recorded and the excel spread sheets are signed and stored for 7 years.
All electronic records are backed-up as needed by the IT Department.
Archived information and access logs are protected against fire, theft, loss, environmental deterioration, vermin, and in the case of electronic records, electronic or magnetic sources. Archived records have limited access and are checked out through an access log at the IT desk or the archive report area.

16.3 Legal Chain of Custody Records

EVIDENTIARY SAMPLE DATA are used as legal evidence.

Policy
Procedures for evidentiary samples are documented below, when applicable.

Procedure
In the event McCampbell Analytical receives 'evidentiary' samples, there will be available, a locked refrigerator with controlled access using a log and internal COC. This section does not refer to the routine (i.e., everyday) samples that McCampbell receives.

While McCampbell Analytical considers all samples to be potentially used for litigation, the procedure is specific to known litigation samples and will employ a

system with resources dedicated in case McCampbell Analytical receives 'evidentiary' samples. When full Legal/Evidentiary Chain Of Custody protocols are required, COC records are used to establish an intact, continuous record of the physical possession, storage and disposal of sample containers, collected samples, sample aliquots, and sample extracts or digestates, The COC records account for all time periods associated with the samples. The COC records identify all individuals who physically handled individual samples. The COC forms remain with the samples during transport or shipment. If shipping containers and/or individual sample containers are submitted with sample custody seals, and any seals are not intact, the lab shall note this on the chain of custody. Other documents pertaining to the transport of the samples, such as receipts from common carriers are kept as part of the documentation.

When evidentiary samples, subsamples, digestates or extracts are transferred to another party they are subject to the requirements of legal chain of custody. These samples are kept in a locked area or refrigerator with the key in possession of the designated sample custodian. An internal COC record is maintained to document all parties who handled the sample(s).

Samples are retained for thirty days from report date unless otherwise instructed by the client or if the samples are part of litigation or have been received under legal/evidentiary requirements, in which case the disposal of the physical sample is accomplished with the concurrence of the affected legal authority. After the retention period samples are either returned to the client or properly disposed of according to federal and state laws and regulations.

Records provide the direct evidence and support for the necessary technical interpretations, judgments, and discussions concerning laboratory results. These records, particularly those that are anticipated to be used as evidentiary data, provide the historical evidence needed for later reviews and analyses. Records should be legible, identifiable, and retrievable, and protected against damage, deterioration or loss. All records referenced in this section are retained for a minimum of seven years.

SECTION 17 – AUDITS AND MANAGEMENT REVIEW

Internal and external audits are conducted regularly at MAI to ensure that the guidance provided in this document and in other related documents is followed. Internal audits are performed by the QA department, which is responsible for all QA/QC functions in the laboratory, and/or members of the professional laboratory staff that do not normally work in the section or analytical unit being audited. Persons who are not direct employees of MAI to provide an independent and unbiased review of laboratory operations conduct external audits. AUDITS measure laboratory performance and verify compliance with accreditation/ certification and project requirements. Audits specifically provide management with an on-going assessment of the quality system. They are also instrumental in identifying areas where improvement in the quality system will increase the reliability of data. Clients are notified of events that cast doubt on the validity of the results.

17.1 Internal Audits

Policy
The laboratory conducts internal audits of its quality systems activities, including data integrity, and the use of trained and qualified personnel at least annually, in accordance with the requirements of ISO/IEC 17025:2005(E). Personnel may not audit their own activities except when it can be demonstrated that an effective audit will be carried out.

Procedure
Annually, the laboratory prepares a schedule of internal audits to be performed during the year. These audits verify compliance with the requirements of the quality system, including analytical methods, SOPs, ethics policies, other laboratory policies, and ISO/IEC 17025:2005(E).

It is the responsibility of the Quality Manager to plan and organize audits as required by the schedule and requested by management.

The area audited, the audit findings, and corrective actions are recorded, depending on the finding a suitable time frame for corrective action response will be allocated.

All investigations that result in findings of inappropriate activity are documented and include any disciplinary actions involved, corrective actions taken, and all appropriate notifications of clients as allowed under employment regulations in the State of California.

Clients are notified when audit findings cast doubt on the validity of the data within 48 hours.
Audits are reviewed after completion to assure that corrective actions were implemented and effective.

17.2 External Audits

Policy
It is the laboratory's policy to cooperate and assist with all external audits, whether performed by clients or an accrediting authority.

Policy
All external audits are fully documented and tracked to closure.

Procedure
Management ensures that all areas of the laboratory are accessible to auditors as applicable and that appropriate personnel are available to assist in conducting the audit.

Any findings related to an external audit follow corrective action procedures.

Management ensures that corrective actions are carried out within the timeframe specified by the auditor(s).

17.2.1 Confidential Business Information (CBI) Considerations

During on-site audits, on-site auditors may come into possession of information claimed as business confidential. A business confidentiality claim is defined as "a claim or allegation that business information is entitled to confidential treatment for reasons of business confidentiality or a request for a determination that such information is entitled to such treatment." When information is claimed as business confidential, the laboratory must place on (or attach to) the information at the time it is submitted to the auditor, a cover sheet, stamped or typed legend or other suitable form of notice, employing language such as "trade secret", "proprietary" or "company confidential". Confidential portions of documents otherwise non-confidential must be clearly identified. CBI may be purged of references to client identity by the responsible laboratory official at the time of removal from the laboratory. However, sample identifiers may not be obscured from the information.

17.3 Performance Audits

Performance audits may be Proficiency Test Samples, internal single-blind samples, double-blind samples through a provider or client, or anything that tests the performance of the analyst and method.

17.4 System Audits and Management Reviews

Policy
The Quality Assurance Manager reviews the quality system annually to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements. Findings from the management review and actions that arise from them shall be recorded.

17.5 Handling Audit Findings

Internal or external audit findings are responded to within the time frame agreed to at the time of the audit. The response may include action plans that could not be completed within the response time frame. A completion date is established by management for each action item and included in the response.

The responsibility for developing and implementing corrective actions to findings is the responsibility of the QAO. Corrective actions are documented through the corrective action process described in Section 14 – "Corrective Actions".
Audit findings that cast doubt on the effectiveness of the laboratory operation to produce data of known and documented quality or that question the correctness or validity of sample results must be investigated. Corrective action procedures described in Section 14 – "Corrective Action" must be followed. Clients must be

notified in writing if the investigation shows the laboratory results have been negatively affected and the clients requirements have not been met. The client must be notified within 48 hours after the laboratory discovers the issue. Laboratory management will ensure that this notification is carried out within the specified time frame.

All investigations that result in findings of inappropriate activity are documented and include any disciplinary actions involved, corrective actions taken, and all appropriate notifications of clients. See Section 19 (Data Integrity Investigation) for additional procedures for handling inappropriate activity.

SECTION 18– MANAGEMENT REVIEW

The Quality Manager performs a quality systems review. The review is documented and maintained. On completion the document is forwarded to the management staff for their review. Any discovery of potential issues shall be handled in a confidential manner until such time as a follow up evaluation, full investigation or other appropriate activity can be conducted. Any corrective actions necessary are processed through the corrective action, non-conformance program. The review shall take into account:

18.1 Management Review Topics

The following are reviewed to ensure their suitability and effectiveness:

a) the suitability of policies and procedures
b) reports from managerial and supervisory personnel;
c) the outcome of recent internal audits;
d) corrective and preventative actions;
e) assessments by external bodies
f) the result of interlaboratory comparisons or proficiency tests;
g) changes in the volume and type of work;
h) client feedback;
i) complaints;
j) other relevant factors, such as quality control activities, resources and staff training.

18.2 Procedure

Annually during the first quarter, the Quality manager will conduct an internal audit and a management review. This review will be electronically documented and sent to the Laboratory Director, Laboratory Manager and Technical Director. Any issues that need corrective actions will be conducted through the laboratory Corrective action process, with dates and timelines for closure.

SECTION 19–DATA INTEGRITY

Policy

Technical managers uphold the spirit and intent by supporting integrity procedures, by enforcing data integrity procedures, and by signing and dating the data integrity procedure training forms.

Policy
Data integrity procedures and evidence of inappropriate actions are reviewed annually or through regularly scheduled internal audits, and are updated by management.

Policy
The mechanism for confidential reporting of ethics and data integrity issues is (1) unrestricted access to senior management, (2) an assurance that personnel will not be treated unfairly for reporting instances of ethics and data integrity breaches, and (3) anonymous reporting.

Policy
Employees are required to understand, through training and review of quality systems documents that any infractions of the laboratory data integrity procedures will result in a detailed investigation that could lead to very serious consequences such as immediate termination, or civil/criminal prosecution.

Policy
Any potential data integrity issue is handled confidentially until a follow-up evaluation, full investigation, or other appropriate actions have been completed and the issues clarified. Inappropriate activities are documented, including disciplinary actions, corrective actions, and notifications of clients, if applicable. These documents are maintained for a minimum of 7 years.

19.1 Ethics and Data Integrity Procedures

Any determination for detailed investigation of data integrity issues must be communicated to senior management. Allegations are investigated and remain confidential to the extent necessary.

Documentation for all investigations that result in findings of inappropriate activity includes any disciplinary actions involved, corrective actions taken, and all appropriate notifications of clients.

Data integrity procedures are reviewed as needed and are periodically monitored through in-depth data review, records review, or other thorough check processes.

McCampbell Analytical and all employees are held to high professional ethical standards in the performance of their duties. All employees are required to read, understand and sign a 'Code of Ethics Statement' 1) attesting to their commitment to honesty and integrity in discharging their public duties. A copy of this document is retained in the employee's Training Documentation File. Improper, unethical or illegal actions may result in censure or termination from McCampbell Analytical.
Unethical activities are defined as intentional falsification of records. Records may be personal credentials, resumes or educational transcripts, instrument logbooks, maintenance logbooks, raw data and data reports.

Scientific misconduct is defined as intentionally not adhering to the prescribed method or Standard Operating Procedure. Falsifications in the environmental laboratory industry McCampbell Analytical will not tolerate include, but are not limited to:

Falsifying data - This includes "dry-labbing," the process of making up/creating data without performing the procedure. This may also include intentionally representing another individual's work as one's own or changing laboratory data results.
Improper peak integration - Intentionally integrating data chromatograms so that the quality control samples meet QC criteria. This is also known as "peak shaving" or "peak juicing."
Improper clock setting - Readjusting the computer clock so that it appears samples were analyzed within hold times. This is also known as time traveling.
Improper representation of quality control samples - Misrepresenting analytical spikes as matrix (digested) spikes. Analyzing a blank or LCS without sending it through the preparatory procedure. Treating a QC sample differently than a client sample.
Improper calibration – Manipulating the calibration or tune so that it meets QC criteria. Examples include deleting/discarding calibration points *along a curve* (that is, deleting mid-points) or forging tuning data so that it appears to have met calibration criteria.
File substitution - Substituting invalid calibration data with valid data from a different time so that the analysis appears to be successful.
Hiding or concealing a problem - Concealing a known analytical or sample problem as well as concealing a known ethical problem.
Such actions are considered personal conduct violations under McCampbell Analytical disciplinary policy. Disciplinary action for ethics violations may include verbal and/or written reprimand, reassignment, or termination depending on the number of infractions observed, the severity of the infraction, or the impact it may cause to the environment and human health.

Management reviews data integrity procedures yearly and updates these procedures as needed.

19.2 Training

Data integrity training is provided as a formal part of new employee orientation and a refresher is given annually for all employees. Employees are required to understand that any infractions of the laboratory data integrity procedures shall result in a detailed investigation that could lead to very serious consequences including immediate termination, debarment or civil/criminal prosecution. This is discussed in the Ethics and Data Integrity Policy that every employee is required to sign annually. Attendance for required training is monitored through a signature attendance sheet.

An agenda is provided to each trainee prior to the training class. Data integrity training emphasizes the importance of proper written narration on the part of the analyst with respect to those cases where analytical data may be useful, but are in

one sense or another partially deficient. The following topics and activities are covered:

- organizational mission and its relationship to the critical need for honesty and full disclosure in all analytical reporting;
- how and when to report data integrity issues;
- record keeping; mistakes are marked with one line and initialed and dated.
- training, including discussion regarding all data integrity procedures;
- data integrity training documentation;
- in-depth data monitoring and data integrity procedure documentation; and
- specific examples of breaches of ethical behavior such as improper data manipulations, adjustments of instrument time clocks, and inappropriate changes in concentrations of standards.

When contracted technical or support personnel are used, the QAO is responsible for ensuring that they are trained to the laboratory's management system and data integrity procedures, competent to perform the assigned tasks, and appropriately supervised.

Topics covered are provided in writing and provided to all trainees.

19.3 Confidential Reporting of Ethics and Data Integrity Issues

Confidential reporting of data integrity issues is assured through the policies listed above.

19.4 Investigations

All investigations resulting from data integrity issues are conducted confidentially. They are documented and notifications are made to clients who received any negatively affected data that did not meet the client's data quality requirements. Procedures for investigation are dependent on the severity, in general the management team will document the sequence of events leading up to the investigation, and all interviews that are conducted. The laboratory director will make the final decision as to what course of action should be taken.

SECTION 20–PERSONNEL

Policy

McCampbell Analytical, Inc. employs competent personnel based on education, training, experience and demonstrated skills as required. The laboratory's organization chart can be found in Section 4.1.

Policy
Only trained personnel are authorized to perform specific tasks.

Policy
Training records are kept on individual training forms.

20.1 Overview

All personnel are responsible for complying with all quality and data integrity policies and procedures that are relevant to their area of responsibility.

All personnel who are involved in activities related to sample analysis, evaluation of results or who sign test reports, must demonstrate competence in their area of responsibility. Appropriate supervision is given to any personnel in training and the trainer is accountable for the quality of the trainees work. Personnel are qualified to perform the tasks they are responsible for based on education, training, experience and demonstrated skills as required for their area of responsibility.

The laboratory provides goals with respect to education, training and skills of laboratory staff. These goals are outlined in personnel job descriptions. Training needs are identified at the time of employment and when personnel are moved to a new position or new responsibilities are added to their job responsibilities. Ongoing training, as needed, is also provided to personnel in their current jobs. The effectiveness of the training must be evaluated before the training is considered complete.

Contracted personnel, when used, must meet the same competency standards and follow the same policies and procedures that laboratory employees must meet.

20.2 Job Descriptions

Job descriptions are available for all positions that manage, perform, or verify work affecting data quality, and are located in Appendix B. An overview of top management's responsibilities are included in Section 5 – "Management".

Job descriptions include the routine duties, minimum education and qualifications, and experience required for each position. Duties are not limited to those found in the appendix.

20.3 Training

All personnel are appropriately trained and competent in their assigned tasks before they contribute to functions that can affect data quality. It is management's responsibility to assure personnel are trained. Training records are used to document management's approval of personnel competency. The date on which authorization and/or competence is confirmed is included.

Training records are maintained by the QAO.

20.3.1 Training for New Staff

New staff members are given introductory training and orientation upon arrival.

The initial training for a new task contains the following steps:

- All documentation involved with a new and unfamiliar task is read and understood by the trainee.
- Training is under the direct supervision of a qualified senior analyst. During the time the analyst is training, the trainee may sign laboratory notebooks or logbooks, but the senior analyst, who is responsible for the data generated, must cosign laboratory notebooks.
- The trainee demonstrates competency in the new task before they can operate independently. The competency for a test method is accomplished by a demonstration of capability as indicated in Section 19. The initials or signature of the qualified senior analyst on the training form notes approval of competency.
- Each step of the training process is documented, as needed.

Addition of New Methods by senior staff:

- Senior staff members work in conjunction with the Laboratory Director. All training documents will be approved by this person.
- All observations and calculations should be documented at the time they are made. The analyst should keep complete and detailed notes of the method development.
- The published method must be acquired and read thoroughly. During the development any deviations from the method should be documented and discussed with management.
- The analyst should compile a method development plan prior to embarking on the project.
- A detailed SOP should be written, including all quality control elements that the laboratory currently includes in its published method SOPs.
- The competency for the test method is accomplished by a demonstration of capability as indicated in Section 19.

20.3.2 Ongoing Training

Ongoing training will consist of the following:

- Annually, the analyst shows continued proficiency in each method they perform by analyzing Performance Testing Samples or Ongoing Demonstrations of Capability.
- Other training as determined by management.

Additional training techniques utilized may include:

- Lectures
- Programmed learning
- Conferences and seminars

- Short courses
- Specialized training by instrument manufacturers

All laboratory personnel are required to review and update (as necessary) all Standard Operating Procedures (SOPs) that pertain to the work they perform within the laboratory. Any updates to SOPs must have the approval of the Management Team and must conform to the policies of the laboratory. It is the responsibility of the Supervisor to ensure that documentation demonstrating that their employees have read, understand and are using the latest version (including drafts) of SOPs is current and on file.

SECTION 21 – ACCOMMODATIONS & ENVIRONMENTAL CONDITIONS

POLICY
Laboratory facilities are designed and organized to facilitate testing of environmental samples. Environmental conditions are monitored to ensure that conditions do not invalidate results or adversely affect the required quality of any measurement.

POLICY
Environmental tests are stopped when the environmental conditions jeopardize the results.

POLICY
Access to, and use of areas affecting the quality of the environmental tests is controlled by restriction of areas to authorized personnel only.

POLICY
The laboratory workspaces are adequate for their use, and appropriately clean to support environmental testing and ensure an unencumbered work area.

Laboratory space is arranged to minimize cross-contamination between incompatible areas of the laboratory.

21.1 Environmental

Laboratory accommodations, test areas, energy sources, lighting, heating and ventilation must be adequate to facilitate proper performance of tests. The environment in which these activities are undertaken shall not invalidate the results or adversely affect the required accuracy of measurement. The laboratory shall provide for the effective monitoring, control and recording of environmental conditions as appropriate. Such environmental conditions may include biological sterility, humidity, and temperature. In instances where monitoring or control of any of the above-mentioned items is specified in a test method or by regulation, the laboratory shall meet and document adherence to those laboratory facility requirements.

21.2 Work Areas

There shall be effective separation between neighboring areas when the activities therein are incompatible (e.g., volatile organic chemicals handling and analytical

areas). Access to and use of all areas affecting the quality of these activities shall be defined and controlled. Adequate measures will be taken to ensure good housekeeping in the laboratory and to ensure that any contamination does not adversely affect data quality or staff safety.
If the laboratory environment is required to be controlled by method or regulation, the adherence is recorded. Testing occurs only within the laboratory. Laboratory space is maintained and monitored to the specifications required for laboratory space and the testing performed. Electronic balances are located away from drafts and doorways and mounted on marble slabs in areas where their use is affected by vibrations. Biological sterility is measured using air density plates and recorded when necessary according to the bacteriological test methods SOPs. Biological work areas are sterilized between uses. Neighboring test areas of incompatible activities are effectively separated. Specific work areas are defined and access is controlled. (Only authorized laboratory personnel and escorted signed-in visitors may enter the work area.) Good housekeeping measures are employed to avoid the possibility of contamination. Smoking is prohibited.

All equipment and reference materials required for the accredited tests are available in the laboratory. Records are maintained for all equipment, reference measurement materials, and services used by the laboratory.

Reference materials traceable to national standards of measurement or to national standard reference materials are stored away from heavy use areas or major equipment that may affect the proper operation of the materials. Certificates of Traceability are available for the reference thermometer and the Class 1 weights. The reference materials are used only for calibration to maintain the validity of performance.

21.3 Floor Plan

A floor plan can be found on the notice board in the laboratory on the north wall.

21.4 Building Security

The laboratory is kept secure during off hours with an alarm, external cameras and a locked gate**.**

A Visitor's Logbook is maintained for every visitor to sign in and out. Visitors must be accompanied by laboratory personnel when in secure areas.

SECTION 22 – TEST METHODS AND METHOD VALIDATION

POLICY
Methods and/or procedures are available for all activities associated with the analysis of the sample including preparation and testing. For purposes of this Section, "method" refers to both the sample preparation and determinative methods.

Before being put into use, a test method is confirmed by a demonstration of capability or method validation process.

All methods are published or documented. Deviations from the methods are allowed only if the deviation is documented, technically justified, authorized by management and accepted by the customer

22.1 Method Selection

A reference method is a method issued by an organization generally recognized as competent to do so. When the laboratory is required to analyze a parameter by a specified method due to a regulatory requirement, the parameter/method combination is recognized as a reference method. The laboratory will use methods that meet the needs of the customer. Such methods will be based on the latest edition of the method unless it does not meet the needs of the customer. The laboratory selects methods that are appropriate to the customer needs. When the regulatory authority mandates or promulgates methods for a specific purpose, only those methods will be used.

If a method proposed by a customer is considered to be inappropriate or out-of-date, the customer is informed and the issue resolved before proceeding with analysis of any samples (see Section 7 – Review of Requests, Tenders and Contracts).

If a method is not specified by the customer, an appropriate method will be selected using the process outlined below. The customer will be informed of the selected method and must approve its use before being used to report data.

All communications between the laboratory and the customer are documented.

When a method is not specified by the customer, or the proposed method is inappropriate, the laboratory will select a method that is appropriate to the end use of the data:

If the data are to be submitted to a regulatory authority, the method(s) specified by the regulatory authority will be used.
For drinking water compliance a method will be selected from those specified in 40 CFR Part 141, or the applicable state regulations.
For NPDES permits, the method will be selected from those specified in 40 CFR Part 136.
If the end use of the data is not regulatory or if the regulatory authority does not specify a method, the laboratory will determine the customer needs in terms of reporting level (e.g., LOD, LOQ), bias (e.g., screening versus quantitative) and the

laboratory capabilities and capacity. Based on these criteria, the laboratory will select an appropriate method based on the following hierarchy:

Resources from published in regional, national or international standards
Methods published by other technical organizations such as ASTM, Standard Methods or AOAC
Methods develop by the instrument manufacturer
Laboratory –developed methods.

22.2 Laboratory-Developed Methods

If the laboratory develops a method, the process of designing and validating the method is carefully planned and documented. All personnel involved in the method design, development and implementation will be in constant communication during all stages of development. The procedure for methods development is outlined in 20.3.1.

22.3 Method Validation

Validation is the confirmation, by examination and objective evidence, that the particular requirements for a specific intended use are fulfilled.

At a minimum, reference methods are validated by performing an initial demonstration of capability. Additional requirements are discussed for each technology.

All methods that are not reference methods are validated before use. The validation is designed so that the laboratory can demonstrate that the method is appropriate for its intended use. All records (e.g., planning, method procedure, raw data and data analysis) shall be retained while the method is in use. Based on the validation process, the laboratory will make a statement in the laboratory SOP, of the intended use requirements and whether or not the validated method meets the use requirements.

Method validation and Demonstration of Capability procedures are as follows:

22.3.1 Demonstration of Capability (DOC)

A DEMONSTRATION OF CAPABILITY (DOC) is a procedure to establish the ability of the analyst to generate data of acceptable accuracy and precision.

WORK CELLS consist of analysts with specifically defined tasks who together perform the method. Work cells together meet specified acceptance criteria and demonstrations of capability.

The DOC is documented on the form in Appendix C of the 2003 NELAC Standard or equivalent, and these completed forms are kept in the training files for each analyst.

A DOC is performed for each analyte whenever the method, analysts, analytes, or instrument type is changed. New laboratory personnel are trained in basic lab techniques, safety and chemical hygiene, chemistry theory of the test procedures employed, quality control procedures, OMEGA LIMS, record keeping and the operating principles and regulations governing the methods employed by McCampbell Analytical Laboratory. A designated chemist/technician and/or Supervisor closely supervise every new employee until he/she exhibits proficiency in accepted laboratory techniques. This process includes reading specific SOP's and other associated references. Once a chemist/technician demonstrates a technological aptitude within the framework of the Quality Assurance program, he/she will perform an Initial Demonstration of Capability (IDOC) study and a Method Detection Limit (MDL) study (if applicable). This training process is documented for each chemist and each method and is retained in the employee's Training Documentation File. Upon completion of analytical or QA/QC training, the Technical Director or Laboratory Manager should certify that the person is qualified to independently perform the procedures.

The Laboratory Manager or Technical Director certifies that technical staff members in their area of expertise are trained and authorized to perform all tests for which we are accredited by signing the DOC form.

22.3.2 On-Going (or Continued) Proficiency

After the demonstration of capability is completed, on-going proficiency is maintained and demonstrated as needed through the analysis of either Performance Testing samples, performing another DOC, or use of four consecutive laboratory control samples compared to pre-determined acceptance limits for precision and accuracy. This is documented in the training file of each analyst.

As an initial and continuing demonstration of proficiency, laboratory analysts are required to successfully analyze annually (at least once per calendar year) either 1) a blind sample, 2) a blind PT sample, 3) at least four consecutive laboratory quality control samples, 4) an authentic sample that has been analyzed by another trained analyst or 5) another acceptable demonstration of capability. The QAO maintains results of initial and continuing proficiency.
Employees are encouraged to participate in advanced training courses, seminars, and professional organizations and meetings as opportunities and funding become available. Additionally, meetings may be held to discuss procedures, work schedules and problems requiring immediate attention. At the discretion of the analyst's Supervisor or Laboratory Manager, an analyst may demonstrate proficiency in a test method without going through the formal training process. A Statement of Capability form (available from the Quality Assurance office) may be used to document the process of "grandfathering" analysts currently performing a procedure or method of analysis. This decision will be based on the analyst's experience, ongoing training workshops, acceptable PT results, or an IDOC study. The completed form will be maintained in the analyst's Training Documentation File.

22.3.3 Initial Test Method Evaluation

For chemical analyses, the INITIAL TEST METHOD EVALUATION involves the determination of the Limit of Detection (LOD), confirmation of the Limit of Quantitation (LOQ), an evaluation of precision and bias, and an evaluation of the selectivity of the method.

22.3.3.1 Limit of Detection (LOD) / Method Detection Limit (MDL)

The METHOD DETECTION LIMIT (MDL) is an estimate of the minimum amount of a substance that an analytical process can reliably detect. An MDL/LOD is analyte-and matrix specific and may be laboratory-dependent.

22.3.3.2 Limit of Quantitation (LOQ) [Practical Quantitation Limit (PQL)/Reporting Limit (RL)]

The LIMIT OF QUANTITATION (LOQ)/PRACTICAL QUANTITATION LIMIT (PQL) is an estimate of the minimum amount of a substance that can be reported quantitatevely.

When required by a specific method or regulation, the LOQ is verified using a quality systems matrix sample spiked at 1-2 times the determined LOQ that returns a concentration within the acceptance criteria for accuracy, according to the requirements of the method or client data quality objectives.

Policy
If an LOD/MDL study is not performed, concentrations less than the Limit of Quantitation are not reported. If results are not reported outside of the calibration range (low), the LOD determination is not required.

Policy
The lowest calibration standard is equal to or lower than the LOQ/PQL.

Policy
The LOQ/RL will always be at or greater than the LOD/MDL.

LOD/MDLs are determined from a quality system matrix using all sample processing steps, and are verified annually or when there is a change in the test method or instruments affects sensitivity.

The MAI Laboratory quality assurance objectives are described in terms of precision, accuracy, representativeness, and comparability. Criteria for data quality indicators such as matrix spikes, laboratory control samples. Method Detection Limits (MDL) and Reporting Limit (RL) Requirements.

22.3.4 Representativeness

The laboratory objective for representativeness is to provide data, which is representative of the sampled medium. Representativeness is defined as the degree to which data represent a characteristic of a population or set of samples and is

measurement of both analytical and field sampling precision. The representativeness of the analytical data is a function of the procedures used in procuring and processing the samples. The representativeness can be documented by the relative percent difference between separately procured, but otherwise identical samples or sample aliquots.

22.3.5 Comparability

The comparability objective is to provide analytical data for which the accuracy, precision, representativeness and reporting limits statistics are similar to the quality indicators generated by the Laboratory over time. The comparability objective is documented by inter-laboratory studies carried out by regulatory agencies or carried out for specific projects, by comparison of periodically generated statements of accuracy, precision and reporting limits with those of other laboratories and by the degree to which approval from the US EPA or other pertinent regulatory agencies is obtained for any procedure for which significant modifications have been made.

22.3.6 Statistically Derived Limits

Selected methods and programs recommend statistically derived precision and accuracy limits. As needed, the Laboratory may utilize statistically derived limits (based upon laboratory derived data) to evaluate method performance and determine when corrective action may be appropriate. These limits must be equal to or more restrictive than the limits specified in the referenced method. The laboratory may periodically update the limits as stated in this manual. The analysts are instructed to use the current limits posted in the laboratory (dated and approved by the Management Team). The Quality Assurance Manager maintains an archive of all limits used within the laboratory. These updated limits may be equal to or tighter than the limits displayed in this QAM. If limits need to be adjusted outside of the limits in this QAM, the QAM will be revised to reflect these changes. Where EPA acceptability criteria do not exist for a given method being utilized for the first time, a reasonable interim value will be assigned and the control limits will be considered as advisory limits only and will not automatically initiate a corrective action if they are not met.

22.3.7 Method Detection Limits/ LOD

Method Detection Limits (MDLs) are set such that the constituent concentration, when processed through the complete method, produces a signal with a 99% probability that it is different from the blank. MDLs are determined using the method specified in the Federal Register, 40 CFR Part 136 Appendix B. MDLs are based on the latest MDL study available at the time this document was published and may be superseded by the results from new studies. MDLs are updated as required by the relevant published method, or any time there is a significant change in laboratory operations. The detection limit is verified by analyzing a standard at 3 times the MDL for single compounds and 4 times the MDL for multi component methods. The compounds just need to be detected.

22.3.8 Practical Quantitation Limits/ LOQ

Practical Quantitation Limits (PQLs) are usually set at the lowest calibration standard unless otherwise noted. Ease of preparation of commercial analytical mixes may dictate to some extent the reported PQL. In some instances, systematic bias (i.e.,

analyte background in reagents, etc.) necessitates that the reported MDL and PQL be elevated to levels that are readily quantifiable.
Published PQLs may be set higher than experimentally determined PQLs to 1) avoid observed positive interferences from matrix effects or common reagent contaminants, or 2) for reporting convenience (i.e., to group common compounds with similar but slightly different experimentally determined PQLs), or 3) to match industry/regulatory limits. Values between the MDL and PQL can be reported as required by a client; however, these values are always reported as estimated values with qualifier code J (so-called "J-Flagging"). Additionally, non-detected analytes are always reported as less than the PQL if the MDL is not reported. The limit is verified by analyzing a standard at the PQL, it must recover ± 50%.

22.3.9 Precision and Bias

PRECISION is the degree to which a set of observations or measurements of the same property, obtained under similar conditions, conform to themselves. Precision is usually expressed as standard deviation, variance, or range, in either absolute or relative terms.

BIAS is the systematic error that contributes to the difference between the mean of a significant number of test results and the accepted reference value.

Precision and bias are determined for standard methods through the performance of a Demonstration of Capability.

Precision and bias using non-standard, modified standard or laboratory-developed methods are compared to the criteria established by the client (when requested), the method, or the laboratory.

Replicate spikes in a quality system matrix are analyzed according to the procedures outlined in the 2003 NELAC Standard, when applicable.

Precision
The laboratory objective for precision is to meet the precision demonstrated for the analytical methods on similar samples (i.e., limits generated from historical data) and to meet data for the analyses published by the US EPA. Precision is defined as the degree of reproducibility of repetitive measurements under a given set of analytical conditions (exclusive of field sampling variability). It is the degree of mutual agreement among independent measurements as the result of repeated application of the same process under similar conditions. Precision is documented on the basis of replicate analysis, usually duplicate or matrix spike duplicate samples.

Accuracy
The laboratory objective for accuracy is to meet the performance for accuracy demonstrated for the analytical methods on similar samples (i.e., limits generated from historical data) and to meet the recovery data published by the US EPA. Accuracy is defined as the degree agreement of a measured value with the true or expected value of the quantity of concern (per John K. Taylor, in *Quality Assurance of Chemistry Measurements*). It is a statistical measurement of correctness and includes components of random error (variability due to imprecision) and systematic error. It reflects the error associated with a measurement. A measurement is accurate when the value reported does not differ within a specified degree from the true value or known concentration of the spike or standard. Analytical accuracy is

typically measured by determining the percent recovery of known target analytes that are spiked into a field sample (i.e., a surrogate or matrix spike) or reagent water (i.e., laboratory control sample or QC check sample). Surrogate compound recovery is reported and is used to assess method performance for each sample analyzed, when surrogate analysis is appropriate. A statement of accuracy is expressed as an interval of acceptance recovery about the mean recovery.

22.4 Estimation of Uncertainty

Estimation of uncertainty: consists of the sum (combining the components) of the uncertainties of the numerous steps of the analytical process, including, but not limited to, sample plan variability, spatial and temporal sample variation, sample heterogeneity, calibration/calibration check variability, extraction variability, and weighing variability.

The laboratory estimates uncertainty using the relative percent deviation calculated from routine quality control spiked samples. Initially close to 20 spiked samples are prepared following the sample prepararion procedure and the relative percent standard deviation is calculated as follows:
Standard Deviation Formula:
Mean : Mean = Sum of X values / N(Number of values)

$$S=\sqrt{\frac{\sum(X-M)^2}{n-1}}$$

Relative Standard Deviation (RSD) = (Standard Deviation of a Data Set / Mean of a Data Set) x 100

22.5 Control of Data

Policy

All calculations and all relevant data are subject to appropriate checks in a systematic manner.

Policy

Commercial off-the-shelf software (e.g. word processing, database and statistical programs) used within the designed application range is considered sufficiently validated when in-house programming is not used.

To ensure that data are protected from inadvertent changes or unintentional destruction, the laboratory uses procedures to check calculations and data transfers (both manual and automated). To protect the integrity and confidentiality of data entry or collection, data storage, data transmission and data processing, procedures are followed as stated in Section 16.Control of Records.

22.5.1 Computer and Electronic Data Requirements

The laboratory assures that computers, user-developed computer software, automated equipment, or microprocessors used for the acquisition, processing, recording, reporting, storage, or retrieval of environmental test data are:

- documented in sufficient detail and validated as being adequate for use;

- protected for integrity and confidentiality of data entry or collection, data storage, data transmission and data processing;
- maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of environmental test data; and
- held secure including the prevention of unauthorized access to, and the unauthorized amendment of, computer records. Data archive security is addressed in Section 16 – "Control of Records" and building security is addressed in Section 21- "Accommodations and Environmental Conditions".
- The laboratory controls access to all programs that are used to acquire, process, record or report data. All programs are password-protected. Each employee is granted access only to those programs that he or she uses.
- The laboratory controls access to all programs that are used to acquire, process, record or report data. All programs have limited access and capabilities are dependent on the level (e.g. programmer, validator, reviewer, and analyst). An employee is granted access depending on his/her responsibilities and job description. A programmer is given access to change the underlying code, but may not access or modify any data entry. A reviewer may review the data input, and may change entries only when a second reviewer concurs with the modification. Analysts input data, and have an opportunity to check data entries before permanently saving them. After the data has been saved, modifications may be made only with the electronic authorization of the supervisor. Validators may only review data and assign any validation codes necessary to help interpret the data. Once the data have been reviewed, the technical manager authorizes the data for release to the client. The technical manager may not change data, but may alert the applicable supervisor and analyst of any errors.
- The laboratory uses spreadsheets to reduce raw data to final results for all test method. To ensure that the worksheet formulae are correct, the laboratory tests each set of cells used for input of the data as well all cells used for calculations by comparing the results of the spread sheet with manually calculated data. On an ongoing basis every data point is compared to a LIMS generated calculation.
  If any changes are made to the spreadsheet program, the laboratory revalidates the entire system before reporting results.
  In addition, the algorithms all spreadsheet calculations or other programs that are used to reduce raw data to a reported value will be verified upon first use and thereafter compared to the LIMS values to ensure that the process produces accurate results.
  Data from all electronic media are backed up daily to ensure that data are no lost. The backed up copies are stored on level 2 of the building. After the spreadsheet is validated, the calculations are protected from inadvertent manipulations.

22.5.2 Data Reduction

The analyst calculates final results from raw data or appropriate computer programs provide the results in a reportable format. The test methods provide required concentration units, calculation formulas and any other information required to obtain final analytical results.

The laboratory has manual integration procedures that must be followed when integrating peaks during data reduction SOP MAI MANINT.
All raw data must be retained, and is stored electronically, and it is maintained as described in Section 16 – "Control of Records".

22.5.3 Data Review Procedures

Data review procedures are located in Section 23.4 – "Data Review".

SECTION 23 – CALIBRATION REQUIREMENTS

23.1 General Equipment Requirements

Policy
The laboratory provides all the necessary equipment required for the correct performance of the scope of environmental testing presented in this *Quality Manual*.

Policy
All equipment and software used for testing and sampling is capable of achieving the accuracy required and complies with the specifications of the environmental test method as specified in the laboratory SOP.

Policy
Only authorized personnel operate equipment.

Policy
MAI Laboratory is equipped with mechanical and computerized instrumentation. A preventive maintenance schedule has been developed for the Skalar, Elementar, and metals instrumentation to minimize instrument downtime, and to obtain reliable data over the life of the instrument. Analysts and technicians are primarily responsible for preventative and routine maintenance and repair of the instruments. The laboratory has three employees on site that can assist with instrument problems. Major repairs that go beyond the expertise of the analysts, Supervisors and/or Managers are contracted to external specialists.

The service intervals are designated as follows: D = daily; W = weekly; M = monthly; Q = quarterly; SA = semi-annually; A = annually; AN = as needed. The preventive maintenance schedules are based primarily on manufacturer guidance, recommendation in the literature, and the experience of the analysts, Supervisors and Managers. Some of the items will be performed as an integral part of each procedure. Others will be followed as closely as possible, balancing to the extent possible the workload and the urgency of the need for preventive maintenance.

Common sense and familiarity with the performance of each instrument will dictate whether the preventive maintenance schedule needs to be accelerated or delayed for that instrument. Trends and excursions from accepted quality assurance requirements such as QC sample results, degradation of peak resolution, a shift in the calibration curve, and loss of sensitivity are monitored to determine if there is instrument malfunction, and in such cases preventive maintenance is provided on an as-needed basis.

Procedure

Proper maintenance of laboratory instrumentation is a key ingredient to both the longevity of the useful life of the instrument and providing reliable analyses. Maintenance and service requires an alert analytical staff that recognizes the need for equipment maintenance coupled with support services provided either by in-house staff or by vendor technicians. All staff members have the responsibility for insuring that primary maintenance is carried out on instrumentation. All observations and attempts to service instruments must be documented at the time they are made. The primary elements of the equipment maintenance program include:

- All major equipment receives a daily check for such things as pump operation, instrument settings, indicator readings, mechanical operation, clean tubing, clean cells, etc.
- Routine preventive maintenance on all major equipment is performed as needed and records are kept in maintenance logs for all repairs
- Instrument utilization records are maintained in the form of analysis logs or instrument run logs
- A conservative inventory of critical spare parts is maintained for high-use instrumentation;
- Vendor-produced operation and maintenance manuals (where available) are maintained for all laboratory instrumentation.

Daily maintenance responsibilities are generally delegated to the chemists/technicians. This measure improves overall lab productivity by minimizing instrument downtime. Other benefits include job knowledge enhancement, maintenance cost reduction and less frequent out-of control situations. In a situation where the analyst is unable to rectify a problem with the instrument, the lead chemist or laboratory manager steps in to help prior to calling the manufacturer's service representative. All maintenance is documented in the maintenance logbooks to be used as a source of information in solving future instrument problems.

Many consumable parts are kept in stock and in many cases vendors are able to provide for overnight shipment of parts that do not require manufacturer's installation.

Instrument maintenance logbook documenting instrument problems, instrument repair and maintenance activities shall be kept for all major pieces of equipment. It is the responsibility of each Section Chemist or analyst to ensure that instrument maintenance logs are kept for all equipment in his/her Section. Documentation must include all major maintenance activities such as contracted preventive maintenance and service, and in-house activities such as the replacement of electrical components. An extensive spare parts inventory is maintained for routine repairs at the laboratory, consisting of GC columns, AA lamps, fuses, printer heads, tubing, and

other instrument components or adjustment to instrument settings. Entries must include the date, the problem, the corrective actions taken, the name of the person performing the service and, when deemed necessary, a statement that the instrument has returned to control and is available for use. When maintenance or repair is performed by an outside agency, service receipts detailing the service performed can be stapled into the logbooks adjacent to pages describing the maintenance performed if needed.

The laboratory has several pieces of analytical equipment in duplicate. This redundancy allows the laboratory to keep performing critical analyses on one instrument while the other is out of service.
In the event of instrument failure or if critical holding times are approaching, the following options exist:
1. Portions of the sample load may be diverted to duplicate instruments within a facility.
2. The analytical technique may be switched to an alternate approved technique (e.g., Total Hardness by ICP to titration).
3. Samples may be shipped to another certified commercial laboratory. When shipping samples to another facility, COC procedures are followed as required.
In the event of equipment malfunction that cannot be resolved, service shall be obtained from the instrument vendor manufacturer, or qualified service technician, if such a service can be tendered. If on-site service is unavailable, arrangements shall be made to have the instrument shipped back to the manufacture for repair. Back up instruments, which have been approved for the analysis, shall perform the analysis normally carried out by the malfunctioning instrument. If a back-up is not available, sample analysis may be delayed or samples sent (subcontracted) to another certified commercial laboratory. Any item of equipment, which has been subjected to overloading or mishandling, which gives suspect results, or has been shown to be defective, shall be taken out of service. The instrument will be clearly identified and, wherever possible, stored in a different location until it has been repaired and shown by calibration, verification or test to perform satisfactorily. The laboratory shall examine the effect of this defect on previous calibrations or tests.

Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) are readily available for use by laboratory personnel.

All equipment is calibrated or checked before being placed into use to ensure that it meets laboratory specifications and the relevant standard specifications.

Test equipment, including hardware and software, are safeguarded from adjustments, which would invalidate the test results measures, by limiting access to the equipment and using password protection where possible.

When equipment is needed for a test that is outside of permanent control of the laboratory, the lab ensures the equipment meets the requirements of this manual prior to its use by inspecting or otherwise testing it.

Each item of equipment and the software used for testing and significant to the results is uniquely identified and records of equipment and software are maintained. This information includes the following:

a) identity of the equipment and its software;
b) manufacturer's name, type identification, serial number or other unique identifier;
c) checks that equipment complies with specifications of applicable tests;
d) current location;
e) manufacturer's instructions, if available, or a reference to their location;
f) dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration;
g) maintenance plan where appropriate, and maintenance carried out to date; documentation on all routine and non-routine maintenance activities and reference material verifications;
h) any damage, malfunction, modification or repair to the equipment;

Instrument #	VOC Equipment	Manufacturer	Model	Serial/ID No.
GC29	MS	Agilent	5975C (G3170A)	US74617902
	GC	Agilent	7890A (G3440A)	CN10808140
	P&T Autosampler	VARIAN	Archon 4552	98103003
	P&T Concentrator	Tekmar		98182001
	Computer	Hewlatt-Packard	7700	2UA7510QZL
GC28	MS	Agilent	5975C (G3170A)	US873317109
	GC	Agilent	7890A (G3440A)	CN10727073
	P&T Autosampler	VARIAN	Archon 4552	3514A38469
	P&T Concentrator	Tekmar		95132006
	Computer	Hewlatt-Packard	7700	2UA7241301
GC16	MS	Agilent	5973 (G2577A)	US63810219
	GC	Agilent	6890A (G1530A)	US00034859
	P&T Autosampler	VARIAN	Archon 4552	CN10537065
	P&T Concentrator	Tekmar	3100	0016T011
	Control	Tekmar	TT130ELASR2-1	HH85998
	Computer	Hewlatt-Packard	KAYAK XA 0503	US93495728
GC18	MS	Agilent	5973 (G2577A)	US03940632
	GC	Agilent	6890A (G1530A)	US00039633
	P&T Autosampler	VARIAN	Archon 4552	3514A38469
	P&T Concentrator	Tekmar	3100	00287008
	Control	Tekmar	TT130ELASR2-1	HH85998
	Computer	DELL		
GC4	MS	Aglient	5973 (G2577A)	US10441883
	GC	Aglient	6890N (G1530N)	US10146001
	P&T Autosampler	VARIAN	Archon 4552	00304001
	P&T Concentrator	Tekmar	3000	96216004
	Control	Tekmar	TT130ELASR2-1	HH209644 3002
	Computer	DELL	DHM	GD00Z01
GC10	MS	Hewlatt-Packard	5973 (G1098A)	US72010690
	GC	Agilent	G1530A	DE00020257
	P&T Autosampler	VARIAN	Archon 4552	95133206
	P&T Concentrator	Tekmar	3100	US02080011
	Computer	DELL		
GC1	GC	HP	5890	234187
		OI Analytical	5220	A226169
	P&T Concentrator	Tekmar		95132236
	P&T Autosampler	VARIAN	Archon 4552	95145006
	Computer	Hewlatt-Packard	workstation x1000	3408A34687
GC24	MS	Agilent	5975B (G3170A)	US62713953
	GC	Agilent	6890N (G1530N)	CN10633047
		Autocan	14-ACAN-000	US06332009
	Computer	DELL		
	Pressurizer	OMEGA	GP01	

Instrument #	Pesticides Equipment	Manufacturer	Model	Serial/ID No.
GC5	GC5	HP	5890	LR47359C
	CB7	HP	G1512A	CN00001567
	TRAY 5	HP	18596C	US64900322
	Injector T4	HP	6890(18593B)	3529A43261
	Injector T5	HP	6890	
	Computer	HP	KAYAK XA 0503	US0362022
	Thermometer	WATLOW		
	Thermometer	WATLOW		
GC20	GC 20	Agilent	6890N(G1530N)	US10317086
	TRAY 16	Agilent	G2614A	US04109500
	Injector T17	Agilent	7683(G2613A)	CN32030927
	Injector	Agilent	7683(G2613A)	
	Computer	DELL	Dimension 4550	DE03002340
	Thermometer	WATLOW		US72101144
	Thermometer	WATLOW		US72102357
GC22	GC22	Agilent	6890N(G1530N)	CN10540047
	TRAY	Agilent	G2614A	CN53736646
	Injector	Agilent	7683B	
	Injector	Agilent	7683B	
	Computer	HP	KAYAK XA 0503	US93495741
	Thermometer	WATLOW		
	Thermometer	WATLOW		
GC9	GC9	HP	G1530A	US00009312
	CB6	HP	G1512A	US72702490
	TRAY 6	HP	18596C	3514A38469
	Injector	HP	7673(18593B)	3120A27546
	Injector	HP	7673(18593B)	US72102357
	Computer	HP	KAYAK XA 0503	
	Detector	DET		HH209644 3002
	Detector	DET		GD00Z01
	Thermometer	WATLOW		US72010690
	Thermometer	WATLOW		DE00020257
GC15	GC15	Agilent	6890A(G1530A)	US00033554
	TRAY 14	HP	G2614A	US94906687
	Injector 15	HP	7683(G2613A)	US95210929
	Injector 16	HP	7683(G2613A)	DE03002340
	Computer	SONY		US72101144
	Thermometer	WATLOW		
	Thermometer	WATLOW		

Instrument #	Pesticides Equipment	Manufacturer	Model	Serial/ID No.
GC23	GC	Agilent	7683	CN60938780
	TRAY	Agilent	7683	CN60938780
	Injector	Agilent	7683	
	Injector	Agilent	7683B	
	Computer	DELL	DHM	F7CS911
	Thermometer	WATLOW		
	Thermometer	WATLOW		

Instrument #	Diesel Equipment	Manufacturer	Model	Serial/ID No.
GC6	GC6	HP	5890	
	CB4	HP	G1512A	3529A02416
	TRAY	HP	18596C	3620A42011
	Injector 6	HP	6890(18593B)	3524A42931
	Injector	HP	6890	
	Computer	HP	KAYAK XA 0503	US93495760
	Thermometer	WATLOW		
	Thermometer	WATLOW		
GC11	GC11	Agilent	G1530A	US00021256
	TRAY 17	Agilent	7683(G2614A)	US01708132
	Injector 17	Agilent	7683(G2613A)	US81100469
	Injector	Agilent	7683(G2613A)	
	Computer	HP	KAYAK XA 0503	US93495742
	Thermometer	WATLOW		
	Thermometer	WATLOW		
GC2	GC2	HP	5890	
	CB	HP	18596C	US71201361
	TRAY2	HP	G2614A	3509A38183
	Injector	HP	6890(G1513A)	US71301546
	Injector	HP	6890(G1513A)	
	Computer	Share with GC11		
	Thermometer	WATLOW		
	Thermometer	WATLOW		

Instrument #	SVOC Equipment	Manufacturer	Model	Serial/ID No.
GC17	GC17	Agilent	6890A(G1530A)	US00037561
	MS	Agilent	5973(G2577A)	US03340462
	TRAY	Agilent	7683	
	Injector	Agilent	7683(G2613A)	US11818842
	Computer	DELL	OPTIPLEX 745	
	Thermometer	WATLOW		
GC21	GC21	Agilent	6890N(G1530N)	CN10537065
	MS	Agilent	5973(G2577A)	US52440548
	TRAY	Agilent	7683	
	Injector	Agilent	7683B(G2913A)	CN62433591
	Computer	HP		CN19CA68C0
	Thermometer	WATLOW		
GC8	GC8	Agilent	6890A(G1530A)	US00006394
	MS	HP	5973(G1098A)	US63810219
	CB	HP	G1512A	US64900376
	TRAY 1	HP	18596B	3408A34687
	Injector	HP	7673(18593B)	3150A20-----
	Injector	HP		
	Computer	DELL	OPTILEX 745	
	Thermometer	WATLOW		
	Thermometer	WATLOW		

Instrument #	Light Gas Equipment	Manufacturer	Model	Serial/ID No.
CG26	GC	VARIAN	CP-3800/3380	103920
	Flame Ion Detector			US72102101
	Thermo Conductive Detector			DE03002340
	Thermo Conductive Detector			US72102101
	Pulsed Discharge Detector	VICI		
	Computer		CM	E85-04765
				80045-609-287-258

Instrument #	G-MBTEX Equipment	Manufacturer	Model	Serial/ID No.
GC19	GC	HP	5890(G1223A)	3240A00181
	P&T Concentrator	HP	3100	US71510666
	Control	HP	TT130ELASR2-1	HH41326
	P&T Autosampler	Tekmar	2016	95300004
	P&T Autosampler	Tekmar	2032	91228029
	Computer			
GC12	GC	HP	5890	
	P&T Concentrator	Tekmar	3000	98086001
	Control	HP	TT130ELASR2-1	HH54720
	P&T Autosampler	Tekmar	2016	98103003
	P&T Autosampler	Tekmar	2032	98182001
	Computer	HP	workstation x1100	
GC3	GC	HP	5890	
	P&T Concentrator	Tekmar	3000	93180005
	Control	Tekmar	TT130ELASR2-1-GY-TEK	HH212273 3502
	P&T Autosampler	Tekmar	2016	93078016
	P&T Autosampler		2032	93223006
	Computer			
GC7	GC	HP	5890	
	P&T Concentrator	Tekmar	3100	US02318003
	Control	Tekmar	TT130ELASR2-1	HH49248
	P&T Autosampler	Tekmar	2016	95241020
	P&T Autosampler	Tekmar	2032	94153009
	Computer	HP	workstatkon x1100	

Instrument #	Micro	Manufacturer	Model	Serial/ID No.
Incubator		Thermolyne	142300	
		VWR		
Microscope		Reichert	Quebec Darkfield Colony Counter	
		VWR	Vista Vision	0629934
		Motic	DMB3-223	30401998
Quanti-Tray Sealer		IDEXX	2X	
Mineral light lamp		UVP	UVGL-58	US72102101
Hotplate		CORNING	PC-101	DE03002340
		VWR		US72010690
Water bath	#1	VWR		DE00020257
	#2	SHEL-LAB	1225PC	
	#3	VWR	1225PC	
	#4	VWR		
	#4(old)	PRECISION	180	
Scale		Excellence	XS2002S	1127133321
Blender		Retsch	GRINDMIX GM200	200302012B
Auto clave		Market Forge	STM	10-6226-D

Instrument #	Extractions Equipment	Manufacturer	Model	Serial/ID No.
H24	Hot Block Hot Block	Environmental Express Environmental Express	Large B CAL-3.6C Small B CAL-16C	
	Timer	CRALAB	173	006869
H25	Hot Block	Environmental Express	CAL-4C	
	Timer	CRALAB		
H26	Furnace	Thermolyne	1400	
	Hot Plate	CORNING	PC-35	
Centrifuge	Centrifuge	IEC	Model K	71653303
	Centrifuge	Fisher Scientific		HH209644 3002
Scale	Scale #1	METTLER TOLEDO	PB1502-S	GD00Z01
	Scale #2	METTLER TOLEDO		US72010690
V1	BIG VORTEXER	GLAS-COL		DE03002340
	Timer	GLAS-COL		US72101144
V2	BIG VORTEXER	GLAS-COL		US72102357
	Timer	GLAS-COL		
V3	BIG VORTEXER	GLAS-COL		
Computer	Computer	DELL	OPTIPLEX GX240	89Y7M11
Label printer	Label printer	SII	240	

Instrument #	HPLC/IC Equipment	Manufacturer	Model	Serial/ID No.
IC1	IC	Agilent	1100(G1314A)	JP43826841
	IC Seperation Center	Metrohm	733	09131
	Pump Unit	Metrohm	752	
	IC Detector	Metrohm	732	08139
	VA Detector	Metrohm	791	02110
	IC Interface	Metrohm	762	04171
	IC Pump	Metrohm	709	
	Suppressor Module	Metrohm	753	
	IC Sample Processor	Metrohm	766	
	Post-Column Reactor	PICKERING	CRX400	
	Computer	HP	workstation x 1000	2716176
IC2	IC	Agilent	1100(G1314A)	JP20216435
	Control	Agilent	G1323B	CN14903353
	IC Sample Processor	Metrohm	766	
	Value Unit	Metrohm	812	DE91607039
	Pump Unit	Metrohm	752	US64401872
	IC Detector	Metrohm	732	DE73300161
	IC Interface	Metrohm	762	DE91607039
	IC Pump	Metrohm	709	98086001
	Pump Unit	Metrohm	752	HH54720
	Computer	HP	workstation x2100	2777193
IC3	IC	Metrohm	850	
	Sample Processor	Metrohm	858	6.2041.440
HPLC1	Degasser	HP	1100(G1322A)	JP72106248
	Quat Pump	HP	1100(G1311A)	US72101999
	ALS	HP	G1313A	US72102101
	FLD	Agilent	1100(G1321A)	DE03002340
	DAD	HP	1100(1315A)	US72101144
	ColComp	HP	G1316A	US72102357
	Post-Column Derivatizer	PICKERING	PCX	1001209
	Computer	DELL	DIMENSION 2350	CN-0G1494-70821-33Q-46VS

Instrument #	HPLC/IC Equipment	Manufacturer	Model	Serial/ID No.
HPLC2	HPLC2	Agilent	1100	
	Degasser	Agilent	1100(G1379A)	JP13210790
	Quat Pump	Agilent	1100(G1311A)	DE33223840
	ALS	HP	1100(G1313A)	US82404283
	ALS Therm	HP	1100(G1330A)	DE733300258
	FLD	Agilent	1100(G1321A)	DE14903921
	DAD	Agilent	1100(G1315B)	DE33219528
	ColComp	Agilent	1100(G1316A)	DE33234735
	Computer	HP	KAYAK XV800	
HPLC3	HPLC3	HP	1100	
	Degasser	HP	1100(G1322A)	JP63204824
	Quat Pump	HP	1100(G1311A)	US70601673
	FLD	Agilent	1200(G1321A)	DE60555623
	DAD	HP	1100(G1315A)	DE91607039
	ColComp	HP	1100(G1316A)	US64401872
	ALS	HP	1100(G1329A)	DE73300161
	ALS Therm	HP	1100(G1330A)	DE82290287
	Computer			
HPLC4	HPLC4	HP	1100	
	Degasser	HP	1100(G1322A)	JP63203653
	Quat Pump	HP	1100(G1311A)	US53600530
	ALS	Agilent	1100(G1313A)	DE33223131
	FLD	Agilent	1100(G1321A)	DE40506261
	DAD	HP	1100(G1315A)	DE61800777
	ColComp	HP	1100(G1316A)	US54000692
HPLC5	HPLC5	Agilent	1100	
	Degasser	Agilent	1200(G1322A)	JP62357755
	Quat Pump	Agilent	1100(G1311A)	DE43828870
	ALS	HP	G1329A	DE82202960
	FLD	Agilent	1100(G1321A)	DE43606488
	RID	Agilent	1100(G1362A)	CN43801575
	ColComp	Agilent	1100(G1316A)	DE43642647
	computer	HP	Pavilion a1000y	MXG60300VZ

Instrument #	Research Equipment	Manufacturer	Model	Serial/ID No.
GC25	GC/MS/MS	VARIAN	4000	0047113487
	Autosampler	VARIAN	CP-8400	05905
	Gas filter	VARIAN	CP17973	
	Thermometer	WATROW		173113
	DS	VARIAN	SQ395	243631
	Computer	DELL	OPTIPLEX745	
GC30	GC	Agilent	7890A(G3440A)	CN10832151
	Detector	Agilent	5975C(G3174A)	US81849985
	Injector	Agilent	7683B	
	Autosampler	Agilent	7683(G2614A)	CN82649346
	Computer	HP	Dc7800	MXL8280-J6M
GC14	GC	Agilent	G1530A	US00032062
AED	AED	HP	35900E	CN00001204
			G2350A	
H27	Lamp	UVP	entela	95-0007-05
	Hot plate	CORNING	PC-600	440937
	Sonicator #1	BRANSON	1210	
H28	Bath	Thermo Fisher Scientific	2846	202664
	Soxhlet	Glas-Col		71653303
	Recirculator	VWR		HH209644 3002
H29	Evaporator #1	Horizon		GD00Z01
		TRENTON		US72010690
H30	GPC	J2	AccuPrep MPS	
	Computer	COMPAQ	268900-999 (KN9X)	USU319048R
Balance	Balance	SAUTER	AR1014	US72010690
H6	Sonicator	BRANSON	1510	DE03002340
	Sonicator	SONICS	vibra cell	US72101144
H8	Evaporator	Horizon	DryVap	US72102357
	PSE	Applied Seperations		
	Evaporator	LABCONCO	RapidVap	

Instrument #	Wet Chemistry Equipment		Manufacturer	Model	Serial/ID No.
SKALAR	Computer		DELL	DIMENSION 2350	CN-0G1494-70821-34P-2C2K
			SKALAR	SAN SYSTEM	
	Digestion UV Control		SKALAR	Total CN	
	Distiller Temp Control		SKALAR	NH3	
	Colorimetric Temp Control	37	SKALAR	NH3	
	Distiller Temp Control	125	SKALAR	Total CN	
	Colorimetric Temp Control	40	SKALAR	Total CN	
	Autosampler				
SKALAR			SKALAR	SAN SYSTEM	
	Digestion UV Control		SKALAR	Total P	
	Crtho Phosphate		SKALAR	Total P	
	Digestion Temp Control	37	SKALAR	Total P	
	Distiller Temp Control	125	SKALAR	Phenol	
	Digestion Temp Control	40	SKALAR	Total N	
	Autosampler				
	Thermometer				
	Balance		METTER TOLEDO		1120503255
	Hot Plate		SOLID STATE	4817	259010
	Hot Plate		CORNING		
	Hot Plate		CORNING		
	Filter		MILLIPORE	LP1000 ZD5111584	F2CM72307Q
	Filter		MILLIPORE	Milli-Q Gardient ZMQ56V001	F6CN17818D
	Washer		BOSCH	FLASKSCRUBBER	
	Washer		LABCONCO		
	chiller		VWR		
H10	Mini Hot plate				

Instrument #	Wet Chemistry Equipment		Manufacturer	Model	Serial/ID No.
H10	Mini Hot plate				
H13	Oven 1	TDS	PRECISION		
	Oven 2	TSS, TS	VWR	1305U	
	Oven 3		VWR		
H14			Environmental Express	EMD1920-106	2130
			Environmental Express	EMD1920-106	2131
H15	Mini Hot plate		VWR	220	
	Mini Hot plate		VWR	200	
	Mini Hot plate		VWR	200	
	Mini Hot plate		VWR	200	
H16	Hot Plate		Thermolyne	nuova II	
	Vacuum Pump		Welch	GEM 10 8890	
H17					
TOC	computer		DELL	OPTIPLEX GX240	
	TOC-V		SHIMADZU	CSH	
	ASI-V		SHIMADZU	ASI-V40954897	638-93141-05
	pH, ISE conductivity meter		Denver Instrument	Model 250	
	Balance	MB1	METTER TOLEDO	AJ100	
	Vacuum Pump		Welch	2003B	KK061295
HACH	Turbidimeter		2100N		
TITRINO	GPT Titrino		Metrohm	799	
	Stirrer		Metrohm	728	
	Dosimat		Metrohm	685	
	TiStand		Metrohm	703	
	KF Coulometer		Metrohm	831	
	Balance		Satorius	CP225D	
			Satorius		
	Computer		DELL	OPTIPLEX GX240	
CNS	CNS		elementar	vario MAX CNS	
	Computer				
	BOMEN	5520	MICHELSON	MB-Series	
ICP-JY	ICP-AES	HORIBA	ULTIMA2	586	ICP-JY
ICP-MS1	ICP-MS		Agilent	G3162A	JP14100
ICP-MS2	ICP-MS		Agilent	7500	JP51202111

23.2 Support Equipment

SUPPORT EQUIPMENT includes, but is not limited to: balances, ovens, refrigerators, freezers, incubators, water baths, temperature measuring devices, volumetric dispensing devices, and thermal/pressure sample preparation devices.

Policy
All support equipment is maintained in proper working order and records are kept of all repair and maintenance activities, including service calls.

All raw data records are retained to document equipment performance. These records include logbooks, data sheets, or equipment computer files.

All support equipment is calibrated or verified annually over the entire range of use using NIST traceable references where available. The results the calibration of support equipment are within specifications or (1) the equipment is removed from service until repaired, or (2) records are maintained of correction factors to correct all measurements.

Support equipment such as balances, thermometers, ovens, refrigerators, freezers, and water baths are checked with appropriate reference standards, traceable to NIST where possible, each day prior to use, to ensure they are operating within the expected range for the application for which the equipment is to be used.

Mechanical volumetric dispensing equipment, including burettes (except Class A glassware), is checked for accuracy quarterly.

Glass micro-liter syringes have a certificate attesting to the established accuracy. If the certificate of accuracy for glass micro-liter syringes is not available, the accuracy of the syringe is demonstrated upon receipt and documented.

For microbiology analyses, records for autoclaves used in the laboratory are required for the following:

- initial performance of the autoclave functional properties (supplier by the installer);
- temperature demonstration of sterilization continuous monitoring device or maximum registering temperature;
- for every cycle, record date, contents, maximum temperature reached, pressure, time in sterilization mode, total run time, and analysts initials;
- regular maintenance check to include a pressure check and calibration of temperature device.

Acceptance Criteria for Support Equipment		
Equipment Identification	**Use**	**Acceptance Criteria**
INC 1	Method 1601/1602, transfer cultures	36°C ± 1.0°C
INC 2	Actinomycetes, Clostridium	28°C ± 1.0°C, 42°C ± 0.5°C
INC 3	Hybridization oven	51°C ± 1.0°C, 80°C ± 1.0°C
INC 4	Fungi, general use	36°C ± 1°C
W/B 1	Melt and temper agar	48°C ± 3.0°C
W/B 2	Method 1602, thaw hosts	37°C ± 1.0°C, 48°C ± 3.0°C
W/B 3	Grow hosts for Method 1601/ 1602	36°C ± 1.0°C
W/B 4	Shaking bath for hybridization	51°C ± 0.2°C
REFRIG 1	Sample storage	1 to 6°C
REFRIG 2	Reagent/ media storage	1 to 6°C
REFRIG 3	Reagent storage	1 to 6°C
FREEZ 2	Ice packs, reagent storage	-20°C to -30°C
FREEZ 3	Host stocks, sewage filtrate, virus stocks, samples	Shelf 1 -70°C ± 10°C Shelf 2 -70°C ± 10°C Shelf 3 -70°C ± 10°C Shelf 4 -50°C ± 10°C Shelf 5 -50°C ± 10°C
FREEZ 4	Sample storage	-70°C ± 10°C

23.2.1 Support Equipment Maintenance

Regular maintenance of support equipment, such as balances and fume hoods is conducted at least annually.

Maintenance on other support equipment, such as ovens, refrigerators, and thermometers is conducted on an as needed basis.

Records of maintenance to support equipment are documented in Instrument Maintenance Logs. Each piece of support equipment does not necessarily have its own logbook. Maintenance logbooks may be shared with equipment that is housed in the same laboratory area.

23.2.2 Support Equipment Calibration

Calibration requirements for analytical support equipment are found in the table below. For analytical instrumentation, the calibration requirements are found below.

Calibration And Maintenance			
Instrument	**Activity**	**Frequency**	**Documentation**
Balance	1. Clean 2. Check with NIST-Weights 3. Outside Service	1. Before use 2. Annually 3. Annually	1) Worksheet/log book 2) Worksheet/logbook 3) Certificates
ASTM Class 1Weights	1. Only use for the intended purpose 2. Use plastic forceps to handle 3. Keep in case 4. Re-calibrate	Recalibrate once every 5 years	Keep certificate
Thermometers: 1. Glass and electronic 2. Dial thermometers	Check at the temperature used, against a reference NIST certified thermometer	1. Annually for glass and electronic 2. Quarterly for dial thermometers	Calibration factor and date of calibration on thermometer and worksheet/log book
pH electrometers	Calibration: 1. pH buffer aliquot are used only once 2. Buffers used for calibration will bracket the pH of the media, reagent, or sample tested.	Before use	Worksheet/log book
pH probe	Maintenance: Use manufacturer's specifications	As needed	Worksheet/log book
Spectrophotometer.	1. Keep cells clean 2. Service contract. Check wavelength settings with standards	Annually	Post service date on spectrophotometer
Automatic or digital type pipettes	Calibrate for accuracy and precision using reagent water and analytical balance	Quarterly	Worksheet/logbook
Refrigerators, Freezers, and BOD incubators	1. Thermometers are immersed in liquid to the appropriate immersion line 2. The thermometers are graduated in increments of 1 °C or less	Temperatures are recorded each day in use	Worksheet/log book
Sterilizer	1. Use a maximum-temperature-registering thermometer or a continuous recording device. 2. Use spore strips or ampules. 3. In house maintenance of autoclave or service contract. 4. Hot air ovens must maintain a stable temperature of 170°C - 180°C for at least two hours	1. Each cycle 2. One sterilizing cycle per month. 3. Once per year	Worksheet/log book
Microbiological incubators, and water baths	1. Thermometers in each unit are immersed in liquid to the appropriate immersion line 2. The thermometers will be graduated in increments of 0.5 °C (0.2 °C increments for tests which are incubated at 44.5 °C) or less	Temperature of incubators and water baths will be recorded twice a day for each day in use with readings separated by at least four hours	Worksheet/log book
DO electrometer	Calibrate as specified in SOP	Before use	Worksheet/log book
DO probe	Maintenance as specify by manufacturer	As needed	Worksheet/log book

23.3 Analytical Equipment

23.3.1 Maintenance for Analytical Equipment

Policy
All equipment is properly maintained, inspected, and cleaned.

Procedure scheduled preventive maintenance or maintenance on an as-needed basis due to instrument malfunction and is documented in Instrument Maintenance Logs, which become part of the laboratory's permanent
Maintenance of analytical instruments and other equipment may include regularly records.

Analytical Equipment Maintenance

Instrument	Procedure	Frequency
AA (Graphite Furnace)	Clean lens and furnace head Replace windows Check or change cuvette Check & drain compressor drain Clean atomizer cell/furnace hood Nebulizer cleaned/dried Clean filters Change graphite tube/platform Empty waste container Remove carbon tube and check wear Check sample introduction probe	Daily As required Daily Daily Daily Weekly or as required Weekly As required Daily Daily Daily
ICP	Check pump tubing Check liquid argon supply Check fluid level in waste container Check filters Clean or replace filters Check torch Check sample spray chamber for debris Clean and align nebulizer Check entrance slit for debris Change printer ribbon Replace pump tubing	Daily Daily Daily Weekly As required Daily Monthly Monthly Monthly As required As required
UV-Vis Spectrophotometer	Clean ambient flow cell Precision check/alignment of flow cell Wavelength verification check	As required As required Semi-annually
IR Spectrophotometer	Clean cell Check/adjust cell alignment	Annually As required
GC/MS	Ion gauge tube degassing Pump oil-level check Pump oil changing Analyzer bake-out Analyzer cleaning MS source c leaning Rinse MCM Baking the trap Change column COMPUTER SYSTEM AND PRINTER: Air filter cleaning Change data system air filter Printer head carriage lubrication Paper sprocket cleaning Drive belt lubrication	As required Monthly Semi-annually As required As required As required As required As required As required As required As required As required As required As required

Analytical Equipment Maintenance		
Instrument	**Procedure**	**Frequency**
Gas Chromatograph	Compare standard response to previous day or since last initial calibration	Daily
	Check carrier gas flow rate in column	Daily via use of known compound retention
	Check temp. of detector, inlet, column oven	Daily
	Septum replacement	Daily
	Glass wool replacement	As required
	Check system for gas leaks with SNOOP	W/cylinder change as required
	Check for loose/fray wires and insulation Bake injector/column	Monthly
		As required
	Change/remove sections of guard column	As required
	Replace connectors/liners	As required
	Change/replace analytical column(s)	As required
Electron Capture Detector (ECD)	Detector wipe test (Ni-63)	Semi-annually
	Detector cleaning	As required
Flame Ionization Detector (FID)	Detector cleaning	As required
Photoionization Detector (PID)	Change O-rings	As required
	Clean lamp window	As required
HPLC	Change guard columns	As required
	Change lamps	As required
	Change pump seals	Semi-annually or as required
	Replace tubing	As required
	Change fuses in power supply	As required
	Filter all samples and solvents	Daily
	Change autosampler rotor/stator	As required
Balances	Class "S" traceable weight check	Daily, when used
	Clean pan and check if level	Daily
	Field service	At least annually
Conductivity Meter	0.01 M KCl calibration	Daily
	Conductivity cell cleaning	As required
Turbidimeter	Check light bulb	Daily, when used
Deionized/Distilled Water	Check conductivity	Daily
	Check deionizer light	Daily
	Monitor for VOA's	Daily
	System cleaning	As required
	Replace cartridge & large mixed bed resins	As required
Drying Ovens	Temperature monitoring	Daily
	Temperature adjustments	As required
Refrigerators/ Freezers	Temperature monitoring	Daily
	Warning system checked	Monthly
	Temperature adjustment	As required
	Defrosting/cleaning	As required
Vacuum Pumps/ Air Compressor	Drained	Weekly
	Belts checked	Monthly
	Lubricated	Semi-annually
pH/Specific Ion Meter	Calibration/check slope	Daily
	Clean electrode	As required
BOD Incubator	Temperature monitoring	Daily
	Coil and incubator cleaning	Monthly
Centrifuge	Check brushes and bearings	As needed
Water Baths	Temperature monitoring	Daily
	Water replaced	Monthly or as needed

23.3.2 Initial Instrument Calibration

Initial instrument calibration and continuing instrument calibration verification are an important part of ensuring data of known and documented quality. If more stringent calibration requirements are included in a mandated method or by regulation, those calibration requirements override any requirements outlined here or in laboratory SOPs. Generally, instrument calibrations are provided in test methods.

Policy
All initial instrument calibrations are verified with a standard obtained from a second source traceable to a national standard when commercially available. If a second source is not available, a standard prepared from a separate lot may be used as long as the manufacturer can demonstrate the lot was prepared independently from other lots purchased.

Policy
Any samples that are analyzed after an unacceptable initial calibration are re-analyzed or the data are reported with qualifiers, appropriate to the scope of the unacceptable condition.

Policy
Quantitation is always determined from the initial calibration unless the test method or applicable regulations require quantitation from the continuing calibration.

Policy
The lowest calibration standard is the lowest concentration for which quantitative results can be reported without qualification. The lowest calibration standard is equal to the Limit of Quantitation and is greater than the limit of detection.

Policy
The highest calibration standard is the highest concentration for which quantitative results can be reported.

Policy
Data reported that are greater than the highest calibration standard without dilution are considered to be an estimate and are reported with a qualifier code and explained in the case narrative.

Initial instrument calibration includes calculations, integrations, acceptance criteria, and associated statistics referenced in the test method SOP.

Sufficient raw data records are collected to allow reconstruction of the initial instrument calibration. These include, at a minimum, calibration date, test method, instrument, analysis date, analyte names, analysts signature or initials in Excel,

concentration and response, calibration curve or response factor, or unique equation or coefficient used to reduce instrument responses to concentration.

Calibration date and expiration date (when recalibration is due) is recorded for equipment requiring calibration, where practicable.

Acceptance criteria are listed in individual method SOP's.

Corrective actions are performed when the initial calibration results are outside acceptance criteria. Calibration points are not dropped from the middle of the curve unless the cause is determined and documented. If the cause cannot be determined, the calibration curve is re-prepared. If the lowest or highest calibration point is dropped from the curve, the working curve is adjusted and sample results outside the curve are qualified.

Results that are less than the lower calibration standard are considered to have increased uncertainty, and are either reported with a qualifier code or explained in the case narrative.

Results that are greater than the highest calibration standard are either diluted to within the calibration range, or considered to be an estimate; and are reported with a qualifier code and explained in the case narrative.

For instrumentation where single point calibration is recommended by manufacturer's instructions, such as with some ICP technologies (with a zero and single point calibration), the following apply:

a) The linear range of the instrument is established by analyzing a series of standards, as required by the relevant analytical method(s).

b) For single point plus zero blank calibrations, the zero point and the single point standard are analyzed prior to the analysis of samples.

c) Zero blank and single point calibration standards are analyzed with each sequence for methods where they are specified.

d) The linearity of single point plus zero blank calibrations is verified at a frequency established by the method or the manufacturer.

23.3.3 Continuing Instrument Calibration

Policy
The validity of the initial calibration is verified prior to sample analysis by use of a continuing instrument calibration verification (CCV) standard.

Policy
Corrective action is initiated for continuing instrument calibration verification results that are outside of acceptance criteria.

Continuing instrument calibration verification is performed at the beginning and end of each analytical batch, except for instances when an internal standard is used. For methods employing internal standards, only one verification is performed at the beginning of the analytical batch.

Continuing instrument calibration verification is performed whenever it is expected that the analytical system may be out of calibration or might not meet verification acceptance criteria.

Continuing instrument calibration verification is performed when the time period for calibration or the most recent calibration verification has expired.

Continuing instrument calibration verification is performed for all analytical systems that have a calibration verification requirement.

Calibration is verified for each compound, element, or other discrete chemical species.

The calculations and associated statistics for continuing instrument calibration are included or referenced in the test method SOP.

Sufficient raw data records are retained to allow reconstruction of the continuing instrument calibration verification. Continuing instrument calibration verification records connect the continuing verification date to the initial instrument calibration. Continuing instrument calibration verification are included in individual SOP's.

23.3.4 Unacceptable Continuing Instrument Calibration Verifications

If routine corrective action for continuing instrument calibration verification fails to produce a second consecutive (immediate) calibration verification within acceptance criteria, then a new calibration is performed or acceptable performance is demonstrated after corrective action with two consecutive calibration verifications.

For any samples analyzed on a system with an unacceptable calibration, some results may be useable if qualified and under the following conditions:

a) If the acceptance criteria are exceeded high (high bias) and the associated samples are below detection, then those sample results that are non-detects may be reported as non-detects.

b) If the acceptance criteria are exceeded low (low bias) and there are samples that exceed the maximum regulatory limit, then those exceeding the regulatory limit may be reported.

SECTION 24 – MEASUREMENT TRACEABILITY

Measurement quality assurance comes in part from traceability of standards to certified materials.

POLICY
All equipment used that affects the quality of test results are calibrated prior being put into service and on a continuing basis. These calibrations are traceable to national standards of measurement where available.

POLICY
Measurements from laboratory equipment provide the uncertainty required by test method or client.

POLICY
If traceability of measurements to SI units is not possible or not relevant, evidence for correlation of results through interlaboratory comparisons, proficiency testing, or independent analysis is provided.

All equipment that affects the quality of test results are calibrated according to the minimum frequency suggested by the manufacturer, by regulation, by method, or as needed.

Clients can verify that required uncertainty is achieved by reviewing the internal quality control data, if requested.

24.1 Reference Standards

REFERENCE STANDARDS are standards of the highest quality available at a given location, from which measurements are derived.

Policy
Reference Standards, such as ASTM Class 1 weights, are used for calibration only and for no other purpose unless it is shown that their performance as reference standards will not be invalidated.

Traceability of measurements shall be assured using a system of documentation, calibration, and analysis of reference standards. The laboratory equipment that are peripheral to analysis and whose calibration is not necessarily documented in a test method analysis or by analysis of a reference standard shall be subject to ongoing certifications of accuracy. At a minimum, these must include procedures for checking specifications ancillary equipment: balances, thermometers, temperature, Deionized (DI) and Reverse Osmosis (RO) water systems, automatic pipettes and other volumetric measuring devices. With the exception of Class A Glassware (including glass microliter syringes that have a certificate of accuracy), quarterly accuracy checks are performed for all mechanical volumetric devices. Wherever possible, subsidiary or peripheral equipment is checked against standard equipment or standards that are traceable to national or international standards. An external certified service engineer services laboratory's balances and pipettes on an annual basis. This service is documented on each balance with a signed and dated

certification sticker. Balances calibrations are checked each day of use. All mercury thermometers are calibrated annually against a traceable reference thermometer. Temperature readings of ovens, refrigerators, and incubators are checked on each day of use. The laboratory's DI and RO water systems have documented preventative maintenance schedules and the conductivity of the water is recorded on each day of use.

Traceability The receipt of all reference standards must be documented. References standards are labeled with a unique Standard Identification Number, date received, and the expiration date. All documentation received with the reference standard is retained as a QC record and references the Standard Identification Number. All standards should be purchased with an accompanying Certificate of Analysis that documents the standard purity. If a standard cannot be purchased from a vendor that supplies a Certificate of Analysis, the purity of the standard is documented by analysis. The documentation of standard purity is archived, and references the Standard Identification Number. All efforts are made to purchase standards that are > 97.0% purity. If this is not possible, the purity is used in performing standards calculations. The accuracy of calibration standards is checked by comparison with a standard from a second source. In cases where a second standard manufacturer is not available, a different lot is acceptable for use as a second source. The appropriate Quality Control (QC) criteria for specific standards are defined in the laboratory's SOPs. In most cases, the analysis of an Initial Calibration Verification (ICV) or the laboratory Control Sample (LCS) is used as the second source confirmation.

Reagents are, in general, required to be analytical reagent grade unless otherwise specified in method SOPs. Reagents must be at a minimum the purity required in the test method. The date of reagent receipt and the date the reagent was opened are documented.

24.2 Reference Materials

REFERENCE MATERIALS are substances that have concentrations that are sufficiently well established to use for calibration or as a frame of reference.

Policy
Reference materials, where commercially available, are traceable to national standards of measurement, or to Certified Reference Materials, usually by a Certificate of Analysis.

Policy
Internal reference materials, such as working standards or intermediate stock solutions, are checked as far as technically and economically possible.

Purchased Reference Materials require a Certificate of Analysis where available. Otherwise, purchased reference materials are verified by application to a certified reference material, interlaboratory comparison, and/or demonstration of capability.

Internal Reference Materials, such as working standards and intermediate stock solutions, are checked with a demonstration of capability, proficiency tests, and/or independent analysis.

a) Internal thermometers are checked annually against the NIST certified reference thermometer.
b) Working class weights are checked against Class 1 weights annually.
c) Class A pipettes are verified for accuracy gravimetrically quarterly.
d) Working standards or intermediate stock solutions are checked against a second source at first time of use. When a second source is not available, a vendor certified different lot is accepted as a second source. In most cases, the analysis of an Initial Calibration Verification (ICV) standard or a Laboratory Control Sample (LCS) can be used as a second source confirmation. Working standards and intermediate stock solutions are given expiration dates when they are prepared based on method or regulatory requirements. These standards are used up or disposed of by the expiration date.

24.3 Transport and Storage of Reference Standards and Materials

Policy
The laboratory handles and transports reference standards and materials in a way that protects their integrity.

Reference standard and material integrity is protected by separation from incompatible materials and/or minimizing exposure to degrading environments or materials.

Reference standards and materials are stored according to manufacturer's recommendations and separately from working standards or samples.

24.4 Labeling of Reference Standards, Reagents, and Materials

Policy
Reference standards and materials are tracked from purchase, receipt, and storage through disposal.

Policy
The receipt of all reference standards must be documented. References standards are labeled with a unique Identification Number, date received, and the expiration date. All documentation received with the reference standard is retained as a QC record.

Policy
Reagent quality is verified prior to usage.

Records for all standards, reagents, reference materials, and media include:

1. the manufacturer/vendor name (or traceability to purchased stocks or neat compounds)
2. the manufacturer's Certificate of Analysis or purity (if supplied)
3. the date of receipt
4. reference to the method of preparation
5. date of preparation
6. recommended storage conditions
7. an expiration date after which the material shall not be used (unless its reliability is verified by the laboratory). It may be documented elsewhere if referenced.
8. preparer's initials (if prepared)

In methods where the purity of reagents is not specified, analytical reagent grade is used. If the purity is specified, that is the minimum acceptable grade. Purity is verified and documented according to Section 9, Purchasing, Services, and Supplies.

All containers of standards, reagents, or materials, whether original or prepared, are labeled with an expiration date.

All containers of prepared standards and reference materials have a preparation date and unique identifier. This laboratory uses Lab Id, Date and Initials.

Standard preparation records are kept in laboratory notebooks and indicate traceability to purchased stocks or neat compounds, reference to the method of preparation, date of preparation, expiration date, and preparer's initials.

Prepared reagents are verified to meet the requirements of the test method through blank analysis.

SECTION 25 – COLLECTION OF SAMPLES

Policy
McCampbell Analytical, Inc. does not provide sampling services. The laboratory's responsibility in the sample collection process lies in supplying the sampler with the necessary coolers, reagent water, sample containers, preservatives, sample labels, custody seals, COC forms, ice, and packing materials required to properly preserve, pack, and ship samples to the laboratory.

25.1 Sampling Containers

The laboratory offers clean sampling containers for use by clients. The containers are certified by the vendor to be of known cleanliness and contain method required preservatives.

25.1.1 Preparing Container Orders

Containers (containing any required preservatives) are provided to the client upon request. A bottle request form is received from the client and given to the sample receiving staff. The appropriate bottles are put into a cooler with packing material, and coolant, if required. Chain of custodies are supplied for the clients use. The coolers are either delivered by McCampbell Analytical, Inc. couriers or shipped using UPS services.

25.1.2 Sampling Containers, Preservation Requirements, Holding Times

Summary of Sampling Container, Preservation and Holding Time Requirements				
Parameter Group	**Approved Method**	**Container (Per Sample)**	**Dechlorinate / Preservation**	**Holding Time**
Water				
Asbestos & Dioxin	Subcontracted	2 x 1 L Amber Glass	Cool 4°C	48 hr/ 7 day
Radiologicals (GA, RA 226, RA 228)	Subcontracted	2 x 1 L HDPE	HNO3 to pH <2	6 Months
TCLP	1311	1 x 1 L Glass min.	Cool 4°C	14 Days
Volatile Organics	(THM) 502.2	3 x 40mL VOA Vials	$Na_2S_2O_3$/ZHS/4°C	14 Days
Volatile Organics	602	3 x 40mL VOA Vials	$Na_2S_2O_3$/HCL pH<2/ZHS/4°C	14 Days
Volatile Organics	8021	4 x 40mL VOA Vials	$Na_2S_2O_3$/HCL pH<2/ZHS/4°C	14 Days
Volatile Organics	524.2	4 x 40mL VOA Vials	$C_6H_8O_6$/HCL pH<2/ZHS/4°C	14 Days
Volatile Organics	624	4 x 40mL VOA Vials	$C_6H_8O_6$/HCL pH<2/ZHS/4°C	14 Days
Volatile Organics	8260	3 x 40mL VOA Vials	$C_6H_8O_6$/HCL pH<2/ZHS/4°C	14 Days
EDB & DBCP	(SOC) 504.1	2 x 40mL VOA Vials	$Na_2S_2O_3$/ZHS/4°C	14 Days
Semi-Volatile Organics	(SOC) 505	2 x 40mL VOA Vials	$Na_2S_2O_3$/ZHS/4°C	7 Days
Nitrogen/Phosphorus Pesticides	(SOC) 507	1 x 1 L Amber Glass	$Na_2S_2O_3$/Cool 4°C	14 Days
Chlorinated Herbicides	(SOC) 515.4	125 mL Amber Glass	$Na_2S_2O_3$/Cool 4°C	14 Days
Endothall	(SOC) 548.1	1 x 250 mL Amber Glass	$Na_2S_2O_3$/Cool 4°C	7 Days
Glyphosate HPLC	(SOC) 547	1 x 250 mL Amber Glass	$Na_2S_2O_3$/Cool 4°C	14 Days
Diquat HPLC	(SOC) 549.2	1 x 250 mLHDPE Amber	Cool 4°C, Dark	7 Days
Phthalate/Adipate/Benzo(a)pyrene	(SOC) 525.2	1 x 1 L Amber Glass	HCL to pH<2	14 Days
Haloacetic Acids	(HAA) 552.2	1 x 250 mL Amber Glass	NH_4Cl	14 Days
Pesticides	608	1 x 1 L Amber Glass	Cool 4°C	7 Days
Herbicides	8151	1 x 1 L Amber Glass	Cool 4°C	7 Days
Organo Phosphorus Pesticides	8141	1 x 1 L Amber Glass	Cool 4°C	7 Days
Base Neutral Acids	625/8270	1 x 1 L Amber Glass	Cool 4°C	7 Days
Carbamates, HPLC	(SOC) 531.1	2 x 40 mL Vials	Chloroacetic Acid to pH<3	28 Days
Gasoline Range Organics	8015	2 x 40 mL VOA Vials	HCL to pH<2, Cool 4°C	14 Days
Diesel Range Organics	8015	1 x 1 L Amber Glass	HCL to pH<2, Cool 4°C	7 Days
PCBs in Oil	8082	1 x 40 mL VOA (min 10 mL)	N/A	N/A
Soils				
TCLP / SPLP	1311, 1312	100 g min	Cool 4°C	14 Days
Volatile Organic Compounds	8021/8260	4 x 40 mL VOA Vials(5g)	MeOH/DI Water	14 Days
Semivolatile Organic Compounds	8270	8 oz Glass	Cool 4°C	14 Days
PCBs/Pesticides/Herbicides	8082/8081/8151	8 oz Glass	Cool 4°C	14 Days

Abbreviations:
HCL= Hydrochloric Acid
HNO_3= Nitric Acid
$Na_2S_2O_3$ = Sodium Thiosulfate
ZHS = Zero Head Space
H_2SO_4= Sulfuric Acid
NaOH= Sodium Hydroxide
$C_6H_8O_6$ = Ascorbic Acid
MeOH = Methanol
NH_4Cl = Ammonium Chloride
HDPE = High Density Polyethylene

If preservation or holding time requirements are not met, the procedures in Section 12 – "Control of Nonconforming Environmental Testing Work" are followed.

26. HANDLING SAMPLES AND TEST ITEMS

26.1 Sample Receipt

Policy
The minimum conditions a sample must meet on receipt are, temperature, pH, bottle type, sample integrity, full-required documentation (sample ID, location, date and time of collection, collector's name, preservation type (outlined below), sample type, and comments), and holding times.

If these conditions are not met, the client is contacted prior to any further processing.

26.1.1 Chain of Custody

The chain of custody or sample submission sheets from the field are reviewed. This documentation is completed in the field and provides a written record of the handling of the samples from the time of collection until they are received at the laboratory. Section 25 – "Collection of Samples" outlines what information is needed on this record. The chain of custody form also provides information on what type of testing is being requested and can act as an order for laboratory services in the absence of a formal contract. Chain of custody and any additional records received at the time of sample submission are maintained by the laboratory.

26.1.1.1 Legal Chain of Custody

The laboratory has procedures for legal chain of custody services. If samples are noted as being used for legal/evidentiary purposes, special chain of custody procedures are put into place by the laboratory. Custody seals are sent by the lab if the sampling containers are ordered from the laboratory, shipping records are maintained with the chain of custody, internal chain of custody is initiated that provides additional documentation of internal handling by analysts and a disposal record is provided.

26.2 Sample Acceptance

The laboratory checks samples for the conditions above, where appropriate, to evaluate sample acceptance.

26.2.1 Preservation Checks

The following preservation checks are performed and documented upon receipt:

Thermal preservation:

a) For temperature preservation, the temperature is recorded on the sample receipt checklist. This checklist is emailed to the client upon the completion of login.

b) For samples that require preservation at 4°C, the acceptable range is "from just above freezing to 6°C".

c) Samples that are delivered to the lab the same day as they are collected are likely not to have reached a fully chilled temperature. This is acceptable if there is evidence that chilling has begun.

d) Record on the receipt form if ice is present and the temperature.

Chlorine checks:

e) Fish toxicity samples, where needed, will be checked for Chlorine using a strip test with 1 ppm sensitivity. It is the responsibility of the sampler/client to check residual chlorine for microbiological samples from chlorinated water systems.

pH checks:

f) The pH of samples requiring acid/base preservation is checked upon sample receipt or upon initiation of analysis.

Sample submission sheets from the field are maintained filed with the Chain-of-Custody and are scanned electronically and kept in an electronic data base.

If the checks performed upon sample receipt indicate the criteria are not met, then 1) the sample is rejected as agreed with the client, 2) the decision to proceed is documented and agreed upon with the client, and 3) the condition is noted on the Chain of Custody form and/or lab receipt documents. The data are qualified in the report only if the Hold Time is exceeded, with an "H" qualifier.

26.3 Sample Identification

Policy
Samples, including subsamples, extracts, and digestates, are uniquely identified in a permanent chronological record (such as a sample receipt log book or database) to prevent mix-up and to document receipt of all sample containers.

Procedure
Samples are assigned sequential numbers that reference more detailed information kept in the electronic database.

See SOP , Sample Log In and Receipt

The following information is collected in the sample receipt log located on the OMEGA LIMS system:

a) Client or project name

b) Date and time of sampling
c) Date and time of receipt at lab
d) Unique laboratory identification number
e) Unique field identification number (may be same as lab #)
f) Initials of recorder
g) Analyses requested
h) Comments regarding rejection (if any).

All documentation received regarding the sample, such as memos or chain of custody, are retained in an electronic data base.

26.4 Sample Aliquots / Subsampling

Sub-sampling within the laboratory is performed according to test method SOPs.

26.5 Sample Storage

Storage conditions are monitored for any required criteria, verified, and the verification recorded in logbooks.

Samples that require thermal preservation are stored under refrigeration that is +/-2°C of the specified preservation temperature unless regulatory or method specific criteria require something different. For samples with a specified storage temperature of 4°C, storage at a temperature above the freezing point of water to 6°C is acceptable.

Samples are held secure, as required. Samples are accessible only to laboratory personnel.

Samples are stored apart from standards, reagents, food or potentially contaminating sources, and such that cross-contamination is minimized. All portions of samples, including extracts, digestates, leachates, or any product of the sample is maintained according to the required conditions.

26.6 Sample Disposal

Policy

Samples are disposed of according to Federal, State and local regulations. Procedures are available for the disposal of samples, digestates, leachates, and extracts.

Samples are retained a minimum of 30 days after the report is sent out unless other arrangements have been made with the client.
Disposal procedures are described in MAISSD SOP.

26.7 Sample Transport

Policy
Samples that are transported under the responsibility of the laboratory, where necessary, are done so safely and according to storage conditions. This includes moving bottles within the laboratory. Specific safety operations, where relevant, may be addressed outside of this document.

26.8 Sampling Records

Policy
MAI Laboratory does not perform field sampling.

Sub-sampling within the laboratory is performed according to test method SOPs.

Relevant sampling data are recorded by the project field sampling team, including the sampling procedure used, 2) the identification of the sampler, 3) environmental conditions (if relevant), 4) the sampling location, and 5) the statistics upon which the sampling procedures are based.

SECTION 27 – QUALITY ASSURANCE FOR ENVIRONMENTAL TESTING

Policy
All essential quality control elements are collected and assessed on a continuing basis.

Policy
The qualities of test results are recorded in such a way that trends are detectable, and where practicable, are statistically evaluated.

Policy
For test methods that do not provide acceptance criteria for an essential quality control element or where no regulatory criteria exist, acceptance criteria are developed. Control limits are developed using the mean, plus or minus 3 standard deviations; or static limits such as +/- 30 percent. These limits can be found in the individual test method SOP's.

Policy
Laboratory personnel follow the quality control procedures specified in test methods. The most stringent of control procedures is used in cases where multiple controls are offered. If it is not clear which is the most stringent, that mandated by test method or regulation is followed.

To monitor the validity of environmental tests performed, review includes any one or combination of the techniques below:

a) use of certified reference materials or cultures and/or internal quality control using secondary reference materials;
b) participation in proficiency testing programs;
c) replicate testing using the same or different methods

In addition to procedures for calibration, the laboratory monitors quality control measurements such as blanks, laboratory control samples (LCS), matrix spikes (MS), duplicates, surrogates and internal standards to assess precision and accuracy. Proficiency Testing samples are also analyzed to assess laboratory performance.

Quality control data are analyzed and, when found to be outside pre-defined criteria, action is taken to correct the problem and to prevent incorrect results from being reported. Data associated with quality control data outside of criteria and still deemed reportable will be qualified so the end user of the data may make a determination of the usability of the data - see Section 28 – "Reporting of Results".

27.1 Essential Quality Control Procedures

The quality control procedures specified in test methods are followed by laboratory personnel. The most stringent of control procedures is used in cases where multiple controls are offered. If it is not clear which is the most stringent, that mandated by test method or regulation is followed.
For test methods that do not provide acceptance criteria for an essential quality control element or where no regulatory criteria exist, acceptance criteria are developed. Usually $\pm$ 20% for Inorganics and $\pm$ 30% for Organics.
Written procedures to monitor routine quality controls including acceptance criteria are located in the test method SOPs, and include such procedures as;

a) use of laboratory control samples and blanks to serve as positive and negative controls for chemistry methods;
b) use of laboratory control samples to monitor test variability of laboratory results;
c) use of calibrations, continuing calibrations, certified reference materials and/or PT samples to monitor accuracy of the test method;
d) measures to monitor test method capability, such as limit of detection, limit of quantitation, and/or range of test applicability, such as linearity;
e) use of regression analysis, internal/external standards, or statistical analysis;
f) use of reagents and standards of appropriate quality;
g) procedures to ensure the selectivity of the test method;
h) measures to assure constant and consistent test conditions, such as temperature, humidity, rotation speed, etc., when required by test method;
i) use of sterility checks for equipment, media and dilution water for microbiology; and

j) use of positive and negative culture controls for microbiology.

27.2 Internal Quality Control Practices

Analytical data generated with QC samples that fall within prescribed acceptance limits indicate the test method is IN CONTROL.

QC samples that fall outside QC limits indicate the test method is OUT OF CONTROL (non-conforming) and that corrective action is required or that the data are qualified.

Policy
Detailed QC procedures and QC limits are included in test method standard operating procedures (SOPs).

Policy
All QC measures are assessed and evaluated on an on-going basis, so that trends are detected.

The following general controls are used:
Positive and Negative Controls such as:

a) Blanks (negative)

b) Laboratory control sample (positive)

c) Reference Toxicants (positive)

d) Sterility checks and control cultures (positive and negative).

Selectivity is assured through:

a) absolute and relative retention times in chromatographic analyses;

b) two-column confirmation when using non-specific detectors;

c) use of acceptance criteria for mass-spectral tuning (found in test method SOPs);

d) use of the correct method according to its scope assessed during method validation; and

e) use of reference cultures (positive and negative) from a recognized manufacturer (where applicable).

Consistency, Variability, Repeatability, and Accuracy are assured through:

a) proper installation and operation of instruments according to manufacturer's recommendations or according to the processes used during method validation;

b) monitoring and controlling environmental conditions (temperature, access, proximity to potential contaminants);

c) selection and use of reagents and standards of appropriate quality; and

d) cleaning glassware appropriate to the level required by the analysis. For microbiology, glassware care the use of detergents designed for laboratory use, testing new test tube batches for alkaline or acid residue with bromothymol blue, and conducting an Inhibitory Residue test when the detergent is changed.

e) following SOPs and documenting any deviation, assessing for impact, and treating data appropriately;

f) testing to define the variability and/or repeatability of the laboratory results, such as replicates;

g) use of measures to assure the accuracy of the test method, including calibration and/or continuing calibrations, use of certified reference materials, proficiency test samples, or other measures;

h) use of duplicate plate counts on positive samples (microbiology only).

Acceptance or rejection criteria are created according to laboratory policy where no method or regulatory criteria exist. Acceptance criteria define the boundary for the appropriate response from laboratory personnel, such as corrective action, reporting with qualifiers, reanalysis, review, and others.

Test Method Capability is assured through:

a) establishment of the limit of detection where appropriate;

b) establishment of the limit of quantitation or reporting level; and/or

c) establishment of the range of applicability such as linearity;

Data conversion is assured to be accurate by:

a) selection of appropriate formulae to convert raw data to final results such as regression;

b) periodic review of data reduction processes to assure applicability;

c) microbiological calculations, data reduction, and statistical interpretations specified by each test method.

The following tables summarize the key elements of a quality control system for a laboratory performing chemistry and microbiology testing.

Essential Quality Control Elements for Chemistry			
Item	**Frequency**	**Acceptance Criteria**	**Corrective action**
Negative Control (Method Blank)	1/batch	Result < MDL, or < PQL, or Method Specific	Qualify data and take corrective action
Positive Control (Laboratory Control Sample)	1/batch	Method specific or determined by laboratory	Reprocess, reanalyze, or qualify data.
Matrix Spike; Matrix Spike Duplicates	Per method requirement	Method specific or determined by laboratory	Corrective action and qualify data.
Surrogate spikes	Per method requirement	Method specific or determined by laboratory	Corrective action and qualify data
Matrix Duplicates	Per method requirement	Method specific or determined by laboratory	Corrective action and qualify data
Continuing Calibration Verification	Per method requirement	Method specific or determined by the laboratory	Reanalyze standard immediately; Corrective action
Initial calibration Verification	Start of each analytical run	Method specific or determined by laboratory	Reanalyze standard immediately; Corrective action

Essential Quality Control Requirements for Microbiology – All Methods			
Item	**Frequency**	**Acceptance Criteria**	**Corrective action**
Sterility blank	Each lot of media prior to first use	No growth	Investigate cause
Sterility check containers	One container (bottle) for each lot or batch sterilized (NSGM)	No growth	Investigate cause
Sterility check dilution water	One per batch of dilution water (NSGM)	No growth	Investigate cause
Positive control[1]	pure culture of target organisms/ each lot or batch of medium (prior to first use of medium)	Positive reaction	Investigate cause If necessary reject the medium
Negative control[1]	Pure culture of non-target organisms/each lot or batch of medium (prior to first use of medium)	Negative reaction	Investigate cause If necessary reject the medium
Duplicate colony counts (For numeric results only)	Every sample, if sufficient sample volume is provided	RPD < 50%	Investigate cause Qualify data
1) Microorganisms may be single use preparations or cultures maintained by documented procedures that demonstrate the continued purity and viability of the organism.			

Essential Quality Control Requirements for Microbiology – Filtration Methods Only			
Item	**Frequency**	**Acceptance Criteria**	**Corrective action**
Sterility blank media	Each lot of media prior to first use	No growth	Investigate cause
Sterility check equipment	Beg/end of each run Select one: - 1 for every 10 samples - Preserilize	No growth	Investigate cause Qualify data
Sterility check filters	One filter for each new lot of membrane filters (NSGM)	No growth	Investigate cause
Target organism verification (D.3.4.b)	Method specific	Confirmation of reaction	Investigate cause

Essential Quality Control Requirements for Microbiology – Pour Plate Methods Only			
Item	**Frequency**	**Acceptance Criteria**	**Corrective action**
Sterility blank media	Each lot of media prior to first use minimum one plate per batch	Internally defined Suggest 1 col/plate	Investigate cause

Stock Cultures		
Item	**Frequency**	**Handling**
Reference cultures	Single use	Preserved and handled per mfg. specifications
Reference culture Reference stock	Culture stocks to make working stocks	Preserved and not refrozen Handling per mfg specs

Stock Cultures		
Item	**Frequency**	**Handling**
Working stocks	Not transferred more than five times. Not sub-cultured to replace reference stocks	

27.2.2 Specific Controls

27.2.2.1 Method Blanks

Policy
Contaminated blanks are identified according to the acceptance limits in the test method SOPs or laboratory documentation.
Policy
Samples associated with a contaminated blank are evaluated as to the appropriate corrective action for the samples (e.g. reprocessing or data qualifying codes).

Method blanks are processed along with and under the same conditions as the associated samples to include all steps in the method. A method blank must be analyzed at a minimum of one per preparation batch. When no separate preparation method is used the batch is defined as the environmental samples that are analyzed with the same method and personnel, using the same lots of reagents, not to exceed the analysis of twenty environmental samples, not including method blanks, LCS, matrix spikes and matrix duplicates. The matrix of the method blank must be similar to the associated samples and be free from any analytes of interest. Method blanks are not required for some analyses such as pH, conductivity, flash point, temperature, etc.

MAI identifies a blank as contaminated when an analyte result is greater than the Method Detection Limit or Practical Quantitation Limit (Reporting Limit), depending on the method, or where the contamination affects the sample results according to test method requirements or client objectives.

When a blank is determined to be contaminated, the cause must be investigated and measures taken to minimize or eliminate the problem.

Data that are unaffected by the blank contamination (non-detects or other analytes) are reported unqualified.

Sample data that are suspect due to the presence of a contaminated blank are reanalyzed or qualified.

27.2.2.2 Laboratory Control Samples

LABORATORY CONTROL SAMPLES (LCS) are prepared from analyte free reagent water, and spiked with verified and known amounts of analytes for the purpose of establishing precision or bias measurements.

Policy
Laboratory control samples are analyzed at a frequency mandated by method, regulation, or client request, whichever is more stringent.

The results of Laboratory Control Samples (LCS) are calculated in percent recovery or other appropriate statistical technique that allows comparison to established acceptance criteria. The laboratory documents the calculation in the various method SOPs.

McCampbell Analytical routinely analyze Laboratory Control Sample even when not required by the analytical method.

The LCS percent recovery is compared to the acceptance criteria as published in the mandated test method, or where there are no established criteria, the laboratory established limits.

For LCS results outside established criteria corrective action is documented or the data are reported with appropriate data qualifying codes.

When no separate preparation method is used the batch is defined as the environmental samples that are analyzed with the same method and personnel, using the same lots of reagents, not to exceed the analysis of twenty environmental samples, not including method blanks, LCS, matrix spikes and matrix duplicates.
The analytes to be spiked in the LCS are specified in the test method SOP. In some cases a client may specify a list of analytes for spiking and the request is handled using the laboratory's nonconformance procedures. For list containing more than 10 analytes. There is an acceptable marginal exceedence.

The number of allowable marginal exceedences determined as follows:
>90 analytes in LCS, no more than 5 analytes allowed in ME of the LCS control limit
71-90 analytes in LCS, no more than 4 analytes allowed in ME of the LCS control limit?
51-70 analytes in LCS, no more than 3 analytes allowed in ME of the LCS control limit?
31-50 analytes in LCS, no more than 2 analytes allowed in ME of the LCS control limit?
11-30 analytes in LCS, no more than 1 analytes allowed in ME of the LCS control limit?
<11 analytes in LCS, no analytes allowed in ME of the LCS control limit?

If the same analyte exceeds the LCS control limit more than 5 consecutive spikes, it is an indication of a systemic problem. The source of the error must be located and corrective action taken.

The results of laboratory control samples (LCS) are calculated in percent recovery or other appropriate statistical technique that allows comparison to established acceptance criteria. The calculation is as follows;

$$\%R = \frac{AV}{TV} \times 100$$

Where
AV = Analyzed Value
TV = True Value

27.2.2.3 Matrix Spikes and Matrix Spike Duplicates

MATRIX SPIKES (MS and MSD [duplicates]) are environmental samples fortified with a known amount of analyte to help assess the effect of the matrix on method performance.

Policy
The MS/MSD results are used to help assess the effect of the sample matrix on method performance.

The laboratory procedure for MS/MSD includes spiking appropriate analytes at appropriate concentrations, calculating percent recoveries and relative percent difference (RPD), and evaluating and reporting the results.

Where there are no established criteria, the laboratory uses 70% to 130% as the control limits for MS/MSD. See the individual acceptance criteria as published in the mandated test method or Standard Operating Procedure for individual requirements.

If the LCS and blank meet criteria, MS/MSD results outside established criteria are attributed to client matrix effects.

The calculation is as follows;

$$\%R = \frac{AV}{TV} \times 100$$

Where
AV = Spike Result – Sample Result
TV = True Value

$$RPD = \frac{|S - D|}{\frac{(S + D)}{2}} \times 100$$

Where:
S=Sample Concentration
D=Duplicate Concentration

27.2.2.4 Surrogate Spikes

Surrogate spikes are substances with chemical properties and behaviors similar to the analytes of interest used to assess method performance in individual samples. Surrogates are added to all samples (in test methods where surrogate use is appropriate) prior to sample preparation or extraction.

Surrogate recovery results are compared to the acceptance criteria as published in the mandated test method. Where there are no established criteria, the laboratory uses 70-130% as surrogate control limits.

For surrogate results outside established criteria, data are evaluated to determine the impact. Corrective actions include rerun and qualifying data.

27.3 Proficiency Test Samples or Interlaboratory Comparisons

Policy
The laboratory participates in proficiency test (PT) samples as required, per certification.

Policy
The laboratory institutes corrective action procedures for failed PT samples.

Policy
The laboratory does not share PT samples with other laboratories, does not communicate with other laboratories regarding current PT sample results, and does not attempt to obtain the assigned value of any PT sample from the PT provider.

27.3.1 Compliance to Accreditation Requirements

The laboratory analyzes at least two TNI-compliant PT samples per calendar year for each accreditation Fields of Proficiency Testing (FoPT) for which the laboratory is accredited. An exception is made for analytes where there is no PT available from any PTPA approved PT provider at least twice per year. In these cases the lab will run the PTs in the minimum time frame the PTs are available and not at all if they are not available.

27.3.2 PT Sample Handling, Analysis and Reporting

Proficiency Testing (PT) samples are treated as typical samples in the normal production process where possible, including the same analysts, preparation, calibration, quality control and acceptance criteria, sequence of analytical steps, number of replicates, and sample log-in. PT samples are not analyzed multiple times unless routine environmental samples are analyzed multiple times. Where PT samples present special problems in the analysis process, they will be treated as laboratory samples where clients have special requests.

The type, composition, concentration and frequency of quality control samples analyzed with the PT samples are the same as with typical samples.

Prior to the closing date of a study, laboratory personnel do not:

- Subcontract analysis of a PT sample to another laboratory being run for accreditation purposes.
- Knowingly receive and analyze a PT for another laboratory being run for accreditation purposes.
- Communicate with an individual from another laboratory concerning the analysis of the PT sample.
- Attempt to find out the assigned value of a PT from the PT Provider.

The laboratory's procedure for handling low level PT samples is to calibrate the instrument at a level appropriate to the PT level, if not report the sample as less than the lowest standard.

PT sample results are put into an excel spread sheet automatically from the instrument or hand entered into the sheet, in the same manner as client samples. The excel spread sheet is uploaded to the PT provider and then downloaded into their data base.

Retention of PT records is similar to that maintained for regular environmental samples. In addition the lab maintains a copy of the data that is electronically uploaded to the PT provider.

27.4 Data Review

Policy
The laboratory reviews all data generated in the laboratory for compliance with method, laboratory and, where appropriate, client requirements.

Policy
All data review is documented.

Initially, the analyst reviews data for acceptability of quality control measures and accuracy of the final result(s). The analyst initial reviews the data in the instrument software, and then exports it to Microsoft EXCEL for calculation and further analysis.

After the initial review, the data is reviewed by a member of the Data Entry department. Data Entry imports the raw data into LIMS and calculates the final results. The results from LIMS are compared to the results generated by the analyst in Microsoft EXCEL. These two calculations are completely independent, using the same raw instrumental data. Should the two calculations match, the data is checked as acceptable in LIMS and a final report is generated. Any discrepancies between the EXCEL and LIMS data are immediately investigated and resolved.

Quality Control criteria are coded into both LIMS and EXCEL, and data that exceeds those criteria are flagged.

Final reports are evaluated by the Laboratory Manager, or appropriate deputy, and if acceptable, all data and QC results are signed before sending to the client.

SECTION 28 – REPORTING OF RESULTS

POLICY
The result of each test carried out is reported accurately, clearly, unambiguously, and objectively and complies with all specific instructions contained in the test method.

POLICY
Data are reported without qualification if they are greater than the lowest calibration standard, lower than the highest calibration standard, and without compromised sample or method integrity.

28.1 Test Reports

Policy
The report format has been designed to accommodate each type of test performed and to minimize the potential for misunderstanding or misuse.

Each test report generated contains the following information (unless not required by the client):

a) a title, such as Test Report or Test Results;

b) the name and address of the laboratory, the location of the laboratory if different from the address, and the phone number and name of a contact person;

c) unique identification of the test report (the "workorder" number) on each page and a pagination system that ensures that each page is recognized as part of the test report and a clear identification of the end of the report, such as 3 of 10;

d) the name and address of the client if applicable;

e) the identification of the test method used;

f) an unambiguous identification of the sample(s), including the client identification code;

g) the date of sample receipt when it is critical to the validity and application of the results, date and time of sample collection, dates the tests were performed, the date of sample preparation and analysis if the required holding time for either activity is less than or equal to 72 hours;

h) reference to the sampling plan and procedures used by the laboratory where these are relevant to the validity or application of the results;

i) the test results with failures identified, units of measurement, an indication of whether results are calculated on a dry weight or wet weight basis, and for Whole Effluent Toxicity, an identification of the statistical package used;

j) the name, function, and signature or an equivalent electronic identification of the person authorizing the test report, and the date of issue;

k) a statement to the effect that the results relate only to the samples;

l) at the laboratory's discretion, a statement that the report shall not be reproduced except in full without written approval of the laboratory (this is not commonly included);

m) certification that the results are in compliance with the appropriate standard (CE ELAP, ISO/IEC 17025:2005, NELAP), where appropriate, if accredited to be in compliance or provide reasons and/or justification if they do not comply.

28.2 Supplemental Test Report Information

When necessary for interpretation of the results or when requested by the client, test reports include the following additional information:

a) deviations from, additions to, or exclusions from the test method, information on specific test conditions, such as environmental conditions, and any non-standard conditions that may have affected the quality of the results, and any information on the use and definitions of data qualifiers;

b) a statement of compliance/non-compliance when requirements of the quality systems are not met, including identification of test results that did not meet sample acceptance requirements, such as holding time, preservation, etc.;

c) where applicable and when requested by the client, a statement on the estimated uncertainty of the measurement;

d) where appropriate and needed, opinions and interpretations

a. When opinions and interpretations are included, the basis upon which the opinions and interpretations are documented. Opinions and interpretations are clearly marked as such in the test report.

e) additional information which may be required by specific methods or client;

f) qualification of results with values outside the working range.

28.3 Environmental Testing Obtained from Subcontractors

Test results obtained from test performed by subcontractors are clearly identified on the test report by subcontractor name and/or accreditation number.

The test results from subcontractors are reported in writing or electronically. A copy of the subcontractors report is be made available to the client if requested.

28.4 Electronic Transmission of Results

Policy
All test results transmitted by telephone, fax, telex, e-mail, or other electronic means comply with the requirements of this *Quality Manual* and associated procedures to protect the confidentiality and proprietary rights of the client.

28.5 Amendments to Test Reports

Policy
Material amendments to a test report after it has been issued are made only in the form of another document or data transfer. All supplemental reports meet all the requirements for the initial report and the requirements of this *Quality Manual*.

Amended test reports include a heading which includes amended report.

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Appendix A

Ethics and Data Integrity Policy

It is the policy of McCampbell Analytical, Inc. (MAI) to always work with the highest of scientific and ethical integrity. It is a basic and expected responsibility of each staff member and manager to hold the highest ethical standard of professional conduct in the Performance of all duties.

I,_____, agree to always conduct myself in a manner of high ethical integrity with respect to the work that I perform. I will follow all prescribed MAI methodological procedures and adhere to the criterion set forth with these methodologies to the best of my ability. It is my responsibility to know every facet of my analysis including, proper handling criterion, reporting limits, acceptance criterion etc. I will not knowingly falsify or manipulate data for any reason. And deviations from standard MAI procedures must be acknowledged and deemed appropriate by my supervisor.

_____
Signature of Employee

_____
Print Name

_____
Date

Appendix B - Job Descriptions

Title	Education Minimum	Experience Minimum	Routine Duties
Inorganic Laboratory Supervisor	BS in scientific or engineering discipline.	Three years of laboratory experience.	1. Over sees analytical personnel 2. Performs analysis when necessary. 3. Develops new methods. 4. Trains personnel 5. Follows QA/QC procedures. 6. Follows ethics and integrity protocol.
Organic Laboratory Supervisor	BS in scientific or engineering discipline.	Three years of laboratory experience.	1. Over sees analytical personnel 2. Performs analysis when necessary. 3. Develops new methods. 4. Trains personnel 5. Follows QA/QC procedures. 6. Follows ethics and integrity protocol.
Microbiology Laboratory Supervisor	BS in science.	Three years of laboratory experience.	1. Over sees analytical personnel 2. Performs analysis when necessary. 3. Develops new methods. 4. Trains personnel 5. Follows QA/QC procedures. 6. Follows ethics and integrity protocol.
GC/MS Operator	BS in scientific or engineering discipline.	Two years of laboratory experience. Experience in Mass spectral interpretation.	1. Performs analysis, is responsible for reporting results. 2. Follows QA/QC procedures. 3. Follows ethics and integrity protocol.
GC Operator	BS in scientific or engineering discipline.	One years of laboratory experience. In lieu of a degree, three years of experience in GC analysis.	1. Performs analysis, is responsible for reporting results. 2. Follows QA/QC procedures. 3. Follows ethics and integrity protocol.

Title	Education Minimum	Experience Minimum	Routine Duties
ICP Spectroscopist	BS in scientific or engineering discipline.	Two years of laboratory experience.	1. Performs analysis, is responsible for reporting results. 2. Follows QA/QC procedures. 3. Follows ethics and integrity protocol.
ICP Operator	BS in scientific or engineering discipline.	One year of laboratory experience. In lieu of a degree, three years of experience in operating an ICP.	1. Performs analysis, is responsible for reporting results. 2. Follows QA/QC procedures. 3. Follows ethics and integrity protocol.
AA Operator	BS in scientific or engineering discipline.	One years of laboratory experience. In lieu of a degree, three years of experience in operating an atomic absorption instrument.	1. Performs analysis, is responsible for reporting results. 2. Follows QA/QC procedures. 3. Follows ethics and integrity protocol.
Microbiology Analyst	High School Education	One year of bench experience in sanitary, water, milk, or food microbiology.	1. Performs analysis, is responsible for reporting results. 2. Follows QA/QC procedures. 3. Follows ethics and integrity protocol.
Wet chemistry Analyst	BS in scientific or engineering discipline.	One year of laboratory experience. In lieu of a degree, two years of laboratory experience.	1. Performs analysis, is responsible for reporting results. 2. Follows QA/QC procedures. 3. Follows ethics and integrity protocol.
Sample Preparation Laboratory Supervisor	High school diploma	Three years of laboratory experience, including at least one year in a supervisory position.	1. Performs sample preparation. 2. Is responsible for training personnel. 3. Follows QA/QC procedures. 4. Follows ethics and integrity protocol.

Title	Education Minimum	Experience Minimum	Routine Duties
Sample Preparation Technician	High school diploma	Training in sample extraction/concentration /digestion.	1. Performs sample preparation. 2. Follows QA/QC procedures. 3. Follows ethics and integrity protocol.
IT Specialist	Bachelor's degree with four or more intermediate courses in programming, information management, database management systems, or systems requirements analysis.	Three years of experience in data or systems management or programming including one year experience with software being utilized for data management and generation of deliverables.	1. Maintains Laboratory programs and computer systems. 2. Follows ethics and integrity protocol.
Information Services	Bachelor's degree with four or more intermediate courses in programming, information management, database management systems, or systems requirements analysis.	Two years of experience in systems or application programming including one year experience with software being utilized for data management and generation of deliverables.	1. Maintains Laboratory Information Management System. 2. Follows ethics and integrity protocol.

Appendix C

Laboratory Accreditation / Certification / Recognition

McCampbell Analytical, Inc. maintains the following certifications and accreditations with numerous state and national entities:

Organization	Certificate Number	Organization	Certificate Number
NELAP	12283CA		
California ELAP	1644		
Alaska DEC	UST 098		
ISO/IEC 17025:2005	L11-143		
Washington State	C972		
UCMR 3	2012		

The certificates and parameter lists, for each organization may be found in the Sales Managers Office.

If accreditation is terminated or suspended, the laboratory will immediately cease to use the certificate number reference in any way and inform clients impacted by the change.

Appendix D

McCampbell Analytical, Inc. Organizational Chart