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South Bend
Quality
Assurance**

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QA - QUALITY ASSURANCE MANUAL

Document Revision and Approval History Table

Issue 2.0 Detail		Implementation 2012-01-05	
<p>Corrected Document Reference #8 document number to 06-QA-F0411 Section 3.1 – Removed Employee Computer Training Manual. Section 3.2 – Corrected paragraph for Radiochemistry DOCs to include 4 Method Blanks and 4 LFBs. The level of the LFBs must be less than the MCL and greater than the MDL. Acceptance criteria are in the RAD SOPs. Section 5 - Removed references to Employee Computer Training Manual. Changed “Lotus Notes” to “Outlook.” Changed UL Employee Manual to US Employee Manual. Section 12 – Clarified the investigative process for QC trends found in the weekly trend report. Added: Actions taken from the trend analysis are documented in the LIMS (Instrument Maintenance Module). When a QC failure occurs and an assignable cause is known the QC results are marked “Not Tracked” in the Data Entry module to prevent inclusion in QC Tracking. All other data, including outliers, whether reportable or not are compiled and may be plotted. Added: When a “trend” is assigned by the Section Manager the analyst is responsible for the following:</p> <ul style="list-style-type: none"> • Investigating the trend of QC data in QC Tracking module. • Recording the findings of the investigation. • Recording the corrective action taken or • Recording the justification for “no action taken.” <p>Section 5 – Did not delete words per Ted’s approval comments after discussion between Ted and Gene. 2012-01-05cps</p>			
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List of Referenced Documents

- 1: Approved Controlled Document List, 06-QA-F0423
- 2: Management / Supervisory Structure, 06-QA-F0434
- 3: QA/QC Responsibilities Chart, 06-QA-F0438
- 4: Demonstration of Capability Certification Statement, 06-QA-F0400
- 5: Building Fact Sheet, 06-QA-F0437
- 6: Chain of Custody Form, 06-LO-F0435
- 7: New Test Approval Form, 06-RD-F0401
- 8: Database Entry Modification Form, 06-QA-F0411
- 9: Glossary of Terms, 06-QA-F0401

1. Quality Assurance Policy

Underwriters Laboratories - South Bend Laboratory provides analytical chemistry, radiochemistry and microbiological services to customers concerned with the public's health in compliance with US EPA Safe Drinking Water Standards. Our goal is to meet and exceed the needs of our customers by providing quality services that set the standard for excellence in the environmental testing industry. The laboratory will continue to maintain a Quality Assurance System that will satisfy all of the elements in the UL Quality Policy stated as follows:

“We, the UL Family of Companies, meet or exceed the expectations of our customers, our accreditors and the public with the highest level of quality and integrity.”

And to satisfy the following specific elements at the South Bend Laboratory:

- Meet current local, state, and federal drinking water regulations.
- Comply with the NELAC standards.
- Meet the requirements of ISO 17025.
- Comply with Department of Defense Quality Systems Manual
- Define our analytical capabilities within the company and to our customers.
- Ensure that the customer's needs are understood and can be met.
- Provide analytical data that is valid, defensible, and have known and documented quality.
- Maintain a workplace atmosphere that ensures conformance to UL's Standards of Business Conduct.

The laboratory is committed to performing analyses using sound professional practice. In all aspects of the company, quality is the highest priority. All laboratory personnel are required to read and understand this Quality Assurance Manual (QAM), and its supporting documents, and to comply with the documented procedures and policies.

The laboratory maintains an organizational environment that fosters individual motivation, innovation, and continuous improvement of our processes, systems, and organizational structure to achieve company goals and meet the needs of our customers.

The South Bend Laboratory is referenced within UL as Water Quality. The Water Systems Group in Northbrook, Illinois performs exposure studies and product certification activities. These two groups comprise the Water Business of UL reporting to a single General Manager and the SVP/Business President of UL.

1.1 Ethics Policy

The laboratory is committed to conformance with ethical standards, ensuring the integrity of data which the laboratory provides to its customers, meeting the quality needs of our customers, and providing our employees with guidelines and an understanding of their ethical, legal, and quality responsibilities in the performance of their work. Analysts are instructed and required not to compromise the quality of results over production or personal interests. All employees are instructed to consult with the Operations Manager, Regional Quality Manager, or the Technical Director when situations arise which may bring into question adherence to ethical issues, proper quality assurance procedures, analytical techniques, or determination and reporting of test results.

The Regional Quality Manager presents and reviews the UL Standards of Business Conduct and the Supplemental Code of Ethics documents referenced below with all new employees. The Operations Manager reviews the Standards of Business Conduct periodically at laboratory staff meetings. The laboratory conducts annual training of its Ethics policies with all employees, and documents their understanding and agreement with UL Standards of Business Conduct and the Supplemental Code of Ethics. This documentation is retained on file in the Quality Assurance Department.

Controlled Document: 00-LE-P0001 Standards of Business Conduct, 06-QA-S0404 Supplemental Code of Ethics

1.2 Quality Assurance and Quality Control

Quality, as the term is used herein, is defined as the level of excellence needed to conform to an accepted standard. Generally, quality refers to the excellence of end results and/or the excellence of performance required to meet established standards.

Quality Assurance (QA) is defined as those planned and systematic activities necessary to provide adequate confidence to the laboratory, its customers, and regulatory agencies that our data and services meet mutually accepted quality standards consistent with analytical method criteria and with customer and regulatory agency quality standards.

Quality Control (QC) is defined as the operational processes that are employed to measure and evaluate the conformance of operating practices and procedures to the standard of quality. Performance criteria are defined for all areas of the laboratory.

These include:

- Administrative and technical policies, methods, and procedures.
- Personnel accountability, authority, and responsibilities.
- Performance monitoring.

- Peer and supervisory reviews, checks, and approvals.

The QA Department provides oversight of all activities that may affect the quality of the analytical data produced. The QA Department functions as the Quality Assurance Unit (QAU) for the purposes intended by the US Department of Defense and Good Automated Laboratory Practices (GALP). The QA Department uses the UL Global Corrective Action Request database to document all findings from internal and external audits, data packet reviews and LIMS Raw Data inspections that require corrective action.

This Quality Assurance Manual describes the organizational structure and departmental QA/QC responsibilities, and identifies the QA systems, policies, and activities required to ensure that the analytical services meet the QA objectives that are identified in this manual. This manual addresses the systems that monitor the QA activities for the purpose of achieving continuous improvement and identifies the QC records that are maintained and the reports that are generated.

The following documents have been used as guidance for writing and revising this manual:

- NELAC Quality System Document, 2003
- ISO/IEC 17025, 2005
- EPA's Good Automated Laboratory Practices Manual, 1995
- EPA 40 CFR Parts 136-149
- Department of Defense Quality Systems Manual for Environmental Laboratories, Version, 4.1 4/22/2009

The Operations Manager, Section Managers, Technical Director and the Regional Quality Manager review this manual annually (and revise it if necessary) to assess its effectiveness in meeting our quality objectives and to address any new method or regulatory requirements. The approval of this manual is documented in the Corporate Published Document Database which uses the Knowledge Management System (KMS) software.

All employees are required to read the manual to ensure that they understand their ethical and quality assurance responsibilities. The effectiveness of the Quality Assurance program depends on the adherence to the policies and procedures by the entire laboratory organization.

1.3 Confidential and Proprietary Information Policy

Employees of the laboratory must adhere to ethical and legal standards to abide by the law, to preserve the Company's integrity and reputation, and to preserve the

confidentiality of its customers. Failure to adhere to this policy will result in disciplinary action, up to and including discharge from employment. In addition, the Corporate Standards of Business Conduct describes the confidential rights of our customers' identity and data. The Corporate Code of Ethics further describes the Company's rights to internal proprietary information.

Controlled Document: 00-LE-P0001.

1.4 Conflicts of Interest

All employees of the laboratory are required to read and document adherence to the Underwriters Laboratories Standards of Business Conduct . The specific section on Conflicts of Interest reads as follows:

“UL employees and their family members are not to become involved with UL customers, subscribers, vendors, competitors of UL, or others in any manner which might influence official decisions or actions or which would tend to impair public confidence in UL. Accordingly:

- (1) No employee or family member of the employee may have a material financial interest, directly or beneficially, in any organization which is a competitor of UL, or which has a current or prospective business with UL as a customer, supplier, or vendor, if the employee is in a position to influence decisions with respect to UL's business with that organization, or if the employee has access to information UL considers to be confidential,
- (2) No employee may hold a position of director, officer, employee, consultant, or agent with any organization which is a competitor of UL, or which has a current or prospective business with UL as a customer, supplier, or vendor, if the employee is in a position to influence decisions with respect to UL's business with that customer, supplier, or vendor, or if the employee has access to information UL considers to be confidential,
- (3) No employee may solicit or accept, directly or indirectly, any gift, gratuity, favor, entertainment, loan, payment of personal expenses, fees, compensation, or purchase any product at a special price for personal use or use by another person, from a person or company who has an interest, financial or otherwise (e.g., UL test results, sales to UL, etc.), that may be substantially affected by the performance or nonperformance of the employee's official UL job responsibilities. Neither may an employee encourage or suggest the boundaries within which acceptances would be permitted, and

(4) No employee may accept employment outside UL without first discussing such employment with the employee's Manager; as such outside employment may result in a conflict of interest. A determination will then be made by UL and in UL's sole discretion if such employment could constitute a conflict of interest detrimental to the best interests of UL and the employee."

1.5 Certifications and Reference Methods

The laboratory maintains certifications in most states and some other government entities. Current certificates are displayed in the laboratory and current copies are maintained in the State Certifications Binder located in the QA Department, and posted on the UL web site. The list of approved Standard Operating Procedures (SOPs) is referenced to this Manual in KMS. The certificates list the methods and/or analytes that the laboratory is certified to perform. All approved SOPs are available to all employees through the UL Intranet under "Published Documents." The Schedule of Services lists all of the analytes and methods that are performed at the laboratory whether or not the laboratory is certified for the analytes or method. Only certified analytes or methods are reported for compliance field samples.

Controlled Document: 06-QA-S0403 Managing Certifications

2. Organization and Responsibilities

It is the objective of the laboratory to provide an organizational structure that enables its employees to achieve UL's corporate quality goals and meet the requirements of its customers. Organizational support to accomplish the quality goals is derived from Corporate Policy Directives and Standard Operating Procedures.

The QA Department oversees the quality achievement and quality verification processes through audits, reviews, and surveillances. The individuals directing, managing, conducting, reviewing, monitoring, and approving the laboratory data are individually and collectively accountable for the quality of the data. The leadership and support of Corporate Management ensure that corporate practices and policies are effectively implemented. The organizational chart for the Management Team is referenced in KMS. Job descriptions for all laboratory personnel are maintained in the Human Resources Department.

2.1 QA/QC Responsibilities

The QA/QC Responsibilities Chart, is referenced in KMS, is a macroscopic view of the company departments and their QA/QC responsibilities. In general, each employee affects the quality of service provided and is obligated to perform specific documented procedures in a professional and ethical manner and to document all discrepancies. All

personnel must understand their responsibilities in the QA effort as described in this Manual and acknowledge their understanding by signing QA training forms.

2.1.1 Procedure Departures

All laboratory employees are required to adhere to all policies and procedures. When a specific situation makes it necessary to depart from the requirements of a Standard Operating Procedure, the employee must first receive signed approval from the appropriate manager to make the departure, and then the employee must clearly document the nature of the departure and the justification for the departure.

2.1.2 Policy Departures

Any departure from this policy must be documented on a Corrective Action Request (Section 16.3) to determine the root cause and the appropriate corrective action.

2.2 Operations Manager

The Operations Manager has the overall responsibility for approving all laboratory policies and supporting the quality activities described in this QA Manual. The Operations Manager provides direction in establishing the Quality Objectives and ensuring that the Regional Quality Manager, Technical Director and the Section Managers understand their responsibilities for maintaining the laboratory's conformance to its quality policies. The Operations Manager has the following specific responsibilities and authorities:

- Participation in the preparation of Annual Operating Plans.
- Designating appropriate Section Managers and defining their job responsibilities.
- Designating an appropriate Technical Director.
- Facilitating the implementation of all corrective actions.
- Identifying the qualifications required for Operations personnel.
- Review of customer Requests for Bid or Proposal (as necessary).
- Review of Customer Contracts (as necessary).
- Review of customer Requests for Bid or Proposal (as necessary).
- Ensuring that appropriate policies and procedures are implemented so that the laboratory produces valid data that conform to applicable quality requirements.
- Designate specific personnel to act as deputy for Operations Manager when absent for more than 15 calendar days. The deputy is trained to perform the assignments and to be responsible for the duties of the absent Operations Manager.

The Operations Manager works closely with the Technical Director to maintain certification compliance and plan for technology improvement within operations.

2.3 Regional Quality Manager

The Regional Quality Manager is responsible for establishing, administering, monitoring, and improving the QA program and all the QA Systems that comprise the program. The Regional Quality Manager has primary reporting responsibility to the Global Quality Director of UL and is independent of all operational and information technology (IT) activities. Under the Regional Quality Manager's supervision, the QA Department has full access to all documents, records and electronic media to perform its designated responsibilities. The Regional Quality Manager has the following specific responsibilities and authorities:

- Supervise the Quality Assurance Department.
- Identify problems affecting quality.
- Identify, recommend or provide solutions to problems affecting quality.
- Identify need for corrective actions affecting quality, initiate corrective action and notify appropriate personnel of requirements for corrective actions, and verify implementation.
- Review and approve all Quality Assurance Department reports.
- Notify the Operations Manager, Technical Director, and the Section Managers (when appropriate) of deficiencies in the quality program.
- Orient new personnel to the Quality Program.
- Administer and direct internal audits of designated technical and non-technical laboratory operations and maintain audit reports in the QA Department.
- Review and respond to all external audit reports.
- Maintain current status of all certifications.
- Assure that, when necessary, further work is stopped or controlled until proper resolution has been achieved for a nonconformance, deficiency, or another unacceptable quality issue.
- Review and approve subcontractor laboratory submissions.
- Review of customer Requests for Bid or Proposal (as necessary).
- Review of Customer Contracts (as necessary).
- Designate specific personnel to act as deputies for QA personnel who are absent. These deputies are trained to perform the assignments and to be responsible for the duties of the absent QA staff member.
- Review the UL Standards of Business Conduct and the Supplemental Code of Ethics with each new employee and describe the consequences for any employee discovered engaging in unethical practices. In the absence of the Regional Quality Manager, a deputy is appointed to address situations that cannot wait to be resolved.

- Maintain resumes for all laboratory personnel and transcripts for managers/lead technical personnel in the QA Department.

2.3.1 Management Review

At least annually, the Regional Quality Manager reviews a report describing the state of the quality system to ensure effectiveness and introduce necessary improvements. This report is prepared with input from the Operations Manager and other invited managers. The review is conducted according to The Global Laboratory Management Review Policy, OO-LC-P0040. The details of the review are documented on the Laboratory Management Review Report, 00-LC-F0033 and subsequent action plans are addressed by the generation of a CAR (Section 16.3).

2.4 Technical Director

The Technical Director is responsible for the technical aspects of Operations and directly oversees Research and Development activities. The Technical Director works closely with Section Managers on various technical issues and directly reports to the Operations Manager. In the absence of the Technical Director for more than two weeks, a deputy is appointed to address situations that cannot wait to be resolved. The specific responsibilities include:

- Signs certification applications as a Technical Director or Laboratory Director if it is necessary, based on specific requirement and description.
- Reviews and approves technical Standard Operating Procedures (SOPs) and Database Entry Modifications (DBEMs).
- Reviews and approves requests for proprietary information, for example, technical SOPs.
- Reviews and approves requests for new method development and expansion.
- Reviews, plans, and directs R&D activities and special projects.
- Review of customer Requests for Bid or Proposal (as necessary).
- Represents UL at conferences, symposia, and trade shows.
- Reviews technical competency and advises capital investment and technology acquisition.
- Interfaces with Section Managers on new technology installation and validation.
- Interfaces with Section Managers to plan technical trainings and to conduct troubleshooting and performance improvement.
- Provide technical support to Business Development.
- Assists Client Services on customer complaints or other technical issues.
- Participates in audits, Proficiency Tests (PTs), Corrective Action Requests (CARs) and other Quality Control (QC) issues.
- Supports new hiring and provides advice if necessary.

2.5 Reporting Manager

The Reporting Manager is responsible for directing Reporting activities and the supervision of personnel in this section and reports directly to the Operations Manager.

The specific responsibilities include:

- Coordination of reporting activities.
- Review of contracts, as necessary.
- Review of customer Requests for Bid or Proposal (as necessary).
- Coordination of Report Finalization.
- Designation of specific personnel to act as deputies for personnel who are absent. These deputies are trained to perform the assignments and be responsible for the duties of the absent Reporting staff member.

2.6 Facilities Manager

The Facilities Manager maintains controlled environmental conditions in the laboratory in order to ensure proper equipment operation and provide a safe and comfortable work environment for the employees. The specific responsibilities include:

- Supervision of Facilities Department personnel.
- Oversight of maintenance and housekeeping activities.
- Ensures the functionality of Uninterrupted Power Supplies (UPS).
- Building Security Systems.
- Grounds keeping and parking lot maintenance.
- Ensures the functionality of analytical hoods.
- Designation of specific personnel to act as deputies for personnel who are absent. These deputies are trained to perform the assignments and be responsible for the duties of the absent Facilities staff member.

2.7 Information Technology (IT) Manager

The IT Manager reports to the Information Technology Director in Northbrook, Illinois.

The specific responsibilities include:

- Coordination of computer back-up systems and processes for SBN.
- Orientation and initial training of all new employees on the use of computer systems.
- Review of customer Requests for Bid or Proposal (as necessary).
- Review of Customer Contracts (as necessary).
- Designation of specific personnel to act as deputies for personnel who are absent. These deputies are trained to perform the assignments and be responsible for the duties of the absent IT staff member.

2.8 Customer Experience Manager

The Customer Experience Manager is responsible for the supervision of the Project Managers (PMs), Shipping and Receiving personnel and reports directly to the Operations Manager. The specific responsibilities include:

- Coordination of Customer Service Activities.
- Management of the Shipping and Receiving Sections.
- Review of Contracts as necessary.
- Coordination, review and preparation of bids and proposals.
- Designation of specific personnel to act as Deputies for personnel who are absent. These deputies are trained to perform the assignments and be responsible for the duties of the absent Customer Service, Shipping and Receiving staff member.

2.9 Project Managers

Project Managers (PMs) are the focus of daily contact with laboratory customers. They are responsible for reviewing bid specifications and contract language to ensure the specifications can be fulfilled within our analytical capability and within regulatory requirements. PMs document specific project requirements and provide this information to analytical personnel. They monitor amendments to contracts and ensure this information is provided to all affected staff. Specific customer, technical, and contractual requirements are documented on the order form. This facilitates the information flow among laboratory departments. PMs may also provide final review of reports prior to providing them to the customer.

2.10 Section Manager

The Section Managers report to the Operations Manager. The Section Managers are responsible for implementation of policies and procedures that ensure only data of the highest attainable quality are produced, that all quality control procedures are followed and that all tasks performed in the laboratory are conducted in accordance with this manual and applicable Standard Operating Procedures (SOPs). They have authority commensurate with their responsibilities for the day-to-day management and monitoring of laboratory activities under their supervision.

The Section Managers have the following specific responsibilities and authorities for their designated areas:

- Assign and schedule work.
- Provide adequate personnel training for assigned analyses.
- Review and approve Demonstration of Capability data.

- Maintain equipment and instrumentation.
- Ensure proper calibration of laboratory equipment and instrumentation.
- Review analytical data for conformance to Quality Control and customer requirements.
- Implement all necessary corrective actions in a timely manner.
- Ensure that Method Detection Limit Studies (MDL) are completed on time and in conformance with method requirements, when applicable.
- Provide or review comments regarding data for which there has been a QC result that exceeded the method control limit but which is judged reportable to the customer with the completion of the appropriate Client Contact.
- Write and review SOPs applicable to their department, or designate an appropriate person.
- Review of customer Requests for Bid or Proposal (as necessary).
- Review of Customer Contracts (as necessary).
- Designation of specific personnel to act as deputies for personnel who are absent. These deputies are trained to perform the assignments and be responsible for the duties of the absent Technical Operations staff member.

2.11 Analysts/Staff

The analysts are responsible for performing the analysis, reducing the data, and performing an initial review of the data for conformance to QC requirements. They are responsible for recording any pertinent observations and reporting any QC result that exceeded the method control limit in the manner described in SOPs or this Manual. They are responsible for understanding and correctly adhering to all applicable SOPs and Quality Control Procedures.

The analysts are responsible for performing QA peer reviews of data packages produced by fellow analytical staff members.

Analytical personnel are responsible for notifying the Customer Services Department of any issues requiring client notification.

Analysts are responsible for submitting MCL (Maximum Contaminant Level) violations to the QA Department for review and approval prior to reporting the results.

Analysts are responsible for completing a Sample Prep Task Request when additional or new materials are needed such as, calibration curves, MDL samples, DOC samples, troubleshooting samples, etc. The completed form is added to the Data Packet associated with the first use of the samples prepared.

Controlled Documents: 06-LO-F0422 Prep Task Request

3. Personnel Qualifications and Training

All personnel must meet the minimum education and experience requirements defined for their assigned responsibilities. During the employee recruitment process, the education and experience of all personnel selected for employment is verified prior to an employment offer. This verification includes employment reference checks and confirmation of college and advanced degrees. This task is performed by the UL Human Resources Department in Northbrook, Illinois.

3.1 Training System

All new personnel are given an orientation during their first week of employment. This includes review of Policies and Procedures, and initial training in the use of the computer network and Laboratory Information Management System (LIMS). A signature log is maintained in the QA Department that is signed by each new employee when they start their employment at the laboratory. Additionally, they are introduced to UL Standards of Business Conduct, Supplemental Code of Ethics, Quality Program and Safety Procedures. Each new employee signs an acknowledgement form confirming that the employee has read and understands the Standards of Business Conduct. All personnel receive training in the analytical procedures and operating practices which are specific to their job responsibilities. This training is directed either by their Section Manager or a person who is assigned by the Section Manager and who is experienced in the applicable procedures.

Analysts must complete specified training and performance requirements before they are permitted to analyze samples for customers. Job training requirements are documented by utilizing the departmental training checklist. Training checklists and any documentation required, to comply with the training checklists are signed by the trainer, trainee, and the Section Manager and filed in the employee's file along with other internal training documents. Other training documents include SOP revision training sheets, and Demonstration of Capability Certification Statements. Resumes, and records of external training or continuing education are maintained in the employee's file in the QA Department.

Controlled Documents: 06-QA-S0405 Training

3.2 Initial Demonstration of Capability (IDOC)

Analysts, as part of their training, must successfully complete a demonstration of capability (DOC) study as described in each analytical SOP. At a minimum, the analysts must demonstrate that they can meet the accuracy and precision requirements of the method by analyzing individually prepared samples, which have been fortified

with the analytes of interest from a source different than the calibration standards when available. The number of samples performed is listed in the individual SOPs.

Initial DOCs for radiochemistry methods include the use of four Laboratory Method Blanks (LMBs) and four Laboratory Fortified Blanks (LFBs) that have the radioanalyte of interest added to them at a known concentration for the relevant method. The activity level of the additions shall be made at a level below the Maximum Contaminant Level (MCL) and above the required detection limit. Acceptance criteria are documented in the individual radiochemical SOPs.

Some analytical tests e.g., color, temperature, and pH do not allow for the creation of DOC samples by spiking reagent water. In these cases, an experienced analyst will analyze a series of samples with a range of results. The analyst in training performs the procedure on the same samples analyzed by the experienced analyst. The Section Manager reviews the results. Based on concurrence of results, the Section Manager documents the acceptability of the DOC for the new analyst.

Some reference methods require an MDL study to be performed by each analyst. The laboratory requires that new analysts demonstrate proficiency by the completion of a DOC study. The MDL study may serve as the DOC study if the accuracy and precision criteria specified in the individual SOPs are met. If the DOC criteria are not met, a separate DOC study must be performed in addition to the MDL study. The DOC Certification Form used for all DOCs is referenced in KMS. The DOC records are maintained in the employee's electronic folder.

Controlled Document: 06-QA-F0400 DOC Certification.

3.3 Continuing Demonstration of Capability

Analysts must continue to demonstrate their capability annually by successfully fulfilling one of the following five criteria:

- Performing a DOC study.
- Acceptable performance on a blind sample (i.e., a PT Sample).
- Analyzing a standard of known concentration on four consecutive analytical runs and obtaining a result for each sample that is within acceptable QC limits
- Successful analysis of a blind sample using a similar test method, which uses the same technology.
- Analysis of at least 4 authentic samples with results statistically indistinguishable from those obtained by another trained analyst when it is not possible to add a known amount of the analyte (e.g., color, temperature, or pH).

3.4 Demonstration of Capability Exclusions

Not all laboratory procedures require performing a DOC. Section Managers may be exempt from DOC requirements at the discretion of the Regional Quality Manager. Analysts are allowed to perform certain procedures without performing a complete DOC. However, anyone who performs any of these procedures must receive proper training. Some of these procedures are listed below:

- Simple volumetric measurements
- Gravimetric measurements
- Non-critical filtration
- Data entry
- Loading auto-samplers with field samples
- Spiking samples
- Preparing standards

3.5 Additional Technical Training

Technical staff members are encouraged to participate in additional technical training outside of UL. Any employee can seek approval to attend technical training. The Section Manager and Operations Manager review the request for applicability and need. Records of attendance at outside training are maintained in the QA Department.

4. Facilities and Equipment

4.1 Facilities Description

Descriptive details of the laboratory building are contained in the Building Fact Sheet, which is referenced in KMS. It is important to maintain controlled environmental conditions in the laboratory in order to ensure proper equipment operation and provide a safe and comfortable work environment for the employees. HVAC units control temperature, humidity and pressure. Temperature is maintained between 68-75°F and the relative percent humidity is maintained at approximately 30%. A slight negative pressure is maintained in the laboratory when all fume hoods are operating. Monitoring of environmental conditions is done only when the conditions could adversely affect test results.

The metals laboratory is maintained with its own HVAC System. The isolated metals laboratory HVAC system eliminates potential sample contamination resulting from the general building HVAC System.

The laboratory is designed to separate incompatible test areas and provide adequate lighting and space to perform analyses. The laboratory fume hoods are located a significant distance from the Volatile Organic Chemical (VOC) analysis area of the

laboratory. The airflow is directed in a manner to reduce possible contamination of VOC samples by solvents used in the organic extraction area.

All employees are expected to keep their individual work areas neat and clean. The Facilities Department routinely cleans the building. Short and long-term facility project schedules are provided as a means to communicate the need for special projects. Short-term projects are those which are expected to be completed in a relatively short period of time and can be completed by the Facilities Department. Long-term projects may require the use of an outside contractor. The maintenance schedules help to prioritize projects, minimize outside contractor costs, coordinate project completion, and provide the status on each project.

Controlled Documents: 06-FM-S0400 Managing Outside Contractors

4.2 Building Security

Access to the building is limited to employees and contracted vendors. The main entrance and the receiving area are secured at all times. Visitors to the receiving area are typically customers dropping off samples and occasionally outside contractors. Visitors to the front entrance sign in and are issued a visitor's badge and are escorted in the facility at all times by an employee. A company issued key is required to enter through employee entrances.

The building is equipped with an electronic security system managed by an outside contractor. The system allows access to the building after hours only for those persons who have an authorized security code. The system also monitors the building's smoke detectors. If an unauthorized access is made, or fire emergency detected, the outside contractor notifies the South Bend Police and/or Fire Departments. An emergency call list is maintained with the receptionist and posted at employee exits so that in the event of a security emergency, the appropriate personnel can be notified.

4.3 Reagent Water

The laboratory maintains reagent water purification systems that can produce ASTM Type I & II quality reagent water. These systems are monitored for water quality parameters at a predetermined frequency. The testing results are recorded and maintained by the Quality Assurance Department.

Milli-RX-75 system by MILLIPORE produces Type II water. The feed water passes initially through the ROPAK pretreatment pack whose function is to protect the reverse osmosis cartridge(s) from damage/fouling by particles, attack by free chlorine, or the formation of mineral scale on the membrane surface. This system produces purified water using two primary technologies in series: reverse osmosis followed by deionization in an ELIX module (ELIX = continuous deionization).

The water produced has a resistivity greater than 1 megohm-cm at 25°C. Water quality is monitored according to the manufacturer's instructions. The purified water is stored in a reservoir for laboratory applications. The water produced is used to clean glassware and feed two additional water purification systems that further treat the water to produce Type I reagent water.

The laboratory maintains a second system that produces Type II reagent water by filtering city tap water through a deionization tank and an activated carbon tank. Water is monitored on a continuing basis for resistivity greater than 1 megohm-cm at 25°C. Records are maintained by the QA Department. In addition, water quality is measured by in-house analytical analyses of reagent blank and lab trip blank QC samples for VOC analyses. Results are recorded in the raw data packets for each analytical run.

System#1, Milli-Q R. G., System#2, Milli-Q Academic, System #3, Milli-Q ELIX5/Gradient and System#5, Milli-Q Elix5/Advantage are manufactured by MILLIPORE. Systems #1 and #2 receive water from the Milli-RX-75 system to produce Type I water. Systems #3 and #5 are separate systems that receive tap water to produce Type I water. The systems are monitored on a continuing basis for resistivity that is greater than 18 megohm-cm at 25°C. The water produced is also tested in-house on a monthly basis for ammonia, conductivity, heterotrophic plate count, pH, total residual chlorine and total organic carbon. In addition, the water from these systems is tested annually in house for select metals. Records are maintained by the Quality Assurance Department.

System #4, Milli-Q Direct-Q, is a separate system that receives tap water to produce Type I water for the IOC/Metals Department. The system combines Reverse Osmosis (RO) and Ion Exchange technology to accomplish this. Water quality is monitored on a continuing basis for resistivity that is greater than 18 megohm-cms at 25°C. Records are maintained in the Quality Assurance Department. In addition, water quality is measured by in-house analytical analyses of reagent blank QC samples. Results are recorded in the raw data packets for each analytical run.

4.4 Glassware Cleaning Procedures

The procedures for cleaning all sample containers and laboratory glassware are described in the SOP entitled, "Glassware Cleaning and Preparation."

Controlled Documents: 06-LO-S0417 Glassware Cleaning

4.5 Reagent Storage

All laboratory chemicals are segregated according to critical chemical properties. For example, strong acids are stored separately from strong bases. Flammable materials are stored separately from oxidizing agents. Dry granular or powder reagents are stored by category indicated by color-coded labels in the storage cabinets in the chemistry and microbiology laboratories. Organic standards are stored in refrigerators and freezers in the Organic Sample Prep, GC/LC and GC/MS areas.

Controlled Document: 06-QA-S0416 Critical Consumables

4.5.1 Radiochemical Standard Storage

Radiochemical standards are locked in a cabinet when not in use. Access to radioactive sources is permitted only to authorized personnel who are trained in radiation safety.

4.6 Equipment

A list of equipment used at the laboratory is provided in the Major Laboratory Equipment Summary. The laboratory maintains partial or full service contracts on many instruments. Routine maintenance and repairs are recorded in the instrument maintenance logs. Requirements for routine preventative maintenance are described in the applicable method SOP.

Controlled Document: 06-QAF0419 Lab Equipment Summary

4.6.1 Equipment and Instrument Maintenance

Instruments and other laboratory equipment require maintenance. This can either be regular and routine maintenance for preventive reasons, or maintenance to correct malfunctions of the equipment. All maintenance activities are documented in the associated instrument maintenance log, which is kept near the equipment so it is readily available to all personnel. At a minimum, the recorded information includes the following:

- Instrument Identification
- Date
- Maintenance Performed
- Name (or initials) of person who performed the maintenance

4.6.2 Service Agreements

Full or partial service agreements are maintained for selected equipment, especially those where the laboratory has limited back-up capability (e.g. ICP/MS). An inventory

of some critical spare parts is maintained to enable a quick return to service of malfunctioning equipment.

5. Computer Systems

The laboratory uses its computer network for many tasks. These include sample login, sample status, data reduction and reporting, electronic data archival and electronic communication within UL, with customers and others outside the company. The US Employee Manual describes acceptable uses of company e-mail and Internet connections. The UL password policy (available at <http://corporate.ul.com/depts/ITD/Support/Passwords/Default.htm>) explains how to create a password of sufficient complexity and also explains how users can change their Windows password. Users are assigned a variety of passwords other than their Windows password including a LIMS password, an Outlook password, and an Internet password. Computer System assistance and problem reporting are handled by the UL Help Desk available by telephone or email.

5.1 Computer System Backup

The Computer System Backup Procedure provides more specific information on the following activities. The network drives (which include raw and processed instrument data as well as general business files) are backed up each night Monday through Thursday. This backup is an incremental backup in that it only records information that has changed or been added during the previous business day. Additionally, the LIMS database is backed up each night (Monday through Friday) in its entirety. These incremental backup tapes (which include a full backup of the LIMS database) are stored on-site by the IT Manager or his designee and the tapes are re-used every fortnight. An additional backup is performed over each weekend that includes all of the information on the network drives and the LIMS database. These full backups are stored on-site in a locked, fireproof bank vault and the tapes are re-used every three months with the exception of the last full backup during each quarter of the year which is retained for 10 years. Back-up tapes are tested periodically to ensure retrievability of data.

Controlled Document: 06-IT-S0401 Computer Back-up.

5.2 Computer System/Software Validation

The Information Technology Department maintains a computer software validation SOP that complies with "The Environmental Protection Agency's (EPA) Good Automated Laboratory Practices Manual", 1995 edition. Software programs that are written by laboratory staff and are utilized to generate or process data that are reported to our customers are submitted to QA. The creator of the program or spreadsheet must have the Section Manager approve the submission, when applicable, and forward the

request to the QA Department. The QA Department determines if the submission must be managed as a controlled document and have a controlled document number assigned. QA determines if the QA Department, the Section Manager or the IT Department shall perform the validation. The selected validator documents how and when the validation was performed. This validation is performed prior to any use of these programs in calculating data, to ensure the generation of the correct results.

Controlled Documents: 06-IT-S0402 Software Validation,

5.3 Database Entry Modification Request

The laboratory utilizes a Database Entry Modification (DBEM) form to request changes to the database. A Database Entry Modification is referenced by this document in KMS. These requests can be initiated by any employee and are controlled by the Regional Quality Manager or a designee. The Operations Manager or the appropriate Section Manager and the Regional Quality Manager review and document their approval or disapproval of the request. Approved requests are forwarded to the IT Department for implementation.

Controlled Documents: 06-QA-F0411 Database Entry Modification, 06-QA-S0407 Database Entry Modification Process

6. Bid, Proposal, and Contract Review

All Requests for Proposal (RFP) and Requests for Bid (RFB) are reviewed by the Customer Experience Manager or designee, the Regional Quality Manager, and/or the Operations Manager using the following procedure: Formal Response Procedure for Request for Proposal/Request for Quote (RFP/RFQ). Any proposal that automatically results in a contract must be reviewed by UL Legal Department. The review focuses on technical, quality assurance, quality control, reporting requirements and contract language including, but not limited to, insurance requirements, indemnification, and payment terms.

Prior to signing a contract, negotiation of contract language is conducted so that the resulting contract contains language that is acceptable to both the laboratory and its customer. The depth of this review depends upon the complexity of the contract terms. An Officer of UL or a designated agent may only sign contracts. Upon approval of the contract terms, the Project Manager includes on the Order all pertinent contract requirements (e.g., QC, report format, report due date(s) etc.). This enables all laboratory personnel to understand the details of the contract and customer requirements.

Controlled Documents: 06-CS-S0400 Analysis & Feasibility of Contracts, Bids and RFP/RFQ, 06-CS-S0401 Response to RFP/RFQ

7. Sample Management and Tracking

The custody procedures for shipping, sample collection, sample receipt, and sample tracking throughout the analytical process are described briefly in the following sections.

7.1 Order Placement

In most cases, the first step in the laboratory process is a customer phone call to the laboratory. During this call, a Project Manager takes information about the customer, requested analyses, required report formats, sample origin, type of report package, and turnaround time needs. This information along with any additional information is compiled into a Shipping Order by using the LIMS application Order Processing.

Controlled Document: 06-CS-S0402 Order Processing

7.2 Shipping

The Shipping Department personnel check the Order Processing application several times during the workday. The information is sorted by the “Send By” date. This date indicates when the shipping kits are expected to be sent to the customer. The shipping department utilizes the order and, when necessary, the Schedule of Services to ensure that the proper type, size, number of sample containers, and preservatives are included in the order. The sample containers are packed into the shipping carton with chain of custody documentation, instructions for sample collection, and ample cool packs to keep samples within the temperature requirements during the return to the laboratory.

Controlled Documents: 06-LO-S0432 Shipping

7.3 Chain of Custody

Chain of Custody (COC) records are maintained for all samples processed at the laboratory. A state-specific COC form is used for customers in South Carolina. The purpose of the COC document is to record the history of sample containers and samples during the container shipping, sample collection, transportation, and receipt process. Sample containers are shipped to the customer along with a COC form, and directions for completing the form. The customer is responsible for the information on the COC form. The customer signs the COC form to verify that they are relinquishing the samples to the custody of the laboratory. The samples arrive at the laboratory by common carrier, or the customer delivers the samples to the laboratory. The laboratory acknowledges the receipt of the samples by signing the COC form. Description of COC procedures is described in the SOP for shipping and sample receipt. A copy of the COC form (06-LO-F0435) is referenced in KMS.

Controlled Documents: 06-LO-S0432 Shipping, 06-LO-S0434 Sample Receipt, 06-LO-F0436 SC Chain of Custody

7.4 Evidentiary Chain of Custody

When an evidentiary COC is required, samples are secured under lock and key, once received at the laboratory. When samples require an in-house COC, the evidentiary COC is used; however the form indicates that a lockbox is not required, therefore evidentiary procedures do not apply. The Regional Quality Manager or designee holds the key. The COC form and the sample containers for these projects are shipped by common carrier (UPS or Federal Express), and the representative of the common carrier will document receipt of the shipping and collection materials by signing the evidentiary chain of custody.

The evidentiary chain of custody procedure requires that when an analyst removes a sample for analysis that the date and time be entered in the appropriate place on the form. Additionally, the analyst and a witness must initial the form. The same procedures are required when returning the sample container to the storage area. If no sample remains after analysis, it must be so documented on the form with the date, time, and the initials of the analyst and witness.

When the samples are too numerous to store in the lock box in the walk-in cooler, the samples are stored in a locked refrigerator to enable the evidentiary chain-of-custody procedures and forms to be utilized. Records are maintained that account for time periods and the identity of individuals who handle the samples from receipt through sample preparation, analysis, and disposal.

Controlled Documents: 06-QA-F0422 Evidentiary Chain of Custody

7.5 Sample Collection

The laboratory is rarely responsible for sample collection. However, when required to do so, a trained staff member performs this function.

The customer usually performs sample collection. When collected, the samples are labeled with the customer's name, location, date and time of collection, analysis requirements and other pertinent information as prescribed in the applicable Sampling and Shipping Instructions for sample collection and preservation. The sampling personnel enter all necessary information onto the COC form and transfer custody to the receiving personnel when the samples are returned to the laboratory. The Sampling and Shipping Instructions describe the specific collection procedures for the different analyses, as well as instructions for returning the samples to the laboratory. The Sampling and Shipping Instructions are maintained as controlled documents.

7.6 Sample Receipt

Upon receipt, the receiving personnel acknowledge receipt by signing the COCs. The shipping containers are opened and the refrigerant (ice packs or wet ice) is inspected to determine if the samples were maintained at the proper temperature during shipment. The temperatures of a representative number of samples in a receipt batch are measured using the temperature gun. The temperature is recorded on the COC. Customers are contacted whenever samples do not meet state-specific temperature requirements. If there are document discrepancies, the samples are damaged, or any other problem is noted, the customer is immediately notified by the PM for clarification and the appropriate corrective action is taken. The action as directed by the customer is recorded on the COC.

The confirmation order is compared to the COC to ensure that samples are received for all requested tests. The sample information is entered into the LIMS system and assigned individual laboratory sample numbers. Sample numbers are recorded on the COC and printed labels with the sample numbers are attached to the sample containers. If required by the customer or project circumstances, an evidentiary COC is initiated and all such samples are maintained secure in the walk-in cooler. The procedure for using the LIMS Receiving application is described in an SOP.

Controlled Document: 06-IT-S0404 Using the Receiving Application

If any samples require chemical preservation upon receipt, the receiving staff is responsible for adding the preservative in accordance with the applicable Schedule of Services. In some circumstances, an analyst may be notified to add the preservatives. If samples were collected in containers that had preservative, those samples are checked for proper preservation upon receipt at the laboratory, unless doing so may result in loss of analyte, such as for volatile compounds. If the preservation technique is not sufficient to meet the criteria of the reference method, the sample is not considered valid, and the customer is contacted to determine how to proceed. The customer contact is documented.

Samples with short holding times are delivered immediately to the appropriate area of the laboratory after login is completed. Other samples are stored in the assigned locations in the walk-in cooler, or in the appropriate area of the lab. The samples and/or extracts may never be stored along with concentrated stock standards or other sources of contamination. The tags with Method Numbers and/or analyte name identify the storage locations in the walk-in coolers. The collection date and time for Laboratory Trip Blanks (LTB) will be the date and time of the earliest collection of an associated sample.

Controlled Documents: 06-LO-S0434 Sample Receipt, 06-LO-S0435 Sample Log-in

7.7 Sample Rejection

The laboratory reserves the right to reject samples. Samples may be rejected for several reasons, some of which include:

- Matrices that appear to have the potential to damage analytical systems.
- Matrices that the laboratory is not able to process.
- Samples received from a customer with poor payment history.
- Samples with known contamination issues that may damage analytical systems.
- Other documentation problems.
- Known unacceptable collection and/or preservation technique to fulfill regulatory compliance. If the customer authorizes the analysis, the laboratory records the decision internally and includes that decision on the final report.

7.8 Sample Tracking

As described above, all samples are given a unique number when they are logged in. These sample ID numbers are used to track samples through preparation, analysis, and reporting and are recorded on all documents relating to sample preparation, analysis, and reporting. The Logbook application in the LIMS is used to monitor the status of samples in the laboratory. The Logbook application shows the dates and times of various process events (e.g., sample receipt, extraction, analysis) and name of employee who performed that step in the process.

Controlled Document: 06-IT-S0405 Using the Logbook Application

7.9 Multiple Sample Container Traceability

When customers submit multiple sample containers for one test from a single sampling site, the laboratory handles those samples as described below to ensure traceability:

- All records of sample ID numbers assume the letter designation "A" unless otherwise recorded.
- Sample Receiving enters the number of containers received into the computer system which produces labels for each container designated as "ID#-A", "ID#-B", "ID#-C", etc. The labels are affixed to the containers and the samples are moved to the appropriate sample storage area.
- Organic Sample Prep records the letter designation other than "A" and the sample ID number when the sample is transferred or an aliquot is taken from the container. The sample ID numbers and letter designations other than "A" may be recorded for a single prep batch as long as the containers are retained until the record is completed.
- Analytical Departments record the letter designation other than "A" and the sample ID number when the sample is transferred or an aliquot is taken from the container.

All final data packets must contain a record of the sample container designation whenever a container other than "A" is used for analysis.

7.10 Sample Disposal

Residual samples are eligible for disposal once reportable data are obtained. Specific samples are held longer as required by the associated customer contracts. A licensed commercial vendor disposes of sample extracts, and any other hazardous materials generated during sample preparation and analyses. Samples requiring an evidentiary COC require the customer's approval prior to disposal. Samples are disposed of according to the Chemical and Microbiological Hygiene Plan.

Controlled Document: 06-SF-S0401 Chemical & Microbiological Hygiene Plan

8. Analytical Procedures

All analyses for regulatory compliance are performed using methods approved under the Safe Drinking Water Act. Any variations to a referenced method are included in the applicable Technical SOP. All procedures currently performed at the laboratory have an SOP. Each SOP has a unique control number that also denotes the revision number of the document. The SOPs utilized at the laboratory are listed in the Controlled Document Master Index.

Controlled Document: 06-QA-F0423 SOP Master Index

The principal references for analytical methods employed at the laboratory are:

- "US EPA Methods for the Determination of Organic Compounds in Drinking Water"
- "US EPA Methods for the Chemical Analysis of Water and Wastes"
- "Standard Methods for the Examination of Water and Wastewater," 19th Edition (1995), 20th Edition (1998), 21st Edition (2005)
- EPA "Prescribed Procedures for Measurement of Radioactivity in Drinking Water," EPA-600/4-80-032, August, 1980

Copies of reference methods are maintained in the QA department. The Technical Director is designated to monitor the Federal Register for regulatory activity, including the approval of new methods and revisions. The laboratory also subscribes to EPA newsletters and industry publications to ensure that the most recent, approved versions of the test methods are referenced.

8.1 Service to the Customer

Customers or their representatives are afforded reasonable access to relevant areas of the laboratory in order to monitor performance as long as the confidentiality of other customers is not compromised in any way. Communication with the customer throughout the process is provided whenever necessary. Customer feedback concerning performance is encouraged. Customer feedback is solicited through the use of customer surveys.

8.2 Subcontractor Approval

No subcontracting occurs without the prior approval of the customer. The Regional Quality Manger and the assigned PM verify that the subcontractor meets the customer's regulatory needs, (i.e., state certifications, ISO 17025 or NELAC certification.) The laboratory utilizes subcontractor laboratories to provide analytical services that it cannot provide. The laboratory maintains a current information file for each subcontractor used to provide the analytical services not performed at South Bend.

The procedure for gaining customer approval to use a subcontractor is described in the SOP for Order Processing. The form used to obtain information about subcontractors is titled "Subcontractor Laboratory Request for Information."

Control Documents: 06-CS-S0403 Subcontractor Laboratory Approval, 06-CS-F0408 Subcontract Laboratory Request for Information,

8.3 Data Generation and Processing

A critical element of the laboratory's production of analytical data reports includes procedures for data handling, review and transfer. Specific sections below describe manual integration requirements, rounding rules and significant figure usage.

8.3.1 Data Acquisition

Data acquisition is mostly automated at the laboratory. Analysts generally use instruments that operate unattended and acquire the sample data using instrument-specific software. For analyses where there is no instrument software for data acquisition or reduction, the results are recorded on a Bench Worksheet or a blank Data Entry Sheet. When a computerized instrument is used, the raw data is saved to a network drive and backed up nightly by the IT Department.

8.3.2 Data Processing

After raw data backup, an analyst processes the analytical data. This may include inspection of chromatography and quality control performance, and checking the results for MCL violations. Printouts of the data are generated. The printouts are assembled into a data packet. The data packet also contains a run log, any original calculations, results of calibration or a reference to a calibration file, and documentation of any

sample preparation. For organic analyses and some inorganic analyses, the processed data are entered into the LIMS system using the Data Entry application. All other data are entered into the LIMS system using a manual entry application. Through the Data Entry application, an individual sample Result Record Sheet is generated. The analyst records any comments regarding data qualification on the applicable Result Record Sheet. Result Record Sheets for the entire analysis are included with the printouts obtained using the instrument software. The analyst reviews the assembled packet for completeness.

Controlled Document: 06-QA-S0410 Data Processing

If there are QC failures, the analyst takes appropriate corrective action as directed in the SOPs. When the analyst determines that re-extraction of samples, QC samples, PT samples or an entire batch is necessary, a Sample Re-extraction Log is completed and forwarded to Organic Prep. If an Internal Chain of Custody exists for the samples, it is included in the submission to Organic Prep. The Organic Prep technician prioritizes the request taking into consideration samples on hand, sample hold-times, available personnel and equipment availability. Organic Prep completes the second half of the form and returns it to the analyst with the re-extracted samples. The completed form is included in the Data Packet for the re-extracted sample run.

If the quality control requirements of the SOP cannot be met, and there is insufficient sample volume or holding time available for repeat analysis, the analyst notifies the PM using the electronic Client Contact Queue. . The Project Manager and/or the customer decide how to proceed.

Controlled Document: 06-LO-F0437 Sample Re-Extraction

8.3.3 Manual Data Integration

The processing of chromatographic data is typically performed utilizing the instrument data processing software. There are limitations in software that may result in processed chromatographic responses in an inaccurate or non-representative manner. When this occurs, manual integrations of chromatographic peaks may be required. The manual adjustment of these data, for all chromatographic analyses is termed “manual integration.” All such manual integrations undergo a peer review as part of the QA Review. The principal guidance in this can be summarized as follows:

- When integration of a chromatographic peak is incorrectly performed by the automated data processing system, the peak area is manually determined in such a way to most accurately reflect the correct and representative area response of the analyte peak under consideration.
- Manual integration must be made consistently in evaluation of calibration standards and sample responses.

- Manual integrations are identified in the data packet or quantitation report and must include a justification that describes why a manual integration was performed. All manual integrations must be initialed and dated by the person who performed the data processing.

Controlled Document: 06-QA-S0402 Manual Integration

8.3.4 MCL/Action Limit Violations

In order to determine if a result equals or exceeds a regulatory limit, the result as it will be reported to the client is compared to the limit. Analytical reported results that equal or exceed a Maximum Contaminant Level (MCL) or a Regulatory Action Limit (RAL) must be confirmed as soon as possible (except as described below) preferably within holding time. RALs are defined in the Regulation and are not limited to the term RAL. The regulation for bottled water uses the term Standard of Quality limit (SOQ).

For methods that are regulated as a summation (e.g. HAAs, THMs, or Radium 226/228) the sum as it will be reported to the client is compared to the limit. Summation reported results that equal or exceed a Maximum Contaminant Level (MCL) or a Regulatory Action Limit (RAL) must be confirmed as soon as possible (except as described below) preferably within holding time.

All results that equal or exceed an MCL or RAL, whether or not the customer ordered that compound, are reported to the customer (except as described below).

The analyst must give the highest priority to verification of these data so that the customer can be notified as soon as possible.

Radiochemistry sample results that exceed MCL levels and are reported with counting uncertainty are not confirmed by reanalysis. All samples that exceed the MCL are retained for a minimum of three months after the analysis date to allow for verification at the request of the customer.

The analyst reanalyzes the sample to verify the occurrence of the MCL or RAL violation. The verification result must be within the Relative Percent Difference (RPD) of the original result as specified in the technical SOP for duplicate precision. After the verification run meets the RPD requirement, the analyst submits results to the QA Department for review. The analyst or the QA Reviewer submits results to Reporting. In the absence of Quality personnel, the Technical Director or another Section Manager will review the analytical results. Upon approval of the results, they are forwarded to the Project Managers (PM). This procedure can also be performed electronically using the Client Contact Queue. Upon verification, if required, the results are submitted by the analyst or reviewer, electronically, to the Client Contact Queue. The Client Contact Queue tracks the approval and the contact made by the PM.

Exceptions to the MCL procedure based on test ordered are as follows: Haloacetic Acids (HAAs), Trihalomethanes (THMs) and Total Coliform and *E. coli* do not require verification but are reported as described earlier.

Exceptions to the MCL procedure based on sample source are as follows: results from Formation Potentials and special matrices such as those produced by engineering studies, exposure studies (EW), waste water (WW), non-aqueous materials (OS), and process water used in manufacturing do not require verification but are reported as described earlier.

Results that exceed the MCL or RAL for samples from Exposure Water (EW) and were submitted by Underwriters Laboratories do not require verification and do not have to be reported prior to the normal reporting process.

The PM must contact the customer as soon as possible after receiving the Notification. The PM records the date and time of the call, and the name of the person who was given the information in the Client Contact Queue.

8.3.5 Other Compounds Detected (OCD)

The laboratory treats Other Compounds Detected (OCD) that exceed the MCL or RAL by the same procedure used for ordered analytes. All analysts shall bring large, unusual chromatographic responses to the attention of their supervisor. A decision will be made on each individual occurrence.

8.3.6 Interfering Peaks

When a sample result cannot be calculated due to the presence of an interfering peak, and the opportunity to process the sample at a dilution does not exist, the Data Packet and the customer report must indicate “No Result for this compound.” The analyst notifies the Project Manager who is responsible for discussing the issue with the client. The comments in the Data Packet and the Report Narrative must explain the problem.

8.4 Data Review

The Data Packet and Result Record Sheets are given to a different analyst who performs a separate review of the data. This step is defined as the “QA Review Step.” During QA Review, the entire data packet is inspected to verify that quality control requirements were met, the data is defensible and traceable, manual integrations were properly documented, MCL violations were noted, and any sample comments are accurate. Manual calculations and transcriptions are verified.

8.4.1 At least 10% of data packets for samples submitted by US Department of Defense customers (e.g., US Army CHPPM or US Air Force) are reviewed by the QA Department.

8.4.2 The sample Result Record Sheets are sent to the Reporting Area. The Data Packets are filed by date of analysis in filing cabinets that are located near the area where the analysis is performed. When these filing cabinets become full, the Data Packets are archived in a different location.

8.5 Data Reporting and Report Review

As analyses are completed, reviewed, and approved, the Result Record Sheets are returned to the On Time Delivery (OTD) desk. The reporter assigned to the OTD desk attaches the Result Record Sheets to the original Confirmation Order. When the Result Record Sheets for all of the requested analyses are turned in, the designated reporter transfers the complete packet for final report generation.

A trained Report Writer using an electronically protected report format, which was specified on the Confirmation Order, writes the customer report within the LIMS system. Information is taken from the Result Record Sheets and transferred to the reports according to the SOP, including any qualifying statements (e.g., QC failures, estimated bias) and indications of the impact of the qualifiers on the validity or usability of the data. The report identifies any violations of regulated limits for applicable analytes (See Section 8.3.4 regarding MCL violations & Regulatory Action Limit violations). If necessary, a case narrative is written to explain method deviations or QC failures. If the case narrative needs to contain an explanation concerning the usability of the data for compliance purposes when there are QC failures, the Section Manager, the Operations Manager, or a member of the QA department will approve the explanation. Opinions and interpretations will be noted as such.

Controlled Documents: 06-LO-S0408 Package A Reports, 06-LO-S0440 Extended QC Reports

Upon request, the laboratory will provide enhanced report packages that may include batch QC results, calibration data, raw data, run logs, negative proofs, etc., as long as the confidentiality of other customers is not compromised.

An experienced Report Writer or another qualified staff member then reviews the report. The report undergoes a final review by a PM or another qualified staff member before being copied and sent to the customer.

The Reporting & Facilities Manager monitors the frequency of reports that are amended at the request of the customer because of an error by the laboratory. The QA department and the Operations Manager review the quantity and causes for amended reports on a regular basis at least annually.

8.5.1 Significant Figures

All reported analytical results contain the number of digits (numbers), which are known to be valid. Significant figures reflect the limit in accuracy of the particular method of analysis and measuring instruments. The number of significant figures that are permitted to be reported in a valid result are limited to the number of significant figures that are associated with the least accurate determination in the measurement process.

Radiochemical results are reported to the same number of decimal places with which the counting uncertainty is reported.

Significant figures contain all digits that are accurately known and a last digit that is estimated. For example, if a concentration is reported as 18.8 mg/L, the first two digits must be accurately known and the decimal, 0.8, must reflect the best estimate of that value (i.e., it is more accurate than 0.7 or 0.9).

The number zero may or may not be significant. If it represents a measured quantity, zero is a significant figure. If a zero is merely a placeholder (i.e., it locates the decimal point), it is not a significant figure. Rules regarding zero as a significant figure are summarized below:

- (a) A zero between two non-zero digits is significant.
- (b) If there are no preceding non-zero digits, a zero before the decimal point is not significant. If there are no non-zero digits preceding a decimal point, the zeros after the decimal point but preceding other non-zero digits, are not significant.
- (c) Final zeros to the right of the decimal point, at the end of a number (i.e., 11.00) are always meant to be significant. Final zeroes in a whole number (i.e., 11,000) may or may not be significant. The following table lists the guidelines for reporting results.

Table 1. Reporting Results Guidelines

Result (ug/L)	Report to Nearest
<1	See Note Below
1.0-9.9	0.1 ug/L
10-99	1 ug/L
100-999	10 ug/L
1000-9,999	100 ug/L
10,000-99,999	1000 ug/L
100,000-999,999	10,000 ug/L

Note: For values less than 1, the result is reported to the same number of decimal places that are used in the MRL. For example, the MRL for Endrin by Method 525.2 is 0.01 ug/L. Therefore all results less than 1 ug/L are reported to the nearest 0.01 ug/L with one significant figure recorded on the Result Record Sheet.

When a customer request or a State-specific report format necessitates the conversion of analytical results into different units of measure than used in the determination, the number of significant figures remains the same as the original result. (e.g., Benzene is found at 3.9 ug/L in a sample. The state report format requires all results to be reported in mg/L. We will report 0.0039 mg/L.)

8.5.2 Rounding Rules

This section will describe the rules that are used at the laboratory for rounding numbers. If the figure following those to be retained is greater than five, the figure is dropped, and the last retained figure is raised by one. For example 12.216 would be rounded to 12.22.

If the figure following those to be retained is less than five, the figure is dropped, and the last retained figure remains the same. For example, 10.224 would be rounded to 10.22. If the figure following those to be retained is five, and if there are no other figures than zeros behind the five, the figure is dropped and the last retained figure is raised by one if it is an odd number, or it is kept unchanged if it is an even number. For example, 12.225 would be rounded to 12.22 and 10.215 would be rounded to 10.22.

If the figure following those to be retained is five, and if there are figures other than zeros after the five, the five is dropped and the last retained figure is raised by one. For example 3.3053 would be rounded to 3.31.

If a series of calculations is to be performed, all figures are to be carried through the calculations. The final answer is then rounded to the correct number of significant figures.

8.5.3 Special Rounding Situations

In the special case where a group of analytes are reported separately and also as the “total” of the analytes, (e.g., Total Trihalomethanes) the individual results are rounded using the laboratory rounding rules first, and then the results are summed to produce the “total” result.

When comparing result percent recoveries to acceptance criteria, the percent recovery value is rounded to the nearest whole number prior to comparison to the acceptance window. This rounding is performed according to the rounding rules listed above, in Section 8.5.2.

At times, samples are diluted in order to get results within the calibration range, or to mitigate matrix affects. In these cases, the raw result of the diluted analysis is compared to the raw MRL in order to determine if the result is reportable. If the procedure is one that employs a correction factor (an adjustment made due to the sample volume that was processed), the corrected result is compared to the corrected, unrounded MRL.

8.5.4 Electronic Data Reporting

Many customers require reporting data in an electronic format. The laboratory offers a standard electronic format and provides a variety of customer specific report formats. All electronic data are reviewed in comparison to the hard copy report to ensure that the electronic data are correct and correspond to the hard copy report. In order to protect the confidentiality of customer data, facsimile cover sheets contain a disclaimer. Also, the signature lines on e-mails sent by the appropriate staff contain a similar disclaimer.

Controlled Documents: 06-QA-F0424 Fax Cover Sheet

8.6 Data Archival

All raw data, data packets and reports are archived for a minimum period of ten (10) years after the report has been sent to the customer. Data are retained in the laboratory as long as space allows. More recent data packets are stored in file cabinets in each section of the laboratory. Each drawer of the file cabinet is labeled to identify the instrument used to generate the data. When the drawers become full, the data is placed in boxes for long-term storage. These boxes are clearly labeled and assigned a location code. The location codes and the contents are identified in the Archived Data Log. The boxes are kept in a designated area of the main laboratory facility. The procedure for storing data is described in the SOP for archiving records. In the event that the laboratory goes out of business, all customers of record will be notified. The customers will be given the option to have their records forwarded to them or to have them destroyed.

Controlled Document: 06-QA-S0411 Archiving Records

8.7 Invoicing

When the data report has been finalized, the invoice is prepared. The invoice detail and total are verified for accuracy as compared to the confirming order. The invoice typically is included with the customer's data report, although some customers require billing on a monthly basis. This is reflected on the order and the monthly charges are accumulated and billed accordingly.

All billing errors are documented using the Corrective Action Request (CAR) form. The QA Department assigns these CARs to the accounting staff and Project Manager for resolution and preventive action.

8.8 Correction of Errors

If a transcription error is found, the error is corrected by placing a single line through the incorrect text or number. The correct information is placed above or next to the error, and the initials of the person making the correction is recorded in the vicinity of the correction, along with the date of the action and an explanation if the reason for the correction is not obvious. When necessary, the error will be corrected in the electronic version and a new data sheet will be printed to replace the incorrect one. If an error is corrected within an electronic text file that is used to submit data to the LIMS the documentation of the correction of the error will be recorded in the analyst notes section of the raw data packet or a statement indicating that the electronic text file was corrected will be noted on the affected hard copy raw data.

Instrument results are reviewed by the analyst and confirmed by mass spectrometry or a secondary column. When the results are “not confirmed” the analyst can make one general statement in the “Analyst’s Notes” that cross outs indicate a lack of confirmation. The analyst is allowed to date and initial the results sheet once as long as the analyst indicates the number of cross outs made. If the results sheet is not paginated, the analyst must date and initial each sheet and indicate the number of corrections on each sheet.

9. Customer Complaints

The laboratory responds to customer complaints based on the specific details of the complaint. Complaints will generally fall into two categories: technical and customer service. The PM of record or an assigned PM is responsible for initiating a CAR as necessary to resolve the cause of the complaint. The PM, Operations Manager, Regional Quality Manager, or the Customer Experience Manager may contact the

customer, depending on the severity of the complaint and the complexity of the action necessary to resolve the issue. The CARs generated as a result of a customer complaint are recorded by the QA Department.

Controlled Documents: 06-CS-S0404 Responding to Customer Complaints

10. Calibration, Traceability, and Instrument Maintenance

10.1 Initial Calibration

All instruments are calibrated prior to use to establish instrument response to a known amount of a reference material. The manner in which various instruments are calibrated is dependent on the type of instrument and its intended use. All sample data are reported from within the calibrated range of the instrument. Preparation of all calibration standards is documented in the applicable Standard Preparation Log or preparation records. Instrument calibration is performed using standards that are traceable, when available, to NIST Standards. At a minimum, all standards are traceable to the manufacturer's lot number and Certificate of Analysis (C of A) or other vendor-provided documentation. The number and concentration of calibration standards used are included in the individual method SOPs. Acceptance criteria for calibration data and calibration verification procedures are specified within individual method SOPs. All analysts have been trained on the principles of calibration and use the training manual as a reference.

Controlled Documents: 06-QA-S0401 Calibration Training Manual

10.1.1 Analytical Initial Calibration

Initial calibration procedures establish the calibration range of the instrument response to concentration relationship. Typically, three to five analyte concentrations are used to establish the instrument calibration over the concentration range of interest.

Each SOP specifies calibration acceptance criteria and the minimum number of contiguous calibration points. At a minimum, the lowest point in the calibration must be at or below the MRL. If not, the MRL must be raised to the lowest concentration that is included in the new calibration range. In instances where more than the minimum number of calibration points are analyzed, standard(s) at either end of the curve may be excluded according to the following guidelines:

- If, for example, detector saturation, significant background, and/or co-elution interferences are noted.

- Other calibration points may be excluded only if there is an assignable cause that is known to the analyst, such as a broken injection needle or an empty autosampler vial.
- Any other reasons for excluding calibration points require supervisor's approval.
- If any calibration point(s) are excluded for any of the reasons above, the analyst must record which point(s) are excluded, and the justification for excluding the point(s).

Once a calibration curve has been established and accepted, points may not be excluded or reinstated and the curve fit and the treatment of the origin must not change. When necessary, raw calibration data may be re-processed to meet customer specifications, such as the requirement of a linear curve. In those cases, a new calibration name is assigned to the re-processed data.

10.1.2 Use of Weighted Fit

If the reference method does not explicitly allow for the use of a weighted fit, justification must first be demonstrated in order to apply a weighted fit to a calibration curve. The first step is to determine the calibration range of the analyte(s). Secondly, the type of equation (linear or quadratic) to be used must be determined. Thirdly, variation of response must be demonstrated across the calibration range. The variation must be either directly or indirectly changing with respect to concentration to allow the use of weighted fit.

10.1.3 Treatment of the Origin

The origin may be included in the calibration curve unless otherwise prohibited by the reference method. The origin may not be forced, unless the reference method requires it.

10.1.4 Initial Calibration Verification

In order to verify that the initial calibration standards were properly prepared, a standard prepared from a second source (a QCS) is analyzed with each instrument calibration. This QCS can be prepared in the same manner as the initial calibration standards. For example, if the calibration standards are not extracted, this QCS does not need to be extracted. The QCS must recover within the acceptable limits defined in the SOP.

10.2 Radiochemical Initial Calibration

All instruments are calibrated prior to use to establish instrument response to a known amount of reference material. The manner in which various instruments are calibrated

is dependent on the type of instrument and its intended use. All sample measurements requiring quench correction are made within the quench calibrated range of the instrument. Sample measurements, which do not require quench correction, are made with an instrument dead time of 20% or less or within 80% of the maximum counts per minute capability of the instrument.

10.2.1 Radiochemical Instrument Calibration

Instrument Calibration consists of an initial calibration and possibly a secondary (quench or self-absorption) calibration. Initial calibration consists only of a single point since activity detection efficiency is independent of actual activity levels except at very high activities where instrument dead-time and peak pile-up become prevalent. Environmental water samples are not expected to have activity levels approaching these upper limits.

Secondary calibrations are often performed to correct for sample quench (e.g., self-absorption curves in gas-flow proportional counting and tritium quench curves in liquid scintillation counting). Secondary calibrations are multi-point calibrations using 2 to 20 varying amounts of quench or absorption agent with equal amounts of radioactivity. Results for secondary calibrations do not need to bracket results and do not need to have a standard near the MRL or DL.

10.3 On-Going Calibration Verification

Calibration curves are verified at the frequencies required in the individual SOPs. For most methods, these verifications are performed by the analysis of Continuing Calibration Checks (CCCs), Continuing Calibration Verifications (CCVs), or Instrument Performance Checks (IPCs) that include all analytes of interest. The concentrations of these calibration verification samples are at or below the midpoint of the calibration range. When specified in the reference method, these verifications may involve measurement of instrument responses above the midpoint or within 90% of the upper end of the calibration range. In all cases, the responses must conform to a specified limit relative to the initial calibration as stated in the technical SOP. Continuing calibration standards (from the same source as the initial calibration standard) are typically analyzed at the beginning, and sometimes the middle and end of an analytical sequence to verify stable calibration throughout the sample analysis. The calibration curves are also verified against a second source standard called a Quality Control Standard (QCS) at a frequency specified in the method SOP and the Quality Manual. Each analytical data packet identifies the date and acquisition file name for the calibration used with that data packet.

When a result for the CCC, CCV or IPC is outside the acceptance criteria, the samples must be reanalyzed, re-extracted and analyzed, or a new calibration curve must be

prepared and analyzed. When a new calibration does not meet the acceptance criteria, as long as the assignable cause is not related to instrument performance, samples may be processed using the previous acceptable calibration curve if all QC standards meet their acceptance criteria. Once an initial calibration has been accepted it must be used to quantitate all results until a new calibration curve is established.

10.3.1 On-Going Calibration Verification for Radiochemistry Instruments

LFB and MS samples serve as calibration verifications as well as method verification. LFB and MS samples are spiked with a radionuclide from a separate source from those used during initial calibration. Radiochemistry instruments are re-calibrated annually or after major maintenance/repair (e.g., window or amplifier replacement, etc.).

10.4 Calibration and Validation of Other Equipment

All supporting equipment used in sample preparation and analysis (thermometers, automatic pipettes, balances, pH meters, etc.) are calibrated before being placed into service and on a continuing basis in accordance with the requirements of the manufacturer, the Metrology SOP, or Method SOPs. The periodic calibration checks are performed by comparing the equipment to NIST calibrated equipment, when applicable. Records of each calibration check are maintained and reviewed by the Regional Quality Manager, or a designee. Custom centrifuge tubes used in the organic sample preparation area are calibrated prior to being put into general use. The calibration is documented using form 06-QA-F0410 Standard, Reagent, Extraction Disk Validation & Expiration Extension Form.

Controlled Document: 06-QA-S0408 Metrology

10.4.1 Balances

Laboratory balances are calibrated and serviced annually using a set of class “S” weights which are NIST-traceable by an authorized vendor. The balance calibration is verified daily with a minimum of two weights which bracket the intended weight to be measured. On a monthly basis, the balance calibration is verified with a minimum of three weights that bracket the intended weight to be measured for balances that provide analytical support for Radiochemistry and Microbiology testing. The results of these daily and weekly checks are documented in the Balance Log.

10.4.2 Thermometers

Thermometers are used to monitor the temperature of refrigerators, freezers, incubators and water baths which are used for sample storage, preparation and analysis. Thermometers used for chemistry analyses are calibrated annually at the Temperature of Use. Thermometers used for microbiology analyses are calibrated

semi-annually at the Temperature of Use. Calibration is performed with a thermometer that is certified to be NIST traceable. A correction factor may be used and documented based on the results of the calibration. Thermometers that differ by more than 1°C from the correct temperature are taken out of service.

10.4.3 Refrigerators, Freezers, Incubators, and Water Baths

Walk-in refrigerator temperatures are monitored daily. All other refrigerator and freezer temperatures are monitored on workdays. All sample refrigerators and freezers are also monitored by the building security system in the event a failure occurs outside of a workday, appropriate personnel can be alerted. The building security-system temperature devices are not NIST calibrated and are not official records of temperature monitoring for these units. The upper and lower limits of these devices are set accordingly for the specific unit. Compliance monitoring is based on the reading of the NIST-traceable thermometer for that unit. Incubator and water bath temperatures are monitored when samples are analyzed. The temperature is recorded on the record sheet that hangs on or near the unit. In the event that the temperature is outside the required range, the Section Manager, Regional Quality Manager, and/or Operations Manager are notified so the appropriate corrective action can be taken. Records are maintained in the QA Department.

10.4.4 Automatic Pipettes

Automatic pipettes used for preparation of samples and standards are calibrated every 3 months. They are labeled with the date of calibration and initials of the person who performed the calibration. The calibration data are also recorded and maintained on file in the QA Department. Multi-volume pipettes are used at or as close as possible to their maximum volume to ensure accuracy of less than 3% as required by US Department of Defense customers.

10.4.5 Glass Syringes

The accuracy and precision of glass syringes must be initially demonstrated and documented before they are used for analytical analyses. The syringes can either be purchased with a certificate attesting to established performance criteria or the laboratory can follow the procedure in the Metrology SOP. The calibration data or the certificates are maintained on file in the QA Department.

10.5 Traceability

Standards are traceable to NIST Standards where they are available. Other standards and reagents are traceable to the manufacturer's lot number and Certificate of Analysis

(C of A). The C of A for standards and reagents are scanned and maintained electronically in the computer system.

All data packets must include the proper documentation to identify the standards, solvents, reagents, and extraction material used to process the samples. This is accomplished by including either standard and reagent lot numbers, or unique identification numbers assigned at the laboratory, in the data packet. Standard and Reagent Preparation Logs are used to document any preparation or dilution steps used to prepare working standards and reagents.

10.5.1 Radiochemistry Traceability

Reference Standards that are used in the radiochemistry laboratory are traceable to NIST and purchased from commercial suppliers that conform to ANSI 42.22 and provide a certificate of calibration as listed in Section 8 of that document.

10.5.2 Vendor Approval

New vendors may be approved if it is determined that product prices are reasonable, the quality of the products meets the needs of the laboratory, and the payment terms are acceptable. In order to compare the quality of the product, side-by-side comparisons with existing vendors' products are conducted, when possible. New products can be verified as acceptable if the quality control objectives of the reference method or project requirements are met. Purchases are done in compliance with the UL Sourcing Policy (00-PS-P0026). The UL-Global Sourcing Department, if necessary, may review product prices and payment terms.

A list of approved vendors is available upon request. Existing vendors can remain on the list as long as their products meet the needs of the laboratory.

10.5.3 Validation of Supplies and Standards

New standards received at the laboratory are verified by comparing analytical results for the new material to the analytical results for the current material. This may be done using concentration, area or response depending on the intended use of the standard. The verification process must be started within two weeks of receipt of the standard and must be completed before being used for the analysis of any field samples.

New standards are treated as a second source standard and analyzed against existing calibration standards to verify concentrations. These new standards are not extracted or processed unless a necessary chemical reaction such as derivatization is required to compare results to the old standards. Agreement between the new and old standards is determined by calculating Relative Percent Difference (RPD). The RPD must be $\leq 1/2$

of the percent recovery acceptance window for the method specific CCC. For example, if the method requires a CCC to recover between 70 and 130%, the RPD between standards must be $\leq 15\%$. The validation summary data is scanned and maintained in the computer system.

Controlled Documents: 06-QA-F0410 Standard, Reagent, Extraction Disk Validation & Expiration Extension Form, and 06-QA-S0416 Critical Consumables

Validation of new shipments or lots of reagents or consumables is conducted on an ongoing basis using one of the following techniques:

(1) The quality of reagents or consumables to be used is included in the analytical SOP by specifying the grade or purity required to ensure the quality of analytical results. Upon receipt the reagent or consumable is inspected to verify that the received material meets or exceeds the specified grade or purity of what was ordered.

(2) Analysis of LMBs and LFBs prepared with reagents or consumables that are critical to the quality of the results are performed with each batch of field samples. Analytical results for LMBs and LFBs are reviewed before field samples are reported. Acceptable results for the LMBs and LFBs validate the reagents and consumables.

All reagents (including standards) are labeled and included on the chemical inventory list. The label information includes date received, date opened and expiration date. Reagents and standards used in sample preparation and analysis are recorded in applicable standard or reagent preparation logbooks.

Controlled Document: 06-QA-S0416 Critical Consumables

New instruments must be validated according to the reference method requirements. At a minimum, the validation must include the analyses of blanks, calibration curves, and MDLs. Other supportive measuring devices (pipettes, balances) are validated according to the Metrology SOP, 06-QA-S0408.

10.5.4 Validation of Radiochemistry Standards

Radiochemistry standards may be verified as LFBs with their first use as long as the instrument calibration standard is from another source. LFBs for second sources must be verified within the 2-standard- deviation control limits on the method QC control charts.

11. Internal Quality Control Procedures

The daily quality of analytical data generated by the laboratory is controlled by conformance to this Quality Assurance Manual and all applicable Standard Operating

Procedures (SOPs). The type, frequency, and acceptance criteria for internal quality control checks are described in this section and in the technical SOPs.

11.1 Quality Control Indicators

To assess the validity of analytical data, a number of Quality Control (QC) samples are included in the measurement system. Acceptance criteria and corrective actions for these samples are defined in the technical SOPs. The laboratory's Quality Objective is to only report sample results from analyses that have demonstrated that the calibration is acceptable, the sample preparation process was performed correctly, and no laboratory contamination is present. If these criteria are not met, the analyst is expected to take the necessary corrective action depending on the amount of sample available, holding time remaining for the test, and turnaround time (TAT) requested by the customer. If the sample is out of holding time, or if there is insufficient sample volume to repeat the process, the laboratory contacts the customer and either recommends data acceptance with qualifying statements or recollection based on sound scientific judgment.

Acceptance criteria for Quality Control Indicators are generally defined as either the limits required by the reference method or statistically determined control limits based on data generated by the laboratory. Compounds analyzed at the laboratory that are not listed in reference methods will use limits established from laboratory data. Descriptions of the different types of Quality Control Indicators are listed in the following sections.

Client or Project Specific QC can be requested and these criteria are entered into the LIMS. The DataEntry application will flag results that do not meet these criteria.

Department of Defense (DoD) requires specific QC criteria. For DoD samples, the method blank will be considered contaminated if: The concentration of any target analyte in the blank exceeds $\frac{1}{2}$ the reporting limit and is greater than $\frac{1}{10}$ the amount measured in any sample or $\frac{1}{10}$ the regulatory limit (whichever is greater); The concentration of any common laboratory contaminant in the blank exceeds the reporting limit and is greater than $\frac{1}{10}$ the amount measured in any sample or $\frac{1}{10}$ the regulatory limit (whichever is greater); The blank result otherwise affects the samples results as per the test method requirements or the project-specific objectives. If the method blank is contaminated as described above, then the laboratory shall reprocess affected samples in a subsequent preparation batch, except when sample results are below the LOD. If insufficient sample volume remains for reprocessing, the results shall be reported with appropriate data qualifiers.

11.1.1 Chemical, Radiochemical, and Microbiological Analyses Terms

All Chemical, Radiochemistry, and Microbiological Analyses terms are found in the “Glossary of Terms” referenced by this document in KMS.

Controlled Document: 06-QA-F0401 Glossary of Terms

11.2 Method Detection Limits (MDLs)

11.2.1 Each Method Detection Limit (MDL) is defined as the lowest measured concentration with a 99% confidence level that the result is non-zero for a given analytical method and sample matrix. MDLs are determined in accordance with the requirements of 40 CFR Part 136 Appendix B titled “Guidelines for Establishing Test Procedures for the Analysis of Pollutants.” A standard deviation and calculated 99% confidence level are determined by the analysis of seven reagent water spikes fortified with the analyte(s) of interest. The determination of MDLs is performed on a frequency based on the analytical method requirement, and on all instruments used in the analysis. In the absence of any method requirement, MDLs will be performed annually. The results of all MDL studies are processed and maintained on the computer system according to the directions provided in the Guidance Document for Administration of MDL Summary Sheets.

The applicable technical SOPs include procedures and acceptance criteria for MDL studies. Section Managers are responsible for maintaining current MDLs and DOCs for their areas of responsibility. Data points obtained in an MDL study may only be dropped if the point is an outlier as determined by the use of the Dixon Test, which is described in Section 11.4 of this manual.

Acceptance criteria for MDLs are as follows:

For compliance (NELAC) methods: The calculated MDL must not be greater than the target concentration, must not be less than 1/10 of the target concentrations, and must not be greater than the Minimum Reporting Limit (MRL).

For in-house methods: The calculated MDL must not be greater than the target concentration and must not be greater than the Minimum Reporting Limit (MRL).

11.2.2 Some analytical methods do not require a MDL study; instead a Lowest Concentration Minimum Reporting Level (LCMRL) is required. The single laboratory LCMRL is the lowest true concentration for which the future recovery is predicted to fall, with high confidence (99%), between 50-150% recovery. In lieu of the MDL study, the following procedure is required to be completed initially on each instrument performing the method.

11.2.2.1 Select a concentration for the MRL to be reported. Note that the calibration curve used in this method must have a point at or below this MRL concentration.

11.2.2.2 Fortify, extract, and analyze seven replicates at the proposed MRL concentration. Calculate the mean and standard deviation for these replicates. Determine the Half Range for the prediction interval of results (*Hrpir*) using the following equation:

$$Hrpir = 3.963 * S$$

Where S= the standard deviation, and 3.963 is a constant value for seven replicates.

11.2.2.3 Confirm that the upper and lower limits for the Prediction Interval of Result (PIR = Mean +/- *Hrpir*) meet the upper and lower recovery limits as described below. The MRL is validated only if both the upper and lower PIR limits meet the criteria. If not, the MRL has been set too low and must be determined again at a higher concentration.

The upper PIR limit must be </- 150% recovery:

$$\left(\bar{X} + Hrpir \right) * 100 \leq 150\%$$

The lower PIR limit must be >/- 50% recovery:

$$\left(\bar{X} - Hrpir \right) * 100 \geq 50\%$$

11.3 Minimum Reporting Limits (MRL)

Each Minimum Reporting Limit (MRL) is established by the laboratory as the lowest analyte concentration that can be reliably quantified and reported by the laboratory. If the result is greater than the MDL and less than the MRL it must be reported with qualification. The MRL is set at or above the lowest calibration standard used in all analyses. MRLs must be supported by valid and current MDLs. The MRL is set equal to, and typically less than, any regulatory (State or Federal) Maximum Contaminant Level or Action Limit for regulated analytes.

The laboratory verifies the validity of MRLs through the use of a Low Level Quantitation Check as described in the EPA Manual for the Certification of Laboratories Analyzing Drinking Water, 5th ed. For methods that require the use of a Low Level Fortified Blank the Low Level Quantitation Check is referred to as the FBL. For Methods that do not require the use of an FBL the Low Level Quantitation Check is referred to as the

Reporting Level Check (RLC). Until a sufficient number of data points are accumulated, the acceptance criterion is 50 – 150% recovery. When sufficient data are accumulated, limits of acceptability are calculated using +/- three (3) standard deviations of the mean of the data.

The State of Minnesota (MN) requires limits of acceptability for the Low-Level Quantitation Check to be set at 60 – 140% recovery. When an analytical run includes a field sample from MN, an additional low-level quantitation check is included in the run and is labeled MNCC. Results for the MNCC outside of the acceptance criteria only apply to the samples from MN. Results for the FBL/RLC outside of the acceptance criteria apply to all non-MN samples. When a failure occurs for either or both low-level quantitation checks, corrective action is taken by reanalyzing the low-level check and the affected samples. When the check fails a second time, the low-level check and the samples are prepped and analyzed again.

11.3.1 Radiochemistry Detection Limit (DL)

For Radiochemistry methods, required instrument sensitivity and Detection Limit (DL) are synonymous. Radiochemical instrument sensitivity is defined as the activity that can be detected with a precision of $\pm 100\%$ at the 95% confidence level. Therefore, the DL is defined as 1.96σ where σ is the standard deviation on the net counting rate of background count rate (40 CFR 141.25(c)). The required DLs for radiochemical techniques approved for the safe drinking water act are listed in 40 CFR 141.26.

For Radiochemical analyses, the detection limit (DL) will be determined at least daily to ensure that samples have been measured to slightly below the regulatory required detection limit (DL). Therefore, for radiochemical analyses, the MRL is set at the calculated DL for the analysis. The calculated DL is reported to the client unless the state required format does not require the DL, in those cases the regulatory required detection limit is reported. For each sample, the calculated radioactivity with uncertainty is reported to the client.

11.4 Outlier Test for Small Data Sets

The Dixon Test is used to determine outliers in small data sets (<10). The data are screened for outliers using the Dixon Test, before calculating the mean and standard deviation. If the data point fails the outlier test it is rejected. If the ratio between the difference in the suspected outlier and the next closer value divided by the total range in values exceeds the Dixon Test statistic at 95% confidence, then the result is considered an outlier and will not be used to calculate the mean and standard deviation.

In performing the test, the sample data are first ordered from smallest to largest. The calculated r-value is compared with the test statistic at a 95% confidence level. The

observation is rejected, if the ratio is too large. Use the following equations and Table to apply the outlier test.

If the smallest value is suspect $r = \frac{Y_2 - Y_1}{Y_n - Y_1}$ then

If the largest value is suspect then $r = \frac{Y_n - Y_{(n-1)}}{Y_n - Y_1}$

Where:

- r = the calculated value.
- Y_1 = the smallest observed value, numbered in consecutive order from smallest to largest.
- Y_2 = the second smallest observed value.
- Y_n = the largest observed value.
- $Y_{(n-1)}$ = the second largest observed value.

Table 2. The Dixon Test - Percentage points of the distribution of r^*_{10}

N	1 - α	
	.95	.99
3	.941	.988
4	.765	.889
5	.642	.780
6	.560	.698
7	.507	.637
8	.468	.590
9	.437	.555
10	.412	.527

12. QC Tracking

QC Tracking is a LIMS application and is used to monitor the performance of quality control samples through the use of control charts. A change in QC results indicates that some variable in the test has changed. The analyst must attempt to identify this variable and correct or control the variable when the QC results fall outside the acceptance limits. QC Charting helps the analyst identify the variables that affect the precision and accuracy of the test method. Outliers are listed in the Data Table in the QC Tracking application.

Data is evaluated for QC trend analysis each week. The weekly result of the trend analysis is stored on the computer system as well as distributed to the technical managers via e-mail. The managers are responsible to have the documented trends investigated in the QC tracking application. Actions taken from the trend analysis are documented in the LIMS (Instrument Maintenance Module). When a QC failure occurs and an assignable cause is known the QC results are marked “Not Tracked” in the Data Entry module to prevent inclusion in QC Tracking. All other data, including outliers, whether reportable or not are compiled and may be plotted. The Regional Quality Manager determines when the established limits need to be reset based on the current results.

When a “trend” is assigned by the Section Manager the analyst is responsible for the following:

- Investigating the trend of QC data in QC Tracking module.
- Recording the findings of the investigation.
- Recording the corrective action taken or
- Recording the justification for “no action taken.”

The details for handling QC failures are documented in each technical SOP. The system for corrective action is described in Section 11 of this Quality Assurance Manual.

QC Limits for the Laboratory Fortified Blank are established for all analytes tested at the laboratory in order to document the current accuracy of the method as performed by the laboratory. Within-run precision is established and documented based on duplicate sample analysis. Between-run precision is based on the standard deviation of the data collected on the LFB. Method accuracy is based on the percent recovery data collected from the LFB.

The results of quality control sample analyses are plotted chronologically. The acceptance limits are based on the LFB results, calculated using percentiles, and applied to the LFB, MS, DOC, CCC, and QCS samples. A minimum of 30 data points, checked using the Grubbs outlier test, are used to establish the limits. The limits contain the central 99.74% of the data, which is equivalent to using the mean ± 3 sd when the data follows a normal Gaussian distribution. .

Established QC acceptance limits apply to non-method analytes, or to methods that require their use. The Regional Quality Manager approves the limits before they are used. Results that fail these limits are flagged when the data is submitted to the database.

Method limits are always used instead of laboratory limits for rejecting data or when qualifying results when a sample cannot be reanalyzed. Failures to established limits will be noted internally and corrective action will be taken. If the established limits exceed the method limits, the cause is determined and corrected to meet our QA objectives. The method limits are used to set the initial upper and lower control limits prior to the generation of in-house limits and when the established limits exceed the method limits. Analyte Recoveries (QC Data) are rounded to the nearest whole number before comparing results to the acceptance limits.

12.1 Outlier Test for Established Limits

The Grubbs outlier test is used to screen the data for outliers and the Westgard's Multi-Rule Shewhart Procedure is utilized for determining trend analyses. The analyst notes on the Result Record Sheet how QC failures may affect the data and why the sample was or was not reanalyzed and why the data were acceptable or not acceptable. The reporter reports the results along with the analyst's comments.

The Grubbs Test is used to determine outliers in large sample sizes, (e.g., 30 or more data points). QC results are evaluated for outliers before the data is included in determining the QC accuracy and precision limits. The suspected outlier is subtracted from the average result and divided by the sample standard deviation. The result is compared to the percentage points for the Grubbs Table. If the result exceeds the value in the table for the number of observations at the 95% confidence interval, the value is considered an outlier and will not be used to calculate accuracy and precision limits or to determine trends.

Table 3. Grubbs Test - Percentage points of T_n or T_1^*

Number of Observations, n	1 - α	
	.95	.99
3	1.15	1.15
4	1.46	1.49
5	1.67	1.75
6	1.83	1.94
7	1.94	2.10
8	2.03	2.22
9	2.11	2.32
10	2.18	2.41
11	2.23	2.48
12	2.29	2.56
13	2.33	2.61
14	2.37	2.66
15	2.41	2.71
16	2.44	2.75

Number of Observations, n	1 - α	
	.95	.99
17	2.47	2.79
18	2.50	2.82
19	2.53	2.85
20	2.56	2.88
21	2.58	2.91
22	2.60	2.94
23	2.62	2.96
24	2.64	2.99
25	2.66	3.01

The sample standard deviation using (n-1) is calculated. The calculated r value is compared with the test statistic at 95% confidence. The observation is rejected, if the ratio is too large.

If the largest value is suspect then

$$r = \frac{Y_n - \frac{\sum Y_n}{n}}{S}$$

If the smallest value is suspect then

$$r = \frac{\frac{\sum Y_n}{n} - Y_1}{S}$$

Where:

s = Standard deviation for (n-1).

r = the calculated value.

Y₁ = the smallest observed value, numbered in consecutive order from smallest to largest.

Y_n = the largest observed value.

12.2 Measurement Uncertainty

Measurement uncertainty based on counting statistics is provided in all reports of Radiochemical analytical results. Measurement uncertainty is not provided routinely for non-Radiochemical analytical methods. If a customer requests the addition of measurement uncertainty for non-Radiochemical analyses, the value provided will be based on the statistical analysis of at least thirty (30) Laboratory Fortified Blank (LFB) results by using the QC Tracking module described above.

13. Holding Time Policy

The applicable holding times for all analytical methods are included in the Schedule of Services. The Section Managers and analysts are responsible to recognize the time left in the sample or extract holding time. If a holding time is exceeded, the Project Manager (PM) is notified, and the customer is contacted for the appropriate action. The holding time requirement is typically measured from the date and hour of sample collection except as noted below.

If the holding time requirement in 40 CFR 141, (method hold time), is expressed in days, then the holding time in the laboratory is calculated in calendar days from the day of sample collection. If the holding time requirement is expressed in hours, then the holding time in the laboratory is calculated in hours from the day and time of sample collection. For example, samples with a 14-day holding time that were collected on 4/1/99 are within holding time if analyzed any time before the end of the 14th day from sample collection or midnight on 4/15/99. Samples with a 48-hour holding time that were collected on 4/1/99 at 2:00 p.m. are within holding time if analyzed any time before 2:00 p.m. on 4/3/99.

The laboratory will adhere to other sample holding time requirements when specifically requested or required in writing from customers or regulatory agencies. These requirements are entered into LIMS and managed through the Sample Scheduling Tool. This tool flags the samples that require a specific hold time calculation that differs from the laboratory's hold time policy.

The analyst is responsible for reviewing the Confirmation Order, and clearly understanding what is required. If the holding times are exceeded, the analyst must notify Customer Services so that they can contact the customer. A PM must record the customer contact and include documentation with the report packet. The analyst must also notify Reporting of the holding time violation by clearly stating the occurrence on the Result Record Sheet or Customer Contact Form. Alternatively, the analyst can document the holding time violation using the Client Contact Queue. The Reporter must list the holding time violation on the customer report.

Samples are tracked in the database using the time and day that the samples were collected, extracted and analyzed, to ensure that the information can be provided to the customer if any holding times are exceeded.

14. New Method Development and Validation

Any New Test Approval requires approval by the Operations Manager and/or the Technical Director before work begins on development of a new analytical method. The process requires that a “New Test Development Request for Approval” form, referenced by this document in KMS, be completed to initiate the process of developing and validating a new method. Any employee can submit such a request. All requests are evaluated and approved or rejected based upon the business need, the laboratory's ability to perform the analysis, and regulatory requirements.

If the request is approved, development and validation is assigned to the appropriate analytical department. The assigned analytical department is responsible for defining the analytical test method, writing the draft SOP and identifying collection and preservation requirements for the prescribed method. The method is validated in accordance with applicable requirements, which at a minimum include the performance of acceptable DOC and MDL studies. The Regional Quality Manager and the Operations Manager review these data. The required Bench Sheets and Data Entry Forms are created and reviewed by the QA department.

Upon approval by the Operations Manager and/or the Technical Director, the appropriate documents are created (or updated) to include the requirements for sample collection and preservation, receiving, analysis, and reporting. The appropriate reporting documentation and formats are created.

A price for the new test is established by the Customer Experience Manager and approved by the Operations Manager. All data and documentation for the new test are provided to the QA Department and the “New Test Approval/Entry Request” form is completed. The QA Department updates the appropriate documents for shipping, sample collection, preservation, sample receipt, and analysis. After completion of all these steps, the test is given a unit price and entered into the database as an orderable test.

Controlled Document: 06-RD-S0400 and 06-RD-F0401

15. Performance and System Audits

Quality Assurance Audits are conducted to verify conformance with the Quality Assurance Program, to evaluate the effectiveness of the QA Program, and to take the

appropriate actions to improve the Quality Assurance Program. Audits are conducted by either laboratory employees (internal), or by other parties (external). Both internal and external audits may evaluate the company's performance or systems.

Performance Audits are conducted to assess the quantifiable aspects of the company's processes. Performance can be assessed in a very objective manner, since the performance either conforms or doesn't conform to prescribed procedures or policies. Some of the most common ways to evaluate performance are by determining adherence to an SOP, approved Policy, the ability to produce acceptable (passing) analytical results, or by obtaining acceptable results in PT Studies.

System Audits evaluate the operational details of the laboratory's QA Program. A System Audit is more subjective in nature. The purpose of the System Audit is to determine if the company's overall quality system is effective in ensuring compliance and conformance to the Quality Objectives.

15.1 External Audits

Regulatory agencies or customers usually conduct external Audits of the laboratory. These are typically scheduled in advance and are performed to ensure compliance with certification or customer requirements. The Operations Manager and Regional Quality Manager are responsible for scheduling and coordinating all external audits.

15.1.1 External Performance Audits

The laboratory participates in four Proficiency Testing (PT) studies per year. Two of these studies are needed to maintain state certifications. Studies are conducted in each quarter of the year. Additional studies may be required by the QA department to make up for analytes that were missed in any of the regular studies. An approved vendor provides the PTs. The laboratory does not know target concentrations at the time of the testing.

When results from a PT Study are received, they are distributed to appropriate laboratory personnel. If there are any analyte failures, a Corrective Action Request is initiated by the QA Department and provided to all applicable Section Managers. The responses are reviewed and approved by the Regional Quality Manager and the Operations Manager. The Regional Quality Manager provides any responses to the customer or the regulatory authority required as a result of the audit.

Controlled Document: 06-QA-S0412 Managing the PT Program

15.1.2 External System Audits

External System Audits are performed at frequencies set by the various State Certification Agencies, and by individual customers. These audits are usually performed on-site, but occasionally, the audits may be performed by reviewing documents that are sent to the requesting party.

15.2 Internal Audits

Internal Audits are performed or initiated by laboratory staff. Each designated section of the company is audited annually. Internal Audits may also include department inspections, double blind studies, random data packet and report reviews, or frequent monitoring of QC failures.

15.2.1 Internal Performance Audits

The laboratory performs at least two Double Blind PT studies per year. These studies are obtained from an approved vendor. The laboratory staff does not know the identification or the presence of the samples. These studies evaluate the laboratory's procedures from the placement of the order, through reporting and invoicing. Feedback is provided to the staff regarding the results of the blind testing and CARs are assigned for non-conformances.

QC Failures are assessed on a weekly basis. QC Failure Reports are generated from the database, and are distributed to the managers. Methods that show high failure rates are identified, and the problems are addressed.

Internal Performance is also audited as part of Internal System Audits.

15.2.2 Internal System Audits

The design of the Internal System Audit Program is intended to assure that all designated areas of the laboratory are audited annually. These audits consist of reviews of applicable laboratory systems, procedures, and documentation. The Regional Quality Manager and QA staff oversees annual Internal System Audits. An Internal Audit Schedule is prepared at the beginning of the year and the Operations Manager monitors conformance to the schedule. All internal audits are completed within the calendar year; however, due to staffing and workflow it is not required that they be completed within the scheduled month. The Operations Manager and Regional Quality Manager assign various staff members to Audit Teams. Auditors must receive auditor training before they can accompany an experienced auditor on an internal audit. Internal auditors must take part in at least one audit before they are qualified to perform as a lead auditor. The Internal Audit Procedure is described in the Internal Audit SOP. At least annually, LIMS Raw Data (LRD) is reviewed by the QA Department by selecting final reports and tracing all analytical data back to their generation point. Any

discrepancies that are found are brought to the attention of the Operations Manager and the IT Manager.

Controlled Documents: 06-QA-S0409 Internal Audits

15.3 Audit Response

Response to deficiencies found in any audit is the responsibility of the appropriate Section Manager. Responses are compiled and documented. If the findings are the result of an external audit, the responses are forwarded to the appropriate State or customer when requested. If the findings are the result of an internal audit, the responses are captured on Corrective Action Request forms. The QA staff coordinates the necessary activities to ensure that any problems are clearly identified, the effect on analytical results is determined, and those customers whose samples were affected are identified. The Regional Quality Manager and Operations Manager will review this information and determine if the findings require any additional corrective action. Where the audit findings cast doubt on the correctness or validity of the laboratory's test results, the laboratory must take immediate corrective action and must notify, in writing, any customer whose data may have been affected.

16. Corrective and Preventive Actions

Corrective Actions may be necessary for many different reasons. The extent of action necessary to correct a problem also varies greatly. In some cases, the corrective action may be as simple as reanalyzing samples that were originally contained in an analytical batch with failed QC. Other times, the action may be as complicated as purchasing new equipment or validating a new technique.

16.1 Immediate Corrective Action

Immediate corrective actions may be necessary because of an increased failure rate of analytical QC measurements on a particular instrument. In this situation, the analyst takes action to restore the instrument to acceptable working condition by performing maintenance or initiating a service call. During the instrument down time, a "Do Not Use" sign is placed on the instrument. All necessary repairs and part replacement is documented in an Instrument Maintenance Log. The instrument is not used to generate sample data until acceptable performance is documented. The analyst uses the SOP on "Handling Defective Equipment" as necessary. As stated in Section 1, the Regional Quality Manager has the authority to stop further analyses until the issue is resolved.

Controlled Document: 06-QA-S0413 Handling Defective Equipment

Data generated with an out of control QC measurement are evaluated for usability in light of the nature of the deficiency. In any event, the Project Manager is notified of the problem, so it can be discussed with the customer. If the deficiency is judged not to impair the usability of the results and the customer agrees, the data are reported and the QC failure is noted in the Case Narrative. In cases where the samples associated with the QC failure are for regulatory compliance, such qualified data may not be acceptable. When such data cannot be reported, corrective action includes sample reanalysis (i.e. if sufficient sample remains or it is still with in holding time) or recollection and reanalysis.

16.2 Long Term Corrective Action

Long-term corrective action is generally initiated to address Quality Assurance issues that are often identified through internal or external audits. These involve more detailed investigation into the root cause of the nonconformance, and may take longer to resolve. Staff training, SOP revisions, or equipment replacement may be indicated as solutions for long-term corrective action.

16.3 Corrective Action Requests

A Corrective Action Request (CAR) is the mechanism by which an employee can identify a quality deficiency and document the necessary steps to remediate the problem or propose an improvement to current procedure. Any employee can initiate a CAR. When a CAR is submitted, the CAR Administrator assigns the CAR to an Owner who has responsibility for determining the root cause, developing the short and long-term plans, and implementing the plans to close the CAR. The “Owner” is responsible for constructing a corrective action plan, and setting a target date for completion. The CAR administrator has the responsibility for administering the CAR process, which includes approving the corrective action plan, verifying the implementation and verifying the effectiveness of both the long and short-term corrective action. Refer to the Lotus Notes Database CAR System Doc# 00-QA-S0010 and the Corrective Action Request Process, Doc# 00-QA-S0006 for details of the corrective action system.

16.4 Preventive Actions

When applicable, a preventive action plan is required as part of a corrective action request. The plan will state the steps that will be implemented to ensure that the deficiency does not reoccur. Other types of preventive actions are those taken to avoid QC failures in analytical batches. The specific actions necessary for each analytical procedure are listed in each technical SOP.

Preventive actions are taken in order to minimize the potential for future non-conformances through continuous process improvement. Additionally, they are

intended to recognize and correct problems before the issue can have a negative impact on the customer. The following practices are used to determine the need for preventive action:

- 1.) Double Blind PT Studies-Section 15.2.1
- 2.) Observations from Internal Systems Audits-Section 15.2.2
- 3.) Annual Review of SOPs-Section 17.0
- 4.) Annual Management Review of the Quality System-Section 2.3.1.

When outcome of these activities indicate potential for improvement, the observations should be documented by the generations of a CAR (Section 16.3). This process provides the controls to insure that an action plan is developed, documented, and implemented by the appropriate personnel.

The laboratory also has established practices to eliminate non-conformances on a routine basis before they negatively impact the customer. The result of these activities may not result in the generations of a CAR, but they are important elements of the preventive action program:

- 1.) Preventive Instrument Maintenance: Section 4.6.1
- 2.) Software Validation: Section 5.2
- 3.) Bid, Proposal, and Contract Review: Section 6.0
- 4.) Subcontractor Approval: Section 8.2
- 5.) Data and Report Review: Sections 8.4 and 8.5
- 6.) Vendor Approval Section: 10.5.2
- 7.) QC Tracking: Section 12
- 8.) New Method Validation: Section 14.0

Finally, employees of the laboratory are encouraged to initiate preventive actions through the CAR system if they have proposed improvements to the facility, equipment, or procedures.

17. Document Control

Activities and information that have been identified as essential to the operation of the business are documented and included in the formal Document Control System to ensure their integrity. The Document Control System ensures that information or instructions are documented in a standardized format, receive management approval when created and revised, are made available to the appropriate personnel, and that previous revisions are removed. Effective control over the documents to prevent the use of incorrect or out-dated information is critical. Review and/or revision of the SOP documents are conducted every year. Annual performance audits are performed to

ensure that these documents are accurate, understood, and followed by the appropriate personnel. Forms, Report Formats, Guidance, Customer, Work Instruction and Job Aid documents are reviewed each time the document is used to determine if any changes are needed. A formal review of these documents is conducted every two years. A copy of the current controlled document and all previous revisions, along with each revision's completed Request for Approval (RFA) form (when applicable) is maintained by the Quality Assurance Department. All approved documents are included in the Controlled Document Master Indexes.

17.1 Revision of Controlled Documents

If a controlled document needs to be revised, the owner of the document saves a copy of the current version of the document to a local drive. The owner edits the document with "Track Changes" turned on. After the editing is completed the owner sends the document to the QA Department via email. The QA Department reviews the document for formatting, adherence to standards, adherence to reference methods and grammar & spelling. The QA Department submits the revised document for approval using the KMS Published Document System.

Controlled Documents: 06-QA-S0415 Documentation Procedures and Document Control

17.2 Staff Training for Standard Operating Procedures

Initial training on Standard Operating Procedures (SOPs) is part of an employee's initial training when they begin employment, or when they are receiving further training. This activity is documented on a training checklist that is kept in the training file. When an SOP is revised, a copy of History page is attached to a Training Form and given to the appropriate Section Manager. That person is responsible for training the affected personnel on the revisions made to the SOP. The personnel receiving the training are required to sign the training attendance form to document that they are aware of the changes.

Controlled Document: 06-QA-F0412 Training/Presentation Attendance Log

17.3 Structure of Controlled Document System

The QA documentation pyramid begins with the QA Manual. The next level of documents includes the SOPs, which utilize any number of additional controlled documents to make the system functional, efficient, and effective. The next level of documents consists of technical and non-technical forms, customer-facing, and internal guidance documents e.g., Sampling Instructions. The lowest level of documents consists of tables, computer spreadsheets, work instructions and job aids. The Master Document Control Index identifies all of the approved SOPs. A unique number identifies each policy and procedure. The effective date and last revision date are

displayed on the table. SOPs are posted in the KMS Published Document System. The laboratory employees are responsible for the review of specific SOPs, which they use, every year at a minimum. Documentation of the review process is maintained in the QA Department. An SOP is maintained for creating and revising documents.

Controlled Documents: 06-QA-F0423 Master SOP Index, 06-QA-F0428 CFG Master Index

18. References

18.1 NELAC Quality System Document, 2003

18.2 ISO/IEC 17025, 2005

18.3 EPA's Good Automated Laboratory Practices Manual, 1995

18.4 EPA 40 CFR Parts 136-149

18.5 EPA 815-B-97-001, March 1997

18.6 Department of Defense Quality Systems Manual for Environmental Laboratories, Version 4.1, April 22, 2009