

# ENERGY LABORATORIES-BILLINGS, MT QUALITY ASSURANCE MANUAL

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## ELI COMMITMENT

Energy Laboratories, Inc. Strives Toward:

1. Being highly skilled in the field of analytical chemistry.
2. Delivering quality and service with integrity.
3. Encouraging the professional development of our staff.
4. Offering our employees a safe and positive work environment.
5. Being profitable and using resources wisely for a sustainable future.

## INTRODUCTION

Energy Laboratories, Inc. provides chemical, industrial hygiene, and environmental analytical services to private industry, agricultural industry, engineering consultants, government agencies, and private individuals. Analytical services include: analysis of waters and soils for inorganic and organic constituents, aquatic toxicity testing, hazardous waste analysis, radiochemistry, industrial hygiene, microbiology, soils and water physical parameters, and petroleum analysis.

Founded in 1952, Energy Laboratories currently incorporates six separate testing laboratories. The main headquarters are located in Billings, MT, with branch laboratories located in Casper, WY; Gillette, WY; College Station, TX; Rapid City, SD and Helena, MT.

ELI, as a coordinated company of six participating branches, has developed a QA program that takes into account the various method types and EPA programs, while also considering sample matrices, to develop a single comprehensive set of QA guidance. We have used scientific approaches, Good Laboratory Practices, EPA Methods and Guidance documents, and accreditation audit guidance to develop our overall QA Program.

The Quality Assurance Program establishes acceptable performance criteria for all routine analytical procedures being performed by laboratory personnel. The Quality Assurance Assessment Program provides a formal system for evaluating the quality of data being generated and reported. The ELI Laboratory Safety Manual & Chemical Hygiene Plan defines the safety and monitoring procedures used by laboratory personnel in laboratory operations. These, in addition to the experience and expertise of our analysts, provide a comprehensive Quality Assurance Program. Energy Laboratories, Inc., in Billings, Montana, is certified under the Safe Drinking Water Act by Region VIII EPA for Wyoming, and the States of Montana, Idaho, Colorado, Nevada, Texas, North Dakota, and South Dakota. ELI-Billings also holds accreditation for Clean Water Act, Safe Drinking Water Act and Resource Conservation Recovery Act (RCRA) parameters through the National Environmental Laboratory Accreditation Program (NELAP), which is supported by the EPA. The NELAP certification is maintained through the state of Florida. Individual State approval for RCRA and CWA (NPDES) is managed through the Federal/State DMRQA program or through reciprocal certifications when required by a specific state. ELI obtains these certifications either through reciprocal recognition of ELI's primary Montana State or NELAP certification. To perform radon testing, ELI is certified under the National Radon Proficiency Program administered by the National Environmental



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Health Association. Branch laboratories of ELI are certified in their own state and in additional states. Copies of ELI's certificates for all laboratories are maintained on ELI's website: [www.energylab.com](http://www.energylab.com).

The ELI Quality Assurance Manual, the ELI Qualifications Manual, and the ELI Technical Services and Fee Schedule together are used to outline the ELI Quality Assurance/Quality Control Program. This Quality Assurance Manual is appropriate to all departments of Energy Laboratories-Billings. The procedures discussed or referenced in this manual describe our day-to-day laboratory practices and adhere to USEPA Safe Drinking Water Act, and TNI (The NELAC Institute) requirements as well as Good Laboratory Practices (GLPs). Information on ELI-Billings applicable accreditations and certifications can be found in Appendix A of this plan. Where possible, ELI uses EPA, AOAC, ASTM, APHA, NIOSH, OSHA, or published analytical methods and follows the procedures with strict adherence to described protocol and recommended QA/QC parameters. The analytical methods approved and in use are described in Standard Operating Procedures, and are available for review at the laboratory. Vital parts of our Quality Assurance Program, Quality Control and Quality Assessment programs are outlined in Chapters One and Two of this manual.

To generate data that will meet project-specific requirements, it is necessary to define the type of decisions that will be made and identify the intended use of the data. Data Quality Objectives (DQOs) are an integrated set of specifications that define data quality requirements and the intended use of the data. Project-specific DQOs will be established as needed for both field and lab operations. Through the DQO process, appropriate reporting limits, extraction/digestion methods, clean-up methods, analytical methods, target analytes, method quality control samples, sample security requirements, quality control acceptance ranges, corrective action procedures, reporting formats and reporting limits can be specified. Professional laboratory project managers are available to assist clients in specifying appropriate laboratory analyses and reporting procedures necessary to meet project requirements.

Client-specific DQOs can be coordinated with the laboratory through our Project Managers via quotations or contracts, or with relevant documentation provided to the laboratory prior to (or at time of) sample receipt. Client-specific requirements are communicated to analysts and final report validators through the laboratory LIMS system. By default, our methods, analytes, and QC parameters are set up to meet the DQOs specified in the referenced method and/or federal/state regulations. ELI encourages clients to provide ELI documentation of any client-specific, regulatory or project monitoring requirements.

Certain types of requests may not be suitable to standardized analytical methods. These custom requests are handled individually with laboratory management and staff scientists. Project-specific methods and reporting packages are available. Attention to documentation of the analytical procedure and use of suitable QC parameters is maintained according to good scientific discipline and Good Laboratory Practice guidelines.

The ELI-Billings laboratory managers, or their designees, will evaluate all new contracts to determine that the laboratory is capable of performing the requested work. This process includes ensuring that the laboratory maintains the required accreditation, equipment and resources. In the event that sample analysis is not performed at our Billings location, clients are



notified that the work is subcontracted to a qualified branch laboratory or an outside laboratory (See Subcontracting Policy – Chapter 6 in this QA Manual and ELI SOP, *Laboratory Policies*, which addresses Contract Reviews).

This Quality Manual and related quality documentation meet requirements of the National Environmental Laboratory Accreditation Program (NELAP), which is an EPA approved accreditation program.



## CHAPTER 1 – QUALITY CONTROL PROGRAM

### Quality Policy Statement

Energy Laboratories, Inc. is committed to producing laboratory data of known and documented quality that is scientifically valid, meets method specifications, satisfies regulatory requirements, and accomplishes the data quality objectives of the client and project. Management ensures that the laboratory maintains current certifications and is in compliance with accreditations through USEPA, State Agencies, and NELAP. Those method, regulatory, and client requirements (as well as the policies, procedures, and all referenced documents) are incorporated into our Quality Assurance Program; which is outlined within this Quality Assurance Manual. Our Quality Systems are designed to comply with the standards as defined by the most current version of the NELAC accreditation standard and ISO 17025 standards. To ensure compliance with these standards, all laboratory personnel are required to be familiar with quality documentation and implement those policies and procedures in their work. ELI is dedicated to the continual improvement of the management system's effectiveness by providing appropriate corporate resources to set objectives, offering training opportunities, and monitoring the quality performance of our staff. ELI also provides facilities and equipment adequate and appropriate to these objectives.

### Quality Assurance Program

The purpose of the Quality Assurance Program is to ensure that the analytical services provided by Energy Laboratories are of high quality, data is within established accuracy and precision limits (required by the referenced method or Standard Operating Procedure), and each analytical result produced meets or exceeds our accreditation requirements. Management ensures that the integrity of the management system is maintained. Technical Directors, or designees, provide that changes to laboratory procedures are planned, implemented and documented.

Management establishes and maintains data integrity by providing the following to ELI's data integrity system:

- 1) Data Integrity Training (Including the highest standards of ethical behavior)
- 2) Periodic review of data integrity procedural documentation
- 3) Annual Review of data integrity procedures with updates as needed
- 4) Periodic, in-depth monitoring of data integrity
- 5) Maintenance of signed data integrity documentation for all laboratory employees

All employees are expected to implement and follow the policies contained within the Quality Assurance Program. Internal documents (controlled and associated with the Quality Assurance Program) are listed in Appendix B.

The quality systems in the program consist of the policies and procedures, and all referenced documents, described in this Quality Assurance Manual. The Quality Control Program also functions to maintain the laboratory's compliance with accreditations through USEPA, State Agencies, and NELAP.





The Quality Control Program requires that the following points be met for each applicable analytical method:

- Performance of any analytical method requires that the proper equipment and instrumentation are available. A list of major equipment is listed in Appendix F. The procedure for operation of an analytical instrument is described in the equipment manufacturer's operating manual, and may also be supplemented with a specific Standard Operating Procedure (SOP) for the instrument and/or the method.
- Specific SOPs cover operation of the instrument including the sequence of operations involved in instrument start-up, calibrating, analyzing, and shutting down. Chapter 13 of this manual includes recommended preventative maintenance, and/or a list of parameters used to identify other types of maintenance. SOPs outline any special safety precautions for operation of the instrument.
- SOPs of well-detailed EPA, ASTM, NIOSH, APHA, OSHA, or published procedures include, as appropriate, a list of any method-specific items or variances, a list of QC parameters and their recommended method performance ranges, recommended or example analytical sequences, specific or unique safety information, method references, and a signed signature page. SOPs details, and format of method SOPs, follow NELAP requirements. Detailed SOPs may be prepared for those procedures that do not have published methods. Further details of SOP format and information required in method SOPs can be found in the ELI SOP, *Preparation, Numbering, Use, and Revision of Standard Operating Procedures*. Written Standard Operating Procedures referenced within this manual are available at the laboratory for review. (ELI SOPs are considered confidential proprietary information and ELI does not allow copies to be removed).
- For radiochemical analysis performed at ELI's branch labs, each method undergoes Method Validation as outlined in EPA's specific method and/or the Multi-Agency Radiological Laboratory Analytical Protocols Manual (MARLAP), Chapter 6.
- The required detection level (RDL) for radiochemical analysis of drinking water samples is calculated based on the requirements in 40 CFR 141.25(c), which is a sample specific determination. The equation is specific for each method and noted in the method-specific SOP.
- The initial test method evaluation for chemical analysis involves Method Detection Limit (MDL) studies, (refer to ELI SOP, *Determination of Method Detection Limits (MDL) and Quantitation Limits*), confirmation of the Limit of Detection (LOD) and/or Practical Quantitation Limit (PQL), also known as the Limit of Quantitation (LOQ), an evaluation of method performance (using four or more replicates of quality control samples), evaluation of the selectivity of the method, and any additional method-specific requirements
- ELI demonstrates that laboratory staff are qualified and capable of performing the method. Analysts are assigned duties based on their skills and experience. Training



records are maintained for all analysts. Curricula vitae of supervisory and senior analysts are described in Appendix E of the ELI Qualifications Manual.

- It is the responsibility of the analyst to become thoroughly familiar with the methodology and instrument operation before performing the analysis. It is the responsibility of the person providing training to monitor all laboratory results generated for a reasonable time. The amount of time necessary may vary depending on the method and the experience of the analyst. At a minimum, the analyst's performance is to be monitored until the analyst demonstrates the ability to generate results of acceptable accuracy and precision according to the method.
- All analysts are required to demonstrate and maintain a record of proof of competency by routinely analyzing quality control samples appropriate to the analytical procedures they perform. Competency in analyzing these control samples is documented in analysts' training files per NELAP requirements (for more information, see ELI SOP, *Personnel Training and Training Records*). For those analyses where external proficiency testing (PT) samples are not routinely analyzed, competency is documented by including the results of routine analysis of method-specific quality control samples (prepared by laboratory staff) and/or a verifying statement of procedural review by a supervisor or trained analyst.
- Each analytical method is subjected to quality control monitoring. The purpose is to demonstrate that results generated meet acceptable accuracy and precision criteria for the method. Precision and bias are determined for standard and non-standard methods. Precision and bias are determined for standard methods through control charting of data from quality control samples. Precision and bias using non-standard, modified standard or laboratory-developed methods are compared to the criteria established by the client (when requested), the method, or the laboratory.

Quality control requirements are outlined in the methods and ELI, at a minimum, follows the guidelines specified in the methods used. Additional QC requirements are also added as appropriate. Statistical method performance is periodically evaluated against method requirements using control charts.

- Quality control monitoring to measure accuracy for each method generally requires that five to ten percent of all samples analyzed be fortified (spiked) with a known concentration of target analytes tested by the method. The percent recovery is then calculated. This provides a means for monitoring method accuracy and evaluating sample matrix effects. Where appropriate, surrogates are included in the method to monitor method performance on each individual sample. Blank spike samples replace matrix spike samples for certain methods, or when there is insufficient sample for a matrix spike analysis. Historical, routine batch QC sample performance can be used to estimate the precision and accuracy of the method.
- Quality control monitoring to measure precision for each method requires replicate samples be prepared and analyzed when appropriate. Actual requirements are outlined in the specific SOP. When replicate samples or matrix spike duplicates are analyzed,



relative percent difference is calculated and used to monitor precision of the method. In instances where there are no specific method requirements, it is the policy of this laboratory to analyze five to ten percent of all samples in duplicate. Duplicate test results must be within the control limits established for each analysis type or data is qualified. Acceptance limits generally follow specifications listed in the method. Matrix spike duplicates replace sample duplicates for most methods.

- When not defined in the method, and as appropriate, method blanks and/or instrument blanks are analyzed one in every 20 samples at a minimum. Method blanks are used to verify that contamination from laboratory reagents and glassware is not present in the analytical sample process. Generally, the method blank should be less than the reporting limit, or 10 times less than the concentration amount in the sample, for the analytical parameter being tested, whichever is greater.
- When not defined in the method, and as appropriate, method spikes (blank spikes) are analyzed one in every 20 samples, at a minimum.
- Calibration standards are analyzed and calibration curves are developed for all applicable methods. For additional information on instrument calibration, see Chapter Seven of this QA manual.
- The initial calibration is continuously monitored by analyzing a continuing calibration standard every 10 to 20 samples, or within a specified time frequency, and at the end of each analytical sequence; depending on the method and instrumentation. Results must be within an established range as described by the method SOP. Initial calibrations are verified against a standard from a second source.
- Proficiency testing samples and further quality control check samples may be required for various methods. Refer to Chapter Two of this QA manual for further details.

### **Estimation of Uncertainty**

The estimation of uncertainty consists of the sum of the uncertainties of the individual steps or processes of an analytical procedure. The variability of the sampling plan, sample heterogeneity, extraction procedure, instrument calibration, instrument drift, systematic bias, and many other factors all contribute to the uncertainty of a measurement or result.

ELI estimates uncertainty utilizing Confidence Intervals defined as  $\pm 2\sigma$  (95%) and  $\pm 3\sigma$  (99%) where  $\sigma$  is the standard deviation of the recovery of quality control samples. The confidence intervals calculated from these QC samples are based on the spike level concentrations for each method. Uncertainty at low concentrations may be one to three times the quantitation limit. Real world samples, depending on matrix interferences, may have a greater amount of uncertainty associated. Due to limitations in assessing the uncertainty for each matrix type, the confidence intervals calculated from method QC samples provides an estimate of uncertainty.

Energy Laboratories, Inc. uses the procedures outlined in ELI SOP, *Control Chart Generation and Maintenance*, for the purpose of evaluating estimation of uncertainty for chemical analyses



and uses the determination of uncertainty on a sample-specific basis for all radiochemistry measurements. These estimates of uncertainty have formulas documented in the individual SOP.

### ***Maintenance of Performance Records***

All quality control monitoring is recorded and documented. Quality control data is recorded in laboratory notebooks, electronic summary files, and/or analysis sheets. Generally, review of QC data and trends is managed within the Laboratory LIMS system. QC data management and control chart generation, maintenance, and usage are described in ELI SOP, *Control Chart Generation and Maintenance*. It is the responsibility of the analyst to see that all results are recorded in a timely manner.

All quality control data is filed and available for inspection and assessment by analysts, supervisors, management, and quality control personnel.

### ***Method Quality Control Specifications***

Summaries of Quality Assurance/Quality Control specifications for a selected subset of procedures offered by ELI are outlined in Appendix C. These types of tables are available upon request for our clients to use in the preparation of Quality Assurance Project Plans (QAPPs). Exact details of method QC can be found in the applicable method SOPs.



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## CHAPTER 2 – QUALITY ASSESSMENT PROGRAM

The function of the Quality Assessment Program is to provide formal evaluation of the quality of data being generated and reported by the laboratory. External and internal quality control measures are used in this assessment. These measures include proficiency testing samples, laboratory quality control check samples, and routine internal and external audits on methodology and documentation procedures.

### ***Proficiency Testing (PT) Samples***

PT samples are supplied by an outside entity and contain known amounts of constituents. The laboratory does not have access to known values of the samples. Only the PT provider has knowledge of constituent levels prior to the formal publishing of the test results.

PT samples are received on a routine basis, with results sent to the providing entity for evaluation. Proficiency Testing (PT) samples for USEPA, NELAP and various State certifications are Water Pollution Study samples (WP or DMRQA), Water Supply Study samples (WS), and LPTP Soil PT samples provided by either Resource Technology Corporation (RTC) and/or Environmental Resource Associates (ERA); both being NELAP approved PT providers. Routine participation in LPTP, WS and WP PT sample studies is used to maintain certifications for Safe Drinking Water Act (SDWA), Clean Water Act (CWA), National Pollutant Discharge Elimination System (NPDES), Discharge Monitoring Report Quality Assurance (DMRQA), permit monitoring analyses, Resource Conservation and Recovery Act (RCRA) analyses, as well as other states and projects requiring method accredited parameter analyses. The samples are analyzed in the same manner as any routine sample in the laboratory. Acceptable results are those that fall within a defined range as determined by the vendor/EPA/ NELAP; based on multi-laboratory study results. The provider sends results to USEPA and other certifying agencies as requested by ELI-Billings. PT study results are posted on the ELI Corporate website [www.energylab.com](http://www.energylab.com).

A copy of the certificate for our primary certifications to perform drinking water analyses issued by the State of Montana and the NELAP certificate from Florida Department of Health are included in Appendix A. The Montana certification includes a list of parameters/methods for which drinking water certification has been granted. The NELAP certificate also includes RCRA methods used for hazardous waste characterizations and CWA parameters/methods which are used for NPDES monitoring permits. ELI also participates in the Federal/State DMRQA programs for clients which require/request this with their NPDES permits. Reciprocal accreditation in other states is based on either of these, or both, depending on specific state certification requirements/parameters. A list of current certifications is maintained on the ELI website at [www.energylab.com](http://www.energylab.com).

Proficiency testing samples for Radon Proficiency testing certification are from the National Environmental Health Association (NEHA), an EPA approved commercial Radon testing certification association. Our own radon sampling canisters are submitted to NEHA for known levels of radon exposure. Acceptable results are those that fall within a defined range based on multi-laboratory study results.



Blind Quality Control Check Samples are samples submitted as regular lab samples and are processed through the system in the same manner as any other sample. The analysts do not know the true values of these samples when performing the analyses. Method performance reports are returned to the analysts. Clients occasionally submit these types of samples for their QAPP.

Inter-Laboratory comparison samples are samples containing known/unknown quantities of analytes that are split and analyzed by more than one laboratory.

### **Quality Control Check Samples**

Quality Control Check Samples are performance evaluation samples used for routine method performance monitoring. As appropriate, analytical procedures include the analysis of a quality control sample with every sample batch analyzed. The materials are obtained from a commercial source when available, or they may be prepared in-house. Acceptable results are within a defined range based on certified ranges, or against statistically determined control limits, method-defined criteria or client defined Data Quality Objectives. Routinely used methods not subjected to PT sample monitoring are evaluated with Quality Control Check Samples, as appropriate.

QC samples are processed through the system in the same manner as any other sample, except the analyst is aware of the source, concentration, and acceptance ranges of target analytes and calculates analyte recoveries to evaluate method performance in real time.

### **Quality Assurance Audits**

Quality Assurance Audits consist of internal and external laboratory inspections designed to monitor adherence to Quality Systems and quality control requirements. These audits check general laboratory operations, overall Quality Systems, adherence to QA program requirements, sample tracking procedures, sample holding times, storage requirements, adherence to procedures during analysis, calculations, completion of required quality control samples within the group surrounding the sample, and proper record-keeping.

Internal quality control audits are conducted or coordinated by the Quality Assurance Manager of the laboratory. See ELI SOP, *Internal Quality Assurance Audits*, for further information. ELI conducts internal inspections on a regular basis to monitor adherence to quality control requirements. Results of formal audits are given to management with possible recommendations for corrective action in the event any discrepancies are found. As necessary, a follow-up review is conducted to determine that identified problems have been addressed. Annually, the overall quality systems of the laboratory are reviewed and a summary report is prepared.

Per NELAP/ISO 17025-2005 requirements, the management of the laboratory will conduct an annual review of the Quality System, including policies, procedures and environmental testing activities. This is done to ensure the continuing suitability and effectiveness of the QA systems, as well as provide the opportunity to introduce necessary changes or improvements. The review shall take into account, at a minimum, the following:



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

The findings from management reviews and the corrective actions that arise from these findings shall be recorded. The management shall ensure that any corrective actions are carried out within an appropriate, pre-determined time frame.

ELI also conducts Peer Audits as part of an internal auditing program established within the company. This process utilizes analysts and supervisors from other branch laboratories to evaluate a designated ELI branch. The Peer Audits serve to not only address conformance issues, but also provide ELI with a tool to continuously improve process and consistency throughout the company. The goals of the Peer Audits are to:

- Encourage relationships between analysts
- Transfer technical knowledge between peers
- Establish consistency of analytical process/method between branch laboratories
- Identify the depth of analysts' knowledge at each position by observing what analysts are doing at the bench
- Determine training needs of personnel
- Document process/method and verify that issues are being corrected when found
- Work with, and in support of, QA department efforts

Depending on the size of the laboratory, a large number of methods and processes are examined during a Peer Audit. Results from these audits are provided to the branch management, as well as Corporate Management. Corrective Action Plans of a Peer Audit are initiated with the assistance of the Corporate Quality Assurance Officer for resolution of any findings.

ELI welcomes external Quality Assurance Audits, by qualified outside auditors, for review and comment on the overall QA program. To maintain certifications, accrediting authorities from the State of Montana, USEPA, and NELAP conduct periodic comprehensive external audits. External audits to meet Quality Assurance Project Plans (QAPPs), as applicable to environmental remediation projects, or for major industries, are conducted as requested. For more information, see ELI SOP, *External Quality Assurance Audits*.



## CHAPTER 3 – LABORATORY FACILITIES

The facility for Energy Laboratories, Inc. – Billings, MT consists of multiple buildings with over 35,000 square feet of total space; these buildings are located in Billings at 1120 South 27th Street, Billings MT 59101.

The phone number for Billings Energy Laboratories, Inc. is (406) 252-6325, the fax number is 406-252-6069, the toll free number is 800-735-4489, and the email address is eli@energylab.com.

Laboratory space includes adequate bench top and floor space to accommodate periods of peak work load. Working space includes sufficient bench top area for processing samples; storage space for reagents, chemicals, glassware, bench and portable equipment items; floor space for stationary equipment; and adequate associated area for cleaning glassware. Laboratory departments are organized and the facilities are designed for specific laboratory operations in order to protect the safety of analysts and to minimize potential sources of contamination between and within department areas (for more information, see ELI SOP, *Facility Description, Access, and Security*).

The laboratory is appropriately ventilated and illuminated, and is not subject to excessive temperature changes. Specific laboratory areas are temperature and humidity controlled as required. Ample cabinets, drawers and shelves are available for storage and protection of glassware. Exhaust fume hoods are available as needed for use during preparation, extraction, and analysis of samples. Employee exposure monitoring is conducted to provide a safe working environment.

To maintain security, all visitors must enter their name on the ELI sign-in log at the front desk and wear a visitor's badge.

The laboratory has provisions for the disposal of chemical and microbiological wastes. These provisions are described in Standard Operating Procedures as well as outlined in the Laboratory Safety Manual & Chemical Hygiene Plan along with other safety and health guidelines. For more information, see ELI SOP, *General Laboratory Waste Management*.





## CHAPTER 4 – PERSONNEL REQUIREMENTS AND LABORATORY ORGANIZATION

### *Relationship between Management, Technical Operations, Support Services and the Quality System*

#### **Laboratory Organization**

The corporate organization of the six ELI laboratories located in Montana (2), Wyoming (2), South Dakota, and Texas is provided in Appendix D. The Billings laboratory is the center for all corporate functions. Each laboratory is managed and operated individually under the supervision of a Branch Manager. Branch laboratories have fiscal and QA/QC responsibilities to Corporate, as well as general operating policies and goals. Quality Assurance Manuals are prepared individually for each branch and follow the QA/QC program outlined in the ELI-Billings QA manual.

The ELI-Billings Organizational Chart is also included in Appendix D with curricula vitae of key ELI-Billings laboratory personnel maintained in Appendix E of this manual. A Personnel Summary for all ELI employees listing title, academic background, and years of relevant experience is maintained. Job descriptions can be found in the ELI SOP: *Roles and Responsibilities*.

Quality Assurance receives direct support from senior management. Branch Quality Assurance Managers report directly to the Corporate Quality Assurance Officer as well as the Branch Manager. Quality Assurance Managers provide independent oversight of Quality Systems within the overall Energy Laboratories structure. When Quality Assurance Managers fill more than one role within the organization, they operate independently of direct environmental data generation while fulfilling quality assurance responsibilities. Quality Assurance Managers facilitate development of and maintain the branch Quality Assurance Manual, provide assistance to personnel on quality assurance / quality control issues, maintain a quality assurance training program, and review quality documentation including SOPs. For more information, see ELI SOP: *Roles and Responsibilities*.

Management ensures the development and implementation of programs and policies to continuously improve the effectiveness of ELI's QA Program and Management Systems. Management performs an annual review of the laboratory's Quality System (policies, procedures, work instructions) to assure their continuing suitability and effectiveness (See ELI SOP: *Management Reviews*, for detailed procedures). As appropriate, management identifies and implements any necessary changes or improvements. Corrective and preventive actions are detailed in a Corrective Action Report and filed with the QA Department. (Refer to ELI SOP: *Nonconformance Procedures and Corrective Action Reports*, for detailed procedures.) In addition, management performs meetings with supervisory and key staff members throughout the year. Supervisors and QA personnel provide input on their specific areas of responsibility and evaluate the following:

- 1) Client-Related Items



- 2) Internal and External Audit Reports
- 3) Proficiency Testing Results
- 4) Review of Performance by Department
- 5) Corrective and Preventive Actions
- 6) Personnel Training Needs
- 7) Quality System Policies and Procedures
- 8) Resources including Personnel, Equipment and Facilities

Laboratory Management Review findings are compiled into a summary report. The report includes deficiencies identified and areas for improvement. The QA department ensures items from the Management Review are tracked, including actions that must be addressed, assignment of parties responsible for the actions to be taken, and recommendations on improvements to the Quality System. The Technical Director, Laboratory Manager, QA Manager or designee, shall assign specific persons to address management review findings and establish deadlines for their completion. The Technical Director, Laboratory Manager, QA Manager or designee, reviews and approves all documents issued to personnel in the laboratory as part of the management system. The Technical Director, or designee, has overall responsibility for the technical operations of the laboratory. Work is stopped when identification of any of the following is made: unapproved departures from the management system, unauthorized deviations from the procedures for performing tests and/or calibrations, and data quality or data integrity issues. The Technical Director, Laboratory Manager, QA Manager, or designee, is responsible for providing authorization for the work to resume once the identified issue has been addressed.

### ***Personnel Requirements***

ELI maintains experienced staff and management. Below is a summary of the primary roles, responsibilities and qualifications for the designated positions. Laboratory experience can be substituted for academic requirements. At ELI's smaller laboratory operations, the technical director may serve multiple roles. Detailed job descriptions can be found in ELI SOP, *Roles and Responsibilities*. Specific titles of employees are at the discretion of the Branch Manager.

### ***Branch Manager***

The Branch Manager is required to have education equivalent to a Bachelor of Science degree in Chemistry or a related science. Five years of relevant laboratory experience is required. .

The Branch Manager is responsible for all operations, client management, analysis scheduling, equipment acquisition, as well as compliance with all employment, safety, environmental and NELAP/ISO 17025 regulations. The Branch Manager may delegate daily activities of these work aspects to appropriate personnel. The Branch Manager reports directly to the Corporate Operations Manager. All Branch Managers have both technical and management responsibilities.



### **Quality Assurance Manager/Quality Assurance Officer**

The Quality Assurance Manager/Quality Assurance Officer is required to have an education or experience equivalent to a Bachelor's of Science degree in Chemistry or a related science. Five years of relevant laboratory experience is preferred.

The Quality Manager/Quality Assurance Officer is responsible for quality systems development, implementation, and management. The Quality Manager/Quality Assurance Officer is also responsible for maintaining and improving compliance with all applicable state and federal regulations as well as maintaining compliance with NELAP/ISO 17025 regulations regarding Quality Systems. The Quality Assurance Manager/Officer or his/her designee manages the laboratory's certification programs to meet government regulatory requirements. The QA program is implemented in cooperation with all levels of management and staff. Quality Assurance Managers/Officers report directly to the Corporate Quality Assurance Officer. The Branch Manager will direct daily laboratory-specific QA/QC requirements.

### **Technical Director**

The Technical Director is required to have a Bachelor of Science degree in Chemistry or a related science. Five years of relevant laboratory experience is required.

The Technical Director is responsible for ensuring compliance with all laboratory policies and that the analyses conducted under their supervision are compliant with all state, EPA, and NELAC/ISO17025 standards. The Technical Director reports directly to the Branch Manager.

The technical director may serve multiple roles. Branch Managers serve as one of the branch technical directors.

### **Laboratory Supervisor**

A Laboratory Supervisor is required to have education equivalent to a Bachelor of Science degree in Chemistry or related science. Two years of relevant laboratory experience is required.

ELI's Laboratory Supervisors are responsible for the day-to-day operation of the laboratories: scheduling testing, assigning work, and completing the technical review of laboratory data. Supervisors are responsible for ensuring compliance with all laboratory policies and ensure that the analyses conducted under their supervision are compliant with all state, EPA, and NELAC/ISO17025 standards. They report directly to the Branch Manager.

### **Analysts**

Laboratory Analysts are required to have an education equivalent to a Bachelor of Science degree in Chemistry (or related science), or a High School diploma with experience as an analyst in training. New analysts require a minimum of six months of on-the-job training, under direct supervision of a qualified analyst, in the measurements being considered for certification. After the initial training period, and on a continuing basis thereafter, the analyst must



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demonstrate acceptable skills through the successful participation in the analysis of applicable performance evaluation and quality control samples.

Laboratory Analysts perform the following duties: Preparation of samples and reagents, analysis and preliminary data input, as well as various other tests. Laboratory Analysts are responsible for complying with all laboratory policies and procedures.

### **Laboratory Technicians**

Laboratory Technicians are required to have a High School Diploma or equivalent. Laboratory Technicians work under the supervision of the primary analyst performing general laboratory tests.

Under the supervision of a primary analyst, Laboratory Technicians perform the following duties: preparation of samples and reagents, analysis, and preliminary data input, as well as various other tests.

Laboratory Technicians are responsible for complying with all laboratory policies and procedures.

### **Approved Signatories**

Signatures for policies are based on appropriate individuals, roles and responsibilities as determined by the policy being reviewed and approved. A list of significant signatories is included below. Additional signatures may be required for specific procedures.

- Branch Manager
- Technical Director
- Quality Assurance Manager
- Corporate Officer- Board of Directors

A master list including signatures and initials for all employees is maintained for reference and signature verification.



## CHAPTER 5 – SAMPLING PROCEDURES

Private individuals or companies, who are responsible for using proper collection procedures, collect most of the samples processed in this laboratory. Members of the staff are acquainted with proper sample collection and handling procedures and advise those who need help in this area. Instructions and forms for initiating Chain-of-Custody are available from ELI. Laboratory procedures for logging in samples for analysis and maintaining Chain-of-Custody are described in ELI SOP, *Sample Receipt, Login, and Labeling*.

When the laboratory has been assigned the responsibility of sample collection, there is strict adherence to correct sampling protocols, initiation of chain-of-custody, sampling documentation, complete sample identification, and prompt transfer of sample(s) to the laboratory. Procedures are described in ELI SOP, *Field Sampling*.

This laboratory provides proper sample containers and preservatives as specified for the procedure. Certified sample bottles may be ordered upon request. Sample containers, preservatives, coolers for shipping, re-sealable plastic bags for ice containment, trip blanks for monitoring contamination during shipping, temperature blanks for accurately monitoring sample receiving temperatures, Chain-of-Custody forms, Chain-of-Custody seals, sample bottle labels, instructions for sampling, sample labeling, sample preservation, and sample packaging/shipping are provided upon request. Sample container type, sample volume, preservation requirements, and maximum holding times, are detailed for each analyte/method in the ELI Technical Services and Fee Schedule. See the ELI website, [www.energylab.com](http://www.energylab.com) for the current pricing.

Energy Laboratories maintains a strict Sample Acceptance Policy. The client is immediately notified (if possible) upon sample receipt if there is any doubt concerning the sample's suitability for testing, including but not limited to, when:

- Samples are received in unacceptable containers;
- Samples have not been properly preserved;
- Samples have labels or chain-of-custody procedures that are incomplete;
- Samples cannot be analyzed within method recommended holding time; or
- The custody seal has been broken.

Samples not collected or documented properly can be rejected for any regulatory-based analysis with re-sampling recommended. If re-sampling is not possible, or the client cannot be contacted, the sample may be analyzed, and if analyzed, the sample will be clearly qualified in the data package.

The laboratory will preserve samples at the time of sample login if samples are unpreserved and preservation is required by the methodology. Aqueous samples for volatile analysis are checked for preservation at the time of analysis. Samples for microbiological analysis are collected in pre-sterilized 120 mL plastic bottles containing sodium thiosulfate.

Sample preservation should be performed immediately upon sample collection. For composite samples, each aliquot should be preserved at collection. Refer to ELI Technical Services and



Fee Schedule for detailed information on sample preservation requirements per applicable method and regulatory requirements.

The laboratory initiates a sample condition report titled Workorder Receipt Checklist at the time of sample receipt. The sample condition report contains Chain-of-Custody procedures, sample preservation status, carrier used for sample shipment, sample receipt temperature, and provides general comments concerning sample condition. The sample condition report is provided with the sample analyses' analytical data report package. For more information, see ELI SOP, *Sample Receipt, Login, and Labeling*.

When any sample is shipped by common carrier or sent through the United States Mail, it must comply with the Department of Transportation Hazardous Materials Regulations (49 CFR Part 172). The person offering such material for transportation is responsible for ensuring such compliance. For the preservation requirements as described in the ELI Technical Services and Fee Schedule, the Office of Hazardous Materials, Material Transportation Bureau, and Department of Transportation has determined the Federal Hazardous Materials Regulations do not apply to the following:

- A) Hydrochloric Acid - (HCl) in water solutions of 0.04 % by weight or less (pH of 1.96 or greater).
- B) Nitric Acid - (HNO<sub>3</sub>) in water solutions of 0.15 % by weight or less (pH of 1.62 or greater).
- C) Sulfuric Acid - (H<sub>2</sub>SO<sub>4</sub>) in water solutions of 0.35% by weight or less (pH of 1.15 or greater).
- D) Sodium Hydroxide - (NaOH) in water solutions of 0.080% by weight or less (pH of 12.30 or less).

For regulatory compliance monitoring, it is required that all samples be analyzed within the prescribed holding times. Holding times are the maximum times allowed between sampling and analysis for results to still be considered valid. Samples should be delivered to the laboratory as soon as possible following collection to assure that holding times can be met. Samples are analyzed as soon as possible after sample receipt. When maximum holding times cannot be met, re-sampling is requested. If samples are analyzed out of hold, data is appropriately qualified.

To ensure that drinking water analysis for radiochemistry is met, the requirements for sample handling, preservation, and instrumentation for radiochemical analysis are included in ELI SOP: "*Sample Receipt, Log-In and Labeling*". (For additional information, refer to "Manual for the Certification of Laboratories Analyzing Drinking Water", Table VI-2: Sample Handling, Preservation, and Instrumentation, EPA 5<sup>th</sup> Edition, January 2005).



## CHAPTER 6 – SAMPLE HANDLING

The ELI laboratory utilizes a sample tracking policy that includes client-initiated chain of custody. Upon receipt, the security of the samples is maintained by the implementation of the laboratory access and security policies. See ELI SOP, *Facility Description, Access and Security*.

### **Sample Receipt**

All samples arriving at the laboratory are logged in the Laboratory Information Management System (LIMS). Each sample container is given a unique laboratory sample number. The sample receipt checklist evaluates Chain-of-Custody procedures, sample preservation status, carrier used for sample shipment, cooler temperature, and provides general comments concerning sample condition. The completed checklist is provided with the analytical report package. Chain-of-Custody forms are checked for pertinent information. If necessary information has been omitted, the collector is notified, if possible, and the missing information is requested.

Samples requiring preservation are checked to determine if the client performed preservation. If requested, ELI staff will preserve or filter samples as appropriate. Samples that degrade quickly or cannot be opened (such as aqueous samples for volatiles) are not preserved at the time of sample login. If samples are improperly preserved, or the maximum holding times are exceeded upon arrival at the laboratory, the client is notified and re-sampling is requested.

Samples are stored per method specifications, or as method/parameter storage requirements are updated per later EPA guidance in Federal Regulations posted in 40CFR (Method Update Rules).

During sample login, all sample information such as sample description, client name and address, analyses requested, special requirements, etc. are entered into the computer database of the Laboratory Information Management System (LIMS). Requested analysis parameters and special requirements are communicated to the analysts via their LIMS work lists. Project-specific requirements are maintained in the LIMS for any samples received from a special project. This process ensures that individual requirements are maintained.

### **Chain-of-Custody**

Evidence level internal chain-of-custody (COC) procedures are available on a project-specific basis. For these procedures, internal COC sample custody is maintained down to the individual analyst level. When transferring the possession of the samples, the transferee must sign and record the date and time on the chain-of-custody record. Every person who takes custody must fill in the appropriate section of the chain-of-custody record. When received by ELI, sample identification information on the sample containers is compared to the custody report form. The sample is inspected and information regarding the condition of the sample and seal (if used) is recorded on a report form; the method of shipping is also documented on the report form. A copy of the report form is kept with the sample data file and a copy is sent to the client with the



analysis report. Internal chain-of-custody forms are used to document the progress of the sample through the laboratory. ELI's routine COC policy is maintained at the laboratory level through our laboratory access and security policies. See ELI SOP, *Facility Description, Access, and Security*.

### **Sample Tracking**

Samples are tracked through the analytical process by the LIMS. Completed analyses, which have been approved by the appropriate reviewer as valid data, are reported in the LIMS. When all analyses are complete, the data is reviewed as a whole to ensure results pass data quality checks. The completed report is signed by an approved signatory. The signed report is sent to the client via requested delivery format. Generation of the invoice automatically completes the work order in the LIMS and removes the samples from the status report. For more information, see ELI SOP, *Document and Record Management, Control and Archiving*.

### **Sample Disposal**

It is preferred that remaining hazardous sample material be returned to the originator (client) for disposal. When this is not possible or reasonable, ELI will dispose of remaining hazardous sample materials with a waste disposal surcharge added to the cost of the analysis.

The disposal of laboratory wastes will be performed in accordance with local, state, and federal regulations which apply to such activities. Each method SOP addresses waste minimization and management specific to the method procedure. See ELI SOP, *General Laboratory Waste Disposal*, for more information.

### **Subcontracting Policy**

The ELI Billings laboratory utilizes the expanded branch laboratory capability and expertise to provide comprehensive analytical services. This occurs when the laboratory is requested to perform an analysis outside of the laboratory's capabilities (If sample overload is experienced; if equipment is out of service; if the laboratory is not accredited for the particular analysis). Upon completion of the analyses, the branch laboratories report the sample results, and their quality control package, to the primary laboratory. The results are reviewed before being reported.

Branch laboratories are certified to perform drinking water analysis in their state and in neighboring states. Samples are forwarded to our branch laboratories only if the laboratory is certified in the state from which the sample originated. Individual branch laboratory Quality Assurance Programs are consistent with the Corporate Quality Assurance Program and are monitored through internal laboratory audits.

To support Energy Laboratories, Inc. Billings analytical services, ELI branch laboratories (which maintain specific instrumentation for specialized analysis) are utilized to provide complete analytical services. Refer to Appendix A for the certificates detailing routine analyses performed by the Billings branch. All branch laboratory certificates are also available on the Energy Laboratories website at [www.energylab.com](http://www.energylab.com).

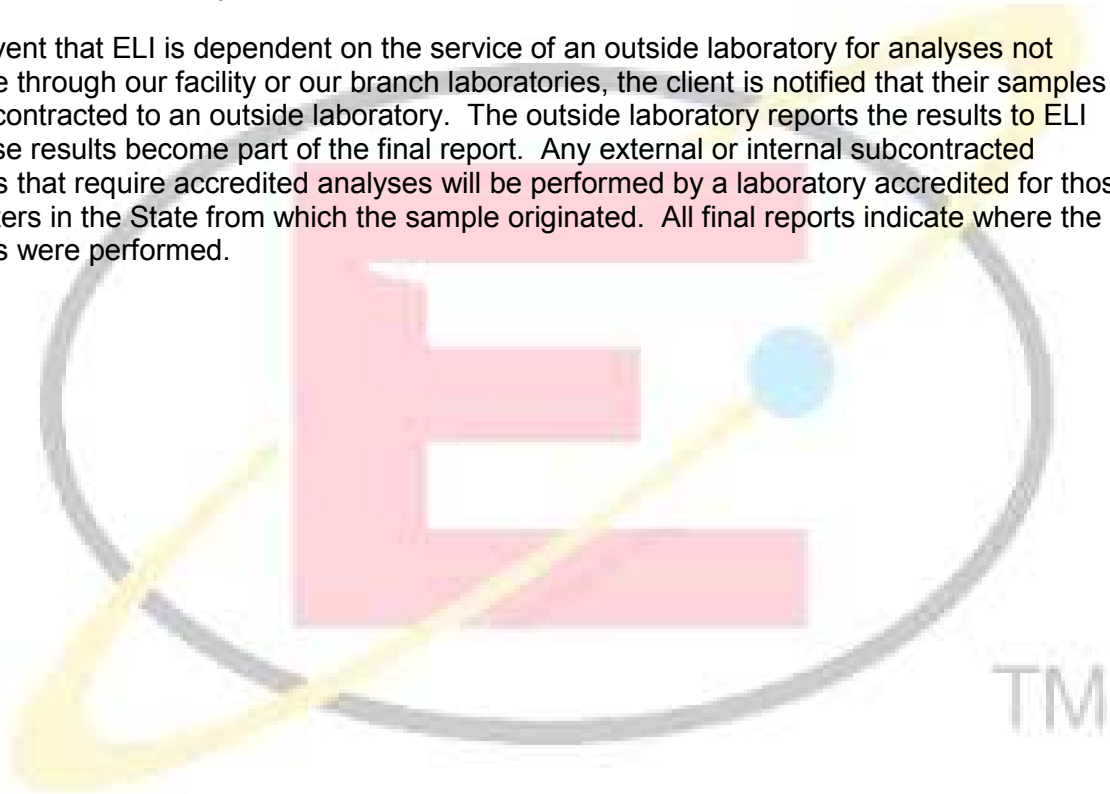




ELI Billings routinely subcontracts the following parameters/methods to branch laboratories:

- Total Organic Halogens (TOX) by SW-846 9020
- Total Arsenic CVAA by ASTM 3114
- Low level EDB and DBCP by EPA 504
- Carbamates by EPA 531.1
- Glyphosate by EPA 547
- Diquat by EPA 549.2
- Total Organic Carbon (TOC/DOC) by A5310 C or A5310B, and SW-846 9060
- Oil & Grease by SW-846 1664A
- All Radiochemistry except Radon

In the event that ELI is dependent on the service of an outside laboratory for analyses not available through our facility or our branch laboratories, the client is notified that their samples are subcontracted to an outside laboratory. The outside laboratory reports the results to ELI and these results become part of the final report. Any external or internal subcontracted analyses that require accredited analyses will be performed by a laboratory accredited for those parameters in the State from which the sample originated. All final reports indicate where the analyses were performed.



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## CHAPTER 7 – INSTRUMENT OPERATION AND CALIBRATION

Laboratory instruments and equipment are operated and calibrated according to the manufacturer's instructions and according to the requirements of the method being used. Exact calibration procedures are outlined in the appropriate SOP. For most instruments, a calibration curve composed of three to five standards covering the concentration range of the samples is prepared. The acceptance criteria for the calibration curves are listed in the individual methods. Unless otherwise specified in the method, at least one of the standards is at or below the practical quantitation limit (PQL) of the method. Routine PQLs for each method are given in the ELI Technical Services and Fee Schedule. Calibration standards are routinely compared to second source calibration standards to verify accuracy. These second source standard results must fall within an established range, as described by the SOP, to be accepted. Whenever possible, the laboratory uses calibration standards prepared from certified stock standards. Initial instrument calibration curves are verified and routinely monitored by analyzing a continuing calibration standard every 10 to 20 samples (or within a specified time frequency) and at the end of every analytical sequence, depending on the analysis method and instrumentation. When applicable to the method, high-level samples, which produce an analytical response outside the calibrated range of the instrument, are diluted (or reduced in mass) and re-analyzed until a response within the calibrated range is obtained and/or the result is appropriately qualified.

System cleanliness is verified through the analysis of reagent/instrument blanks prior to analysis, between highly contaminated samples, and at regular intervals during the analysis.

Use of measuring equipment and reagents (glassware, water, chemical reagents, and industrial gases) conform to Good Laboratory Practice guidelines. Good Laboratory Practices (GLPs) are laboratory guidelines which were established by the Food and Drug Administration and published in the Federal Register (21 CFR, part 58). The GLP guidelines were adopted by the Environmental Protection Agency. SOPs are developed in accordance with GLP and NELAP guidelines. Laboratory volumetric glassware conforms to National Institute of Standards and Technology (NIST), American Society for Testing and Materials (ASTM) Class A or B standards. All mechanical pipettes are calibrated at least quarterly. Laboratory balances are serviced annually and calibrated by certified technicians. Calibration checks of balances are performed each day of use, using ASTM Class 1 or 2 weights. Laboratory thermometers are calibrated annually against a NIST traceable thermometer and routinely checked for accuracy. Laboratory drying ovens, incubators, freezers, refrigerators, and water bath temperatures are monitored and recorded each working day, or at frequencies as described in the specific SOP. Laboratory pure water is generated by commercial water purification systems and is monitored and documented each working day in accordance with specifications needed for applicable methods. The routine analysis of laboratory blanks is used to verify laboratory water quality and the suitability of sampling containers. Chemical reagents and gases meet or exceed purity requirements for their intended uses. Laboratory stock and working standards are derived from ISO 17025 and/or 9001 (or equivalent-certified) commercially available primary standards whenever possible. Standard preparation notebooks document the reagent/standard type, source, purity, content, concentrations, preparation date, and analyst. All calibrations standards are documented in each daily analytical sequence such that they are uniquely identified and traceable to stock standards and their source.



Standard Operating Procedures (SOPs) detail the sequence of operations involved in instrument start-up, calibration, analysis, shut-down, and routine maintenance. Suggestions for corrective action are included with the SOPs and parameters are identified which dictate certain types of maintenance. Instrument and method detection limit studies are performed at the method required frequency or whenever there is a significant change in instrumentation. Method Detection Limits are determined according to EPA guidelines found in 40 CFR, part 136, Appendix B and 40 CFR 141.25 (c) for Radiochemistry (except for the few methods that are not amenable to MDLs). Refer to ELI's Technical Analytical Services and Fee Schedule for practical quantitation limits (method reporting limits). Acceptable instrument response/performance criteria are based upon the manufacturer or the analytical method specifications. SOPs exist for all major pieces of analytical equipment/methods.

Instrument logbooks are used to document instrument maintenance and repairs. Instruments that are no longer being utilized are documented in the applicable instrument logbook as "out-of-service" with the date the instrument was taken out of use noted. All out-of-service instruments are labeled with an out-of-service tag that identifies the effective date the instrument was taken out of use.

Laboratory analysts record and document all instrumental runs in Laboratory Instrument Logbooks or computer files. Instrument Logbooks and/or dated computer files record instrument performance data, analytical sequences, instrument maintenance, calibration standards data, and any other additional information pertinent to operation of the instrument.



## CHAPTER 8 – RECORDS AND REPORTING

### **Document Management**

Energy Laboratories Inc. QA manages three types of documents: 1) controlled, 2) approved, and 3) obsolete.

A CONTROLLED document is one that is uniquely identified, issued, tracked, and kept current as part of the Quality System. Controlled documents may be internal documents or external documents. A list of ELI's controlled documents is listed in Appendix B. All ELI controlled documents are written and reviewed by personnel technically competent to perform that procedure and approved for use by the Branch Manager as well as the Quality Assurance Manager/Officer.

APPROVED documents have been reviewed, signed and dated by the technical reviewer, the Quality Assurance Manager/Officer and the Branch Manager.

OBSOLETE documents are documents that have been superseded by more recent versions. Obsolete documents are retained for legal use or historical knowledge preservation. Old or archived SOPs are available for review using the laboratory's electronic document system. ELI's OBSOLETE document records are maintained for at least ten years.

Documents are reviewed on an annual basis to ensure their contents are suitable and in compliance with the current quality systems requirements, and accurately describe current operations. SOPs include a Record of Review/Revision page, which details revisions or reviews. The branch Quality Assurance Manager/Officer maintains a master list of controlled documents (which include title, author, and date of issue).

Procedures for identification, collection, access, filing, storage, and disposal of records are found in ELI SOP, *Document and Record Management Control and Archiving*.

### **Laboratory Notebooks**

Several different types of Laboratory Notebooks are maintained at the ELI Laboratory. These include, but are not limited to, the following:

- Method/Parameter Notebooks
- Project Notebooks
- Instrument/Equipment Use and Maintenance Notebooks
- Standard Preparation Logbooks
- Balance Calibration Logbooks
- Pipet Calibration Logbooks
- General Logbooks

The general purpose of maintaining each of these Laboratory Notebooks is to record the details that may be important in repeating a procedure, interpreting data, or documenting certain



operations. Entries in the notebook may include data such as standard and sample weights, pH measurements, instrument operating parameters, preparation of calibration curves, analytical run sequences, calculations, recording of instrument operating parameters, sample condition, etc. The analyst's notebook is particularly important in documenting analyses that deviate in any way from routine or standard practices. It can also be an important training record. All pertinent data is to be recorded directly in the notebook. Some notebooks or data records are maintained in electronic format (LIMS, spreadsheets, or databases). Electronic data records are duplicated using hardcopy and/or alternate electronic backup techniques.

It is the responsibility of each analyst to maintain a laboratory notebook according to Good Laboratory Practices (GLP) Guidelines. Procedures for use and maintenance of laboratory notebooks are detailed in ELI SOP, *Laboratory Notebooks*. All physical laboratory notebooks are assigned a unique logbook control number and are assigned to an analyst or supervisor. These notebooks remain the responsibility of the ELI staff member to whom they are assigned until they are formally transferred to another staff member, until they are completely filled and returned to the ELI QA Department for archiving, or until the staff member resigns and returns them as a part of the check-out process. ELI staff members, other than the individual to whom the laboratory notebook is issued to, may make entries in the notebook as long as those entries are consistent with the intended use of the notebook and such entries are initialed and dated. Procedures for use and maintenance of laboratory notebooks are detailed in ELI SOP, *Laboratory Notebooks*.

### **Records**

The laboratory maintains records of all chemical analyses, including all quality control records, for a minimum of ten years. In the event that Energy Laboratories, Inc., or any individual laboratory transfers ownership or goes out of business, the records will be transferred to the new owners. If a branch laboratory is closed, records will be maintained by Energy Laboratories Corporate office in Billings, Montana. Energy Laboratories, Inc. reserves the right to offer the records to the clients in the event of complete closure. Details are described in ELI SOP, *Document and Record Management, Control and Archiving*.

### **Data Reduction**

Data reduction refers to the process of converting raw data to reportable units. The reporting units used and analytical methods performed are described in the ELI Technical Services and Fee Schedule.

Wherever possible, the instrument is calibrated to read out directly in the units reported. In this case, the value is recorded directly into a laboratory notebook, logbook, bench sheet, or electronic file and presented for review.

In cases such as titration, gravimetric measurements, or other techniques that require calculation prior to reporting, raw data is recorded in the appropriate laboratory notebook or electronic file, or on the appropriate laboratory form. The calculations specified in the methods are used to determine the reported value. That value is also entered into the laboratory



notebook or bench sheet. Most calculations are automated to reduce the chance of arithmetic or transcription errors.

Wherever possible, electronic data results are transmitted throughout the laboratory via the LIMS computer network. This process is intended to minimize manual data transcriptions within the laboratory. Additional advantages include the opportunity for rapid comprehensive data validation by supervisors, and more rapid data reporting.

### **Validation**

Data validation includes the procedures used to ensure that the reported values are consistent with the raw data, calculated values, sample type, sample history, and other analysis parameters requested.

The data recorded is validated with several review steps. The analyst who submits the analytical results checks all the values reported for omissions and accuracy. Elements of this review also evaluate all instrument and method QC results. Automated data management programs are designed with an interactive step allowing data review by the analyst. Results to be reported are approved by the analyst.

The report is reviewed for the suitability of the data according to project and method performance specifications. Analytical results for each requested parameter may be evaluated against other requested parameters, project specifications, other samples within the set, historical files associated with the project/client, and/or any other information provided with the sample.

The reports are generated, proofread, and reviewed by designated reporting staff.

Laboratory managers, project managers, supervisors, QA managers or their designees, may also examine the data included in the final report.

Internal and external laboratory audits review selected sets of data to ensure that the analytical results are correct and accurate, analytical methods are appropriate, documentation and record keeping procedures are complete, and that there is compliance to the overall objectives of the Quality Assurance Program. Data integrity is being monitored on an on-going basis. See ELI SOP: *Assessment of Data Integrity*, for details.

All controlled automated programs used to process and report data are initially verified using manually calculated results. Whenever a modification is performed to a program, re-verification of overall software function is performed.

One step of the Quality Control process involves data outlier detection; data that falls outside of established limits. If an outlier is observed, corrective action is taken as appropriate, to investigate and/or correct the cause. Actions to correct these causes may include, but are not limited to, inspection of the instrumentation, checking calibrations, checking sample numbers or dilutions, rerunning samples or calibrations.



## Reporting

One copy of the report is distributed to the client, via requested delivery format, after the report is validated and signed. A standardized report format is used unless otherwise specified. Client-specified report formats are available upon request. Results can be sent via physical media, email, EDD, website FTP and/or FAX when requested by the client. Energy Laboratories, Inc. offers its clients access to electronic records through our Energy Source Portal.

Various levels of data reporting are available. All analytical results, regardless of the level of reporting used, have record keeping procedures which allow an appropriate "data validation package" to be produced. Note that a comprehensive "data validation package" is most easily generated at the time of sample analysis. Example data packages are available upon request.

Safe Drinking Water Act (SDWA) compliance monitoring samples for microbiological and chemistry samples that exceed the SDWA maximum contaminant level (MCL) may require notification to the appropriate state agencies. Generally, notification to the client, and to the state, of any SDWA MCL exceedance must be within 24 hours of completion of analysis/review, or by noon the next business day. If requested by the client, additional copies of the report will be sent to a specified address or person.

The final copy of a completed report is maintained in an electronic format. An electronic copy of this file is available upon request. Energy Source is a client resource of ELI that provides secure online access for clients to view their data and documents. Clients are able to access their electronic files through ELI's secure website @ <https://energysource.energylab.com/>. For more information, see ELI SOP, *Document and Record Management, Control and Archiving*.

In addition to traditional ink signatures, Energy Laboratories has approved the use of electronic signatures within our company-produced PDF documents. These signatures comply with Title 15 of the US Code Section 101 regarding legal requirements of a digital signature.

Electronic signatures verify that the document has not changed after it was produced. Upon opening the document, notifications automatically display to inform the recipient of the validity of the sender's electronic signature and all included certificates. Should any changes be detected, an alert message is automatically displayed, noting that the signatures cannot be validated due to changes made to the document.

Detailed instructions on how to view or validate electronic signatures are available to our clients on the ELI website at: <http://www.energylab.com>.



## CHAPTER 9 – GENERAL LABORATORY PRACTICES

### *Chemicals and Reagents*

When available and appropriate, chemicals used in the laboratory are analytical reagent grade (AR) chemicals purchased from reliable suppliers. Reagents are prepared, standardized, and made fresh as mandated by the method, their stability, and according to Good Laboratory Practices. Procedures for purchasing of materials may be found in ELI SOP, *Property Procurement, Inventory, and Control*.

Normalized standards are checked regularly against independently prepared reference materials.

All standards and reagents are dated when received, opened, or prepared, and each is labeled with an expiration date when applicable. Standards and reagents are checked for discoloration or signs of degradation and are discarded if these are observed.

Certified primary standards are obtained from ISO accredited commercial sources when available. Standards used for calibration are verified against second source standards. Secondary and working standards are accurately prepared with volumetric flasks, or other calibrated labware, from primary standards and stored in appropriate containers.

ELI has determined 5 years to be a reasonable expiration date for stable salts where the manufacturer does not supply such information. Titrants, standards, and other solutions used for analytical purposes are frequently standardized upon preparation with certified or traceable standards. Method SOPs specify if standardization is necessary. The date and analyst's initials must be recorded on the container whenever re-standardized and these records are maintained in a laboratory notebook or in the LIMS.

Individual SOPs may also provide additional details for reagent requirements.

### **Reagent Interference**

To determine the extent of reagent interference, method blanks are analyzed prior to sample analysis whenever appropriate.

If any interference cannot be eliminated, the magnitude of the interference is considered when calculating the concentration of the specific constituent in the sample, but only when permitted within the applicable method.

If reagents, materials, or solvents contain substances that interfere with a particular determination, they are replaced.

Individual method SOPs may also provide additional requirements for handling reagent interferences.





## **Glassware Preparation**

All glassware used for inorganic and radiochemical analysis is washed in warm detergent solution and thoroughly rinsed in tap water. Glassware is then rinsed well three times with laboratory-purified water. This cleaning procedure is sufficient for many analytical needs, but individual SOPs detail additional procedures when necessary. Glassware washing procedures for inorganic analysis are described in ELI SOP, *Cleaning of Glassware Used in Inorganic Analyte Sample Preparation and Analysis*.

All glassware used for organic analysis is washed in warm synthetic detergent solution and thoroughly rinsed in tap water. The glassware is then rinsed well with laboratory-purified water, followed by rinses with acetone to remove any residual organics. Prior to use, the glassware is rinsed three times with the organic solvent to be used with the glassware. Glassware washing procedures for cleaning glassware for organic analysis are described in ELI SOP, *Cleaning of Glassware Used in Volatile and Semivolatile Analyte Sample Preparation and Analysis*.

All glassware used for microbiological analysis is washed in warm detergent solution. The detergent must be proven to contain no bacteriostatic or inhibiting substances. The glassware is rinsed thoroughly with laboratory-purified water. Specific details are described in SOPs.

Disposable, glassware/plasticware is preferred for many procedures in the laboratory. The cleanliness and suitability of disposable glassware/plasticware is continuously evaluated for each test with the routine analysis of method blanks.

All volumetric glassware used in precise measurements of volume is Class A or laboratory calibrated.

## **Laboratory Pure Water**

Laboratory-purified water is used in the laboratory for dilution, preparation of reagent solutions and final rinsing of glassware. For organic analysis, organic-free water is prepared and used. Energy Laboratories, Inc. uses water purification systems that are designed to produce deionized water that meets the requirements of the methods. Use and maintenance of laboratory reagent water systems are described in ELI SOP, *Use and Maintenance of the Milli-Q Water System*.

Water quality is monitored for acceptability in the procedure in which it is used. Specific details are listed in the appropriate SOPs.

## **Employee Training**

All new ELI employees and contract personnel are given an initial general orientation and tour of the laboratory facilities. Personnel are shown the locations of safety equipment such as safety showers, eye wash fountains, fire extinguishers, and first aid supplies. Personal protective equipment such as lab coats, disposable gloves, and safety glasses (if applicable) are issued at this time.



Safety considerations are a vital part of the training process. All hazards associated with the performance of a procedure or with the operation of an instrument are to be understood by the trainee before training can be considered complete. General laboratory safety procedures are a part of the new and current employee training. Specific safety procedures are outlined in SOPs and in instrument Operator's Manuals. Training in use of protective clothing, eye protection, ventilation, and general safety are provided to each employee. Each employee is required to read and sign the *Laboratory Safety Manual & Chemical Hygiene Plan*.

All new and existing employees must demonstrate capability prior to performing an analytical procedure independently (see Chapter 1). Method performance on Quality Control Samples is used to document employee training and work quality. Employees are required to read the Quality Assurance Manual and all appropriate SOPs. Employees are required to sign a Quality Assurance Manual Acknowledgement form which states that they have read, understood, and will comply with the requirements of the Quality Assurance Manual. Employees also are required to sign, for all applicable SOPs, a Record of Acknowledgement Form that states they have read, understood, and agree to abide by the SOP. In the case of method SOPs, the employees sign a Record of Acknowledgement form that states they have read, understood, and agree to abide by the SOP using the latest method technology.

Employees also receive training on general laboratory policies including ethics and conflict of interest. All employees are required to read, understand and comply with the Corporate Compliance & Ethics Manual. Data integrity training is provided for all employees initially upon hire and annually thereafter. In addition to the *Corporate Compliance & Ethics Manual*, the ELI Quality Assurance department maintains a *Laboratory Ethics & Data Integrity Manual*, which supplements the corporate manual and provides specific training on data integrity. All employees are required to read, understand and comply with the ELI *Laboratory Ethics & Data Integrity Manual*. An annual Ethics training course is given to all laboratory employees. Attendance is required and is recorded with a signature attendance sheet or other form of documentation that demonstrates all staff have participated and understand their obligations related to data integrity and ethics policies. For details pertaining to ethics training and additional ethical procedures and policies refer to ELI SOP, *Personnel Training and Training Records*.

ELI encourages attendance at courses, workshops and other forms of continuing education available from on-site seminars, private institutions, local schools, and State and Federal regulatory agencies. Staff and department meetings are held routinely to communicate company policies and procedures. All training on procedures and policies is documented, per NELAP guidelines, in employee training files. For more information see ELI SOP, *Personnel Training and Training Records*.

### **Data Integrity**

In order to provide for the integrity of ELI and client data, the laboratory has multiple controls on the network, LIMS and applications used. These controls limit access to and the ability to change data as well as provide for redundancy in case of loss.

These include but are not limited to:



- Users connecting to ELI computer systems are authenticated through a user name and password combination.
- Passwords are required to be changed on a regular basis.
- Permissions within ELI applications are role based with different roles having various levels of access and control. Users (analysts, supervisors, and managers) are assigned to these roles.
- In the LIMS, analytical data locks after a period of time and cannot be modified without special handling.
- Certain information has been identified for additional tracking and logging. Changes to this information is not only tracked in an audit log but also reported to select personnel.
- Information on ELI servers including the ELI LIMS system is backed up and recoverable.

### **Standard Operating Procedures**

Laboratory operations and procedures are documented in Standard Operating Procedures (SOPs). SOPs provide information on the consistent and safe operation of the laboratory... For analytical methods, SOPs provide information on the details of the analysis that is not specified in a published analytical method. For routine procedures other than analytical methods, SOPs define the steps required in accomplishing a given task. All SOPs are reviewed and updated periodically to reflect any changes in laboratory operations. Method SOPs follow NELAP requirements. For more information on generation and distribution of SOPs, see ELI SOP, *Preparation, Numbering, Use, and Revision of Standard Operating Procedures*.

### **Client Confidentiality**

Each employee has the responsibility to maintain confidentiality in all matters pertaining to our clients, samples submitted, and Energy Laboratories, Inc. Information obtained during employment with this laboratory, regarding the specific business of this laboratory, or its clients shall at no time be revealed to any outside sources without permission from the owner of the data.

Sample submittal, analysis and the report contents are considered confidential information of the client. When requested to provide results (either in person, via telephone or email), the employees shall verify that the requestor is either the person associated with the project, on the COC, or on a list provided by the client who are authorized to receive data. If a person who is not associated with the project personnel (or is not on the approved list), the base client will be contacted to inquire about authorization to release data. These contacts are documented and associated with the work order in the LIMS system to provide archival proof of authorization to release data. If the client does not authorize a release of data, the requestor will be contacted and told of this decision.

Client confidentiality is maintained electronically through the use of password-protected logins on all laboratory computer systems. Additionally, the laboratory maintains network security such as



anti-virus programs and firewalls that prevent any unauthorized outside access. All copies of the original report are stored on the laboratory's document archival system, which is also protected from unauthorized use by the network security systems. Raw data, reports, and LIMS records are kept in a secure location of the laboratory or off-site. All client confidential paper waste, including printouts, is shredded. For more information, see ELI SOP, *Laboratory Policies*.



## CHAPTER 10 – QUALITY CONTROL MONITORING

### *Routine Monitoring*

Temperatures of incubators, water baths, refrigerators, and ovens are checked and recorded according to a prescribed schedule using a continuous monitoring system.

Conductivity of the laboratory-purified water is continuously monitored using an automated monitoring system and as method blanks in routine analytical runs.

Reagents are dated and initialed at the time of receipt. Expiration dates are assigned as a fundamental component of their receipt and/or preparation. Reagents are not used after manufacturer's expiration date is exceeded.

Balances are checked daily, or as required, against ASTM Class 1 or 2 NIST traceable weights and are calibrated and serviced by certified technicians annually.

SOPs are reviewed periodically for accuracy.

Laboratory Notebooks are reviewed periodically for correctness and accuracy by supervisors.

Proficiency Testing (PT) Samples are analyzed as required (See Chapter Two of this QA Manual).

Quality Control Check Samples are analyzed with each analytical batch.

Internal and external audits are performed as specified or requested (See Chapter Two of this QA Manual for additional discussion).

Additional monitoring requirements may also be specified in individual SOPs.

The Laboratory maintains an active fraud protection program that is implemented through the laboratory ethics policy. Additionally, the potential of fraud is monitored through analyst supervision, management supervision, regular internal audits, PT study participation, and an active quality assurance program.

### *Instruments/Methods*

Calibration is performed as outlined in Chapter Seven of this QA Manual.

Generally, and depending on method requirements, the standard curve is verified with a known second source reference sample. The reference sample results must fall within the appropriate target range for the calibration to be accepted.

In most cases, the calibration stability is checked by running a continuing calibration standard every 10 to 20 samples, depending on the analysis and instrumentation. The verification



standard results must fall within an established range as described by the SOP.

All laboratory instruments are subjected to preventive maintenance schedules. Preventive maintenance schedules are specified in instrument maintenance logbooks.

As appropriate, instrument and/or method detection limits are determined annually, or more frequently if changes in instrument performance are noted or per method requirements. Procedures for the determination of instrument detection and method detection limits are described in ELI SOP, *Determination of Method Detection Limits and Quantitation Limits*.

Precision and accuracy requirements for each method are specified in the SOPs. General guidelines are given below.

- Each analytical batch will contain QC samples to measure the accuracy of the method. Each QC sample result is monitored to be within QC specifications of the method. Results of blank spiked sample analysis must be within the established control limits. Quality Control Limits are specified in the SOPs and meet recommended QC limits as described in the referenced method.
- Each analytical batch will contain QC samples to measure the precision of the method. (See Chapter One for discussion on duplicate sample analysis.) Criteria for duplicate sample acceptance are found in the SOP and are generally taken from the referenced method.
- Each analytical batch will contain QC samples to measure the performance of the method on the sample matrix. These are typically identified as a matrix spike analysis and may be performed in duplicate to assess method precision. Typically the sample is fortified with a known amount of target analyte and spike recoveries are calculated. Results outside of method QC guidance are flagged. Quality control limits and appropriate corrective actions steps are specified in the method SOP.

Several methods are considered to be concurrent methods in that they are either nearly identical or are identical to a method with a different citation. Even if two methodologies are identical in procedure, slight differences in the QC requirements might be the only difference between the two methodologies. These types of methods may also be considered "concurrent" if the procedures are identical and the more stringent of the two method criteria are used. During data reduction and reporting, the referenced method specifications and criteria will always take priority.

As appropriate, the performance trends of QC sample results are evaluated with Quality Control Charts. Suitability of existing QC limits is evaluated and possibly adjusted, but not to exceed method specification.



## CHAPTER 11 – CORRECTIVE ACTION

When the quality control checks indicate that an analysis is not within the established control limits, corrective action is needed. This section gives general guidelines for corrective action. Corrective actions for each method or instrument are detailed in individual SOPs. Records are maintained of non-conformances requiring corrective action to show that the root cause(s) was investigated, and includes the results of the investigation. The QA Manager/Officer will monitor implementation and documentation of the corrective action to assure that the corrective actions were effective.

Method QC samples that fail to fall within QC control limits may be analyzed again to verify if a problem exists. However, matrix spike or matrix spike duplicate QC samples are not required to be re-analyzed if the performance can be attributed to matrix effects; data results are then reported and flagged.

If the repeat analysis is not within control limits, the particular instrument or procedure is checked according to the specific protocols outlined in the method or according to the instrument manufacturer's guidelines. Once results are within control limits, analysis of all samples that were analyzed while the procedure was out of control are repeated, i.e., all analyses are repeated back to the previous acceptable control sample. In the case of radiochemical analysis, the term "analyze again" means to recount the final sample on the same (or different) detector.

If the analyst is unable to achieve acceptable results after following the corrective action guidelines detailed in the SOP, a supervisor is consulted. If necessary, the appropriate service personnel are contacted if the problem is determined to be due to instrument error, and cannot be resolved. It is also possible that the result is due to statistical variation of the results based on the tolerable error rate that has been determined for the analysis (usually 0.05). In certain cases, where control limits are exceeded, it is possible that problems cannot be corrected to satisfy QC criteria. This could be due to problems such as matrix interference, instrument problems, lack of sufficient sample, missed holding times, high blank contamination, etc. If all possible solutions available to correct the problem are examined and the sample results are still considered valid, qualifying comments are attached to the sample report describing the non-compliance and probable cause.

In the case of a single radiochemistry detector being returned to service, this refers only to the samples counted on that detector. For example, an individual gas proportional counter instrument may have up to 16 detectors; if only one does not pass the QC check the others are still valid and sample analyses performed on the others do not need to be repeated.

In the event that a QC audit or other informational review shows an analysis report to be incorrect, incomplete, or adversely compromised, a revised report and explanation is submitted to the client within ten business days unless otherwise communicated to the client with another time period. The report will clearly be identified as a revised report. As appropriate, an explanation submitted to the client should give a detailed review of the problem and document any unapproved deviations from the regulations, standard operating procedures, or project-



specific scope of work that may have caused it. The explanation to the client may include, but not be limited to, the following components:

- 1) What actions have been taken regarding the affected data set(s),
- 2) Identification of the cause, and
- 3) Corrective action(s) taken to prevent future occurrence.

In the event that a QC check fails, the analyst will follow the procedures outlined in the QA/QC summary of the SOP.

Quality Control Checks for each method or instrument may vary. Energy Laboratories Inc. follows the QC checks set by each governing method. Due to the wide variations between methods, specifics are listed within each SOP for the given method. Please reference the SOP for specific QC checks for the given method. The QC checks may include: ICV, MB, CCV, CCB, LCS, LCSD, LOD, MS, MSD or others specific to that method.

The following table lists the typical actions to be taken upon discovery of a QC sample failure. The purpose of this table is not to supersede the actions stipulated in the method SOP or the Method criteria.

QA Indicator	Frequency	Acceptance Criteria	Corrective Action For Failure	Comments
ICV	At the beginning of the run, immediately after the ICAL.	Usually $\pm 10\%$ . Method Dependent. Some methods have more stringent criteria.	<b>Option 1</b> – Re-analyze the ICV. <b>Option 2</b> – Stop run and re-calibrate the instrument.	-Evaluates calibration accuracy and method performance. Must be prepared from Second source standard. Know and follow any method specifications regarding the ICV.
CCV	At the beginning of run, and every ten samples. Must have a closing CCV at the end of the run.	Typically $\pm 10\%$ recovery. Very method dependent. See SOP & Method.	<b>Option 1</b> – Immediately re-run CCV upon failure. <b>Option 2</b> –Invalidate all samples not bracketed by passing CCVs, recalibrate, and re-analyze all invalidated samples.	-Evaluates instrument drift throughout analytical sequence. Typically uses midpoint calibration standard. Know and follow any method specifications regarding the CCV.
CCB	Every ten samples	CCB<PQL	<b>Option 1</b> – Stop run, invalidate all samples not bracketed by passing CCBs. Re-calibrate and re-analyze samples.	-Evaluates baseline drift, contamination in the analytical system, and analyte carryover. – Know and follow any method specifications regarding the CCB.
LCS	One per sample batch of 20, or less if tighter criteria specified in the published method.	Typically $\pm 10\%$ recovery. Very method dependent.	<b>Option 1</b> – Re-analyze LCS for recovery. <b>Option 2</b> – Stop run, recalibrate, re-extract and/or re-analyze all samples.	- Evaluates overall method accuracy/bias for the Preparatory Batch. Know and follow any method specifications regarding the LCS.





QA Indicator	Frequency	Acceptance Criteria	Corrective Action For Failure	Comments
MS	One per sample batch of 20, or less if tighter criteria specified in the published method	Typically $\pm$ 30% recovery. Very method dependent.	<b>Option 1</b> - Report Spike as Analyzed. LCS/LFB must be passing. Flag sample for possible matrix effects. <b>Option 2</b> –Re-analyze MS/MSD, only if there was an error making the MS, for either recovery or RPD failure.	-Evaluates effect of matrix on method performance. Know and follow any method specifications regarding the MS.
MSD	One per sample batch of 20, or less if tighter criteria specified in the published method.	Typically $\pm$ 30% Recovery. Very method dependent.  10-30% RPD –Check method for exact specifications.	Same as for MS.	-MSD also evaluates method precision. Know and follow any method specifications regarding the MSD.
MBLK	One per sample batch of 20, or less if tighter criteria specified in the published method.	MBLK < PQL	<b>Option 1</b> – Re-analyze the entire run. All organic runs with blank detections must be re-analyzed. <b>Option 2</b> – Flag data on report as having compound in blank.	-Evaluates overall method including possible contamination in reagents and glassware utilized in preparatory batch. Know and follow any method specifications regarding the MBLK.
DUP	One per sample batch of 20, or less if tighter criteria specified in the published method. (The DUP can be satisfied by a MS/MSD).	10-30% RPD –Check method for exact specifications.	<b>Option 1</b> – Re-analyze sample. <b>Option 2</b> – Flag analysis as having a failing DUP RPD for reporting.	Evaluates method precision. MSD duplicate analyses preferred on some methods.

Deviation from the method or SOP shall be documented in laboratory records. A deviation must receive the approval of the Quality Assurance Manager/Officer, the area supervisor or the laboratory manager.



## Procedure for Dealing with Complaints

### DEFINITIONS

**Complaint:** For the purposes of this procedure, a complaint comes from a client, a user of our data, or employee. The complaint might cover issues about the quality of our data, sample turnaround time, method used, pricing, or other expectations.

**Client:** The client is a person or company that ordered and paid for the services.

**Procedure:** The staff person receiving the complaint exercises judgment in deciding the severity and disposition of every complaint. The judgment must be used to decide whom, if anyone, is alerted to the complaint and what actions are appropriate. The complaint issued should be handled with a high degree of discretion and tact by the supervisor or manager involved. The individual handling the complaint is instructed to follow ELI's guidelines provided in this section on how to handle the complaint. This involves listening to the client and getting adequate information so the complaint can be investigated and resolved. The appropriate laboratory staff is notified and a solution to the problem, as well as a timeline for action, is given.

After the complaint is investigated or resolved, as necessary, the client is made aware of the results and determination is made as to what further actions are needed. Complaints and investigations may result in the need to submit a revised report or invoice. Complaints that are straightforward and can be resolved using the resources available to the person handling the complaint should be resolved there. These include such things as minor revisions of reports or invoices. If other decisions need to be made, the appropriate person should be contacted.

It may be appropriate to initiate or prepare a non-compliance report. This report should be completed with the intention of informing the affected staff about the problem so that we can all learn from it, change our procedures and improve our service. A procedure to document non-compliance reports is documented in ELI SOP, *Nonconformance Procedures and Corrective/Preventive Action Reports*.

If an employee or former employee sees an issue, they are encouraged to report concerns regarding Quality Systems, unethical behavior, and/or financial mismanagement. This issue should initially be brought to the attention of their supervisor. The supervisor will take appropriate action to resolve the concern. If the employee is uncomfortable with approaching their supervisor or feels that the issue was not properly dealt with, they may approach higher levels of management with their issue.

Energy Laboratories, Inc., has also implemented a program to facilitate confidential reporting to upper management. This tool allows employees, customers, vendors, auditors and other interested parties to report situations or behaviors that they consider to be unethical, immoral, or improper. It also allows the reporting of suggestions or comments. The program has been implemented at ELI so that anyone reporting a situation can be assured that there will not be retaliation for reporting. It is meant to encourage parties to communicate with upper management when there appears to be no alternative for resolving the types of issues already described. There are currently multiple options to utilize the program. Access to the program



is available via both the ELI internal and external websites as well as a 24-hour telephone hotline number (877-874-8416).

***Penalty for Improper, Unethical or Illegal Actions***

Energy Laboratories, Inc. employees are expected to work in an ethical, proper, and legal manner. They are expected to perform laboratory analyses according to the cited method(s) and in conjunction with the SOP and the Quality Assurance Plan. Employees are expected and required to report any violations of this policy. All employees are mandated to participate in an ethics-training program as part of their orientation upon hire.

Improper, unethical, or illegal actions by an employee will be addressed on a case-by-case basis as determined by the seriousness of the offense. Corrective actions may include disciplinary action up to and including discharge.



## CHAPTER 12 – MAJOR EQUIPMENT AND METHODS

A summarized listing of major instrumentation utilized in the laboratory is included in Appendix F. See attached NELAP certificate in Appendix A for a complete list of accredited methods and analytes that ELI performs to support SDWA, RCRA and CWA regulated methods. Refer to the ELI Technical Services and Fee Schedule, located on the ELI website <http://energylab.com>, for a list of all methods and analyte parameters that Energy Laboratories, Inc. Billings, Montana performs.



## CHAPTER 13 – PREVENTIVE MAINTENANCE

Preventive maintenance is performed on laboratory equipment according to the manufacturer's guidelines and our operational experience. Repairs and maintenance are accomplished in-house by experienced laboratory personnel whenever possible. Other than consumable equipment items, an inventory of spare parts is not maintained. Spare parts are available from outside vendors on an as needed basis. (To ensure method capability, some methods have more than one instrument available). An example of maintenance performed follows:

<b>Instrument</b>	<b>Maintenance</b>	<b>Frequency – Note that Daily is based on use.</b>
Balances	Check with Class 1 weights	Daily
	Independent Service	Annually
Pipettes	Check volume	Quarterly/Daily
ICP-Atomic Emission	Check Pump Tubing	Daily
	Check Coolant Levels	Monthly
	Lubricate Autosampler	As needed
	Air Filter	Quarterly
	Optics Servicing	As needed
ICP-Mass Spectrometry	Check Pump Tubing	Daily
	Check Coolant Levels	Monthly
	Check Electron Multiplier	Monthly
	Lubricate Autosampler	As needed
	Air Filter	Quarterly
Gas Chromatograph	Change Septum	As needed
	Check Injection Liner	Daily
	Clean Detector	As needed
	Change Gas Cylinders	At 200 psi
	Change Column	As needed
Auto Analyzers	Check For Leaks	Daily
	Change Tubing	When wear is visible
	Lubricate Pumps	Annually
	Lubricate Sampler	Annually
Mass Spectrometers	Monitor Vacuum Pressures	Daily
	Monitor Background Levels	Daily
	Monitor Electron Multiplier	Daily
	Change Pump Oil	As Needed
Microbiology	Monitor Room Temperature	Twice daily
	Monitor Incubator Temperature	Twice daily
	Autoclave Maintenance	Annually
Reagent Water Systems	Monitor Water Bath Temperature	Twice daily
Compressed Gases	Change/Check Cartridges	Quarterly, or as needed
Liquid Chromatograph	Change Gas Cylinders	At 50 psi, monitor daily
	Flush System	Daily
	Change Filters	As needed
	Replace Seals	As needed
Continuous Monitoring System	Check Temperatures	Daily, calibrated annually



## CHAPTER 14 - REFERENCES

ANSI N42.23-1996, American National Standard Measurement and Associated Instrument Quality Assurance for Radioassay Laboratories.

ASTM Annual Book of Standards, Part 31 (water), American Society for Testing and Materials.

ASTM D 7282-06 Standard Practices for Set-up, Calibration, and Quality Control of Instruments Used for Radioactive Measurements.

Handbook for Analytical Quality Control in Water and Wastewater Laboratories, Environmental Protection Agency. EPA 600/4-79-019

ELI Technical Services and Fee Schedule, Current Revision, Energy Laboratories, Inc.

Manual for the Certification of Laboratories Analyzing Drinking Water, 5th Ed., EPA 815-R-05-004, 2005.

Manual for the Certification of Laboratories Analyzing Drinking Water, Supplement to 5<sup>th</sup> Ed., EPA 815-F-08-006, June 2008.

Methods for Chemical Analysis of Water and Wastes Environmental Protection Agency, 600/4-79-020.

Methods for the Determination of Metals in Environmental Samples – Supplement I, EPA/600/R-94-111, May 1994.

Methods for the Determination of Inorganic Substances in Environmental Samples, EPA/600/R-93-100, August 1993.

Methods for the Determination of Organic Compounds in Drinking Water, EPA/600/4-88/039, December 1998.

Methods for the Determination of Organic Compounds in Drinking Water – Supplement I, EPA/600/4-90/020, July 1990.

Methods for the Determination of Organic Compounds in Drinking Water – Supplement II, EPA/600/R-92/129, August 1992.

NELAC Chapter 5: Quality System Standard, 2003 or most current version approved by Florida and Texas NELAC Accreditation program.

NELAP, National Environmental Laboratory Accreditation Program <http://www.nelac-institute.org/newnelap.php>

Qualifications Manual, Current Revision, Energy Laboratories, Inc.



*Quality Assurance Plan*

*Energy Laboratories, Inc.*

*Billings, Montana*

Standard Methods for the Examination of Water and Wastewater; 20<sup>th</sup>, 21<sup>st</sup> and -22<sup>nd</sup> Editions, APHA.

Technical Notes on Drinking Water Methods, EPA/600/R-94/173, October 1994.

Test Methods for Evaluating Solid Waste, Physical/Chemical Methods (SW846), Environmental Protection Agency. <http://www.epa.gov/epawaste/hazard/testmethods/sw846/online/index.htm>

TNI Standard, Volume 1 (EL-V1-2009), The NELAP Institute.



## CHAPTER 15 – GLOSSARY OF TERMS

**Accuracy** - The degree of agreement between an observed value and an accepted reference value.

**Analyst** - The designated individual who performs the “hands-on” analytical methods and associated techniques and who is the one responsible for applying required laboratory practices and other pertinent quality controls to meet the required level of quality.

**Analytical Sample** - Any solution or media introduced into an instrument on which an analysis is performed, excluding instrument calibration, initial calibration verification, initial calibration blank, continuing calibration verification, and continuing calibration blank.

**Audit or Assessment**- A systematic evaluation to determine the conformance to quantitative specifications of some operational function or activity.

**Batch** - Environmental samples that are prepared and/or analyzed together with the same process and personnel, using the same lot(s) of reagents. A preparation batch is composed of one to twenty environmental samples of the same matrix, meeting the criteria above. An analytical batch is composed of prepared environmental samples, extracts, digestates, or concentrates, which are analyzed together as a group.

**Blank (BLK)** - A sample of clean water that accompanies the samples through different aspects of sampling and/or sample preparation. It is used to monitor contamination during sampling, transport, storage or analysis. The blank is subjected to the usual analytical and measurement process to establish a zero baseline or background value. There are various types of blanks: equipment blank, field blank, instrument blank, method blank, and reagent blank.

**Blank Spike** - See Laboratory Fortified Blank.

**Blind QC Check Samples** - Samples whose analyte concentrations are not known to the analyst. That the sample is a QC check sample may or may not be known to the analyst.

**Calibration** - The set of operations that establish, under specified conditions, the relationship between values indicated by the measuring instrument and the corresponding known value of the property being measured.

**Calibration Blank** - A volume of reagent water fortified with the same matrix as the calibration standards, but without the analytes, internal standards, or surrogate analytes.

**Calibration Check Standard** - See Check Standard.

**Calibration Curve** – The graphical relationship between the known values and the instrument responses for a series of calibration standards.

**Calibration Standard** - A solution of known concentration used in the calibration of an analytical instrument.





**Chain of Custody Form**- A record that documents the possession of the samples from the time of collection to receipt in the laboratory. This record generally includes: the number and types of containers; the mode of collection; collector; time of collection; preservation; and requested analyses.

**Check Standard** - A material of known composition that is analyzed concurrently with test samples to evaluate a measurement process.

**Clean Water Act** - Public Law PL 92-500. Found at 40 CFR 100-140 and 400-470. The act regulates the discharge of pollutants into surface waters.

**Comprehensive Environmental Response, Compensation and Liability Act (CERCLA)** - The enabling legislation (42 USC 9601 - 9675 et seq., as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA), 42 USC 9601 et seq.), to eliminate the health and environmental threats posed by hazardous waste sites.

**Continuing Calibration Blank (CCB)** – See Check Standard.

**Continuing Calibration Standard** - See Check Standard.

**Continuing Calibration Verification (CCV)** - See Check Standard.

**Control Limits** - A range within which specified measurement results must fall to be compliant.

**Control Standard** - See Check Standard.

**Corrective Action (CA)** - An action taken to eliminate the causes of an existing nonconformity, defect, or other undesirable situation in order to prevent recurrence.

**Data Quality Objectives (DQO)** - An integrated set of specifications that define data quality requirements and the intended use of the data.

**Demonstration of Capability (DOC)** - A procedure to establish the ability of the analyst to generate data of acceptable quality.

**Detectability** – For radiochemical analysis, detectability as a Lower Limit Detection (LLD) or Minimum Detection Concentration (MDC), is assessed based on the requirements of 40 CFR 141.25(c) and is a sample-specific determination. The equation is specific for each method and noted in the method SOP.

**Detection Limit** - See Practical Quantitation Limit and Method Detection Limit. Reporting of detection in radiochemistry is based on specific formulas identified in individual procedures. Single activity point standards are used for efficiency calibration. When required, multiple energy emitters are used for energy calibration.



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

**Duplicate (DUP)** - A second aliquot of a sample that is treated the same as the original sample to determine the precision of the method.

**Duplicate Sample** - See Duplicate.

**Fortified Sample** - See Matrix Spike.

**Holding Times (Maximum Allowable Holding Times)** - The maximum time that samples may be held prior to analysis and still be considered valid or not compromised.

**Initial Calibration Verification (ICV)**- A sample of known concentration, from a source other than that of the calibration standards, analyzed following calibration to demonstrate validity of the calibration.

**Instrument Blank** - See Calibration Blank.

**Internal Standard** – A known amount of standard added to a test portion of a sample as a reference for evaluating and controlling the precision and bias of the applied analytical method.

**Laboratory Control Sample (LCS)** – A sample with a known concentration prepared and/or analyzed as a measure of accuracy for the method.

**Laboratory Fortified Blank (LFB)** – An aliquot of reagent water to which known quantities of specific compounds are added and which is analyzed as a measure of method recovery.

**Laboratory Inter-comparison Sample** - A performance evaluation sample analyzed by numerous laboratories. Acceptance criteria are often based statistically on the analysis results.

**Limit of Detection (LOD)** - For chemical analysis, the LOD is an estimate of the minimum amount of a substance that an analytical process can reliably detect. An LOD is analyte and matrix specific and may be laboratory-dependent.

**Limit of Quantitation (LOQ)** – For chemical analysis, the LOQ is an estimate of the minimum amount of a substance that can be reported with a specified degree of confidence. An LOQ is an evaluation of precision and bias.

**LIMS** - Laboratory Information Management System.

**Matrix** – The substrate of a test sample.

**Matrix Spike - (MS)** – An aliquot of a sample to which known quantities of specific compounds are added, and which is carried through the entire analytical process to determine the effect of the matrix on the methods recovery efficiency.



**Matrix Spike Duplicate (MSD)** – A second aliquot of a sample to which known quantities of specific compounds are added, and which is carried through the entire analytical process to determine the effect of the matrix on the method's recovery efficiency and the precision of the method.

**Maximum Contaminant Level (MCL)** – Regulatory action levels for a contaminant of concern.

**Method Detection Limit (MDL)** - A measure of the limit of detection for an analytical method determined according to the procedure given in 40 CFR Part 136 Appendix B.

**Method Blank (MBLK)**- A clean sample processed simultaneously with, and under the same conditions as, samples containing an analyte of interest through all steps of the analytical procedure.

**Method Validation** - The confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled (NELAC 2003) (MARLAP 2004 for radiochemical methods).

**NELAC** - National Environmental Laboratory Accreditation Conference.

**NELAP** - National Environmental Laboratory Accreditation Program.

**NPDES** - National Pollutant Discharge Elimination System- A discharge permit system authorized under the Clean Water Act.

**Performance Evaluation (PE) Sample** - A sample with a composition unknown to the analyst that is provided to test whether the analyst/laboratory can produce analytical results within specified limits.

**Practical Quantitation Limit (PQL)** – The lowest concentration or amount of the target analyte that can be identified, measured and reported with confidence that the analyte concentration is not a false positive value.

**Precision** - The degree to which a set of observations or measurements of the same property conform to themselves.

**Preservation** - Refrigeration and/or reagents added at the time of sample collection to maintain the chemical and/or biological integrity of the sample.

**Proficiency Testing (PT) Sample** - A sample with a composition unknown to the analyst which is provided to test whether the analyst/laboratory can produce analytical results within specified limits.

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



**Quality Assurance Project Plan (QAPP)** - A formal document describing the detailed quality control procedures pertaining to a specific project. For environmental clean-up projects, this is typically produced by an engineering firm with references to include a laboratory's Quality Assurance Manual.

**Quality Control** – The overall system of technical activities whose purpose is to measure and control the quality of a product or service so that it meets the needs of users.

**Quality Control Sample** – A sample used to assess the performance of all, or a portion, of the measurement system.

**Replicate** - See Duplicate.

**Reporting Limit (RL)** –. The lowest level of concentration reported for an analyte.

**Resource Conservation and Recovery Act (RCRA)** - The enabling legislation under 42 USC 321 et seq. (1976) that gives EPA the authority to control hazardous waste.

**Safe Drinking Water Act (SDWA)** - The enabling legislation, 42 USC 300f et seq. (1974), which requires the USEPA to protect the quality of drinking water in the U.S. by setting maximum allowable contaminant levels, monitoring, and enforcing violations.

**Sample (SAMP)** - A portion of material to be analyzed.

**Spiked Sample** – See Matrix Spike.

**Standardization** - See Calibration.

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

**TNI** – The NELAC Institute

**Traceability** – The property of a result of a measurement whereby it can be related to appropriate standards.

**Trip Blank** - One type of Field Blank. An aliquot of analyte-free water or solvent transported to the field in a sealed container and returned to the laboratory with the sample containers.



**Acronyms and Abbreviations**

AA	- Accrediting Authority
AB	- Accrediting Body
ANSI	- American National Standards Institute
AOAC	- The Scientific Association Dedicated to Analytical Excellence
APHA	- American Public Health Association
ASQC	- American Society for Quality Control
ASTM	- American Society for Testing and Materials
Bq	- Becquerel
BLK	- Blank
Bg	- Background
°C	- Degrees Celsius
Cal	- Calibration
CAS	- Chemical Abstract Service
CCB	- Continuing Calibration Blank
CCV	- Continuing Calibration Verification
COC	- Chain of Custody
DOC	- Demonstration of Capability
DO	- Dissolved Oxygen
DQO	- Data Quality Objectives
DMRQA	- NPDES Discharge Monitoring Report Quality Assurance
DUP	- Duplicate
ELI	- Energy Laboratories, Inc.
EPA	- Environmental Protection Agency
FDA	- Food and Drug Administration
g/L	- Grams per Liter
GC	- Gas Chromatography
GC-MS	- Gas Chromatography-Mass Spectrometry
ICP-AES)	- Inductively Coupled Plasma Atomic Emission Spectrophotometry
ICP-MS	- Inductively Coupled Plasma-Mass Spectrometry
ICV	- Initial Calibration Verification
ISO	- International Organization for Standardization
LCS	- Laboratory Control Sample
LFB	- Laboratory Fortified Blank
LIMS	- Laboratory Information Management System
LLD	- Low Limit Detection
LOD	- Limit of Detection
LOQ	- Limit of Quantitation
MDC	- Minimum Detection Concentration
MDL	- Method Detection Limit
MBLK	- Method Blank
MS/MSD	- Matrix Spike/Matrix Spike Duplicate
NEHA	- National Environmental Health Association
NELAC	- National Environmental Laboratory Accreditation Conference
NELAP	- National Environmental Laboratory Accreditation Program
NIOSH	- National Institute for Occupational Safety and Health
NIST	- National Institute of Standards and Technology
NPDES	- National Pollutant Discharge Elimination System
OSHA	- Occupational Safety and Health Administration
pCi/L	- Picocuries per Liter



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*Quality Assurance Plan*

*Energy Laboratories, Inc.*

*Billings, Montana*

PT	- Proficiency Testing
QA/QC	- Quality Assurance / Quality Control
QS	- Quality Systems
QAM	- Quality Assurance Manual
RDL	- Required Detection Level
RCRA	- Resource Conservation and Recovery Act
RL	- Reporting Limit
RPD	- Relative Percent Difference
RSD	- Relative Standard Deviation
SOP	- Standard Operating Procedure
SPK	- Spike
Std	- Standard
SVOC	- Semi-Volatile Organic Compound
TNI	- The NELAC Institute
ug/L	- Micrograms Per Liter
UV/VIS	- Ultraviolet/Visible Spectroscopy
VOC	- Volatile Organic Compound
WET	- Whole Effluent Toxicity



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## APPENDIX A

### Laboratory Certifications

The following are included in this Appendix:

- Montana State Drinking Water Certificate



MT State Drinking  
Water Certificate

- NELAP Accreditation Certificate
- NELAP Accredited Analyte List



Nelap Certification  
and List

Certifications and performance evaluation studies found on the EnergyLab.com Website include:

- North Dakota State Certification
- South Dakota State Certification
- Wyoming State Certification (EPA Region VIII)
- Idaho State Certification
- Colorado State Certification
- Nevada State Certification
- Recent EPA WS and WP/DMRQA Study Results
- Recent NELAC Water/Soil Study Results



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## APPENDIX B

### Quality Systems Controlled Documents



Quality Systems  
Controlled  
Documents



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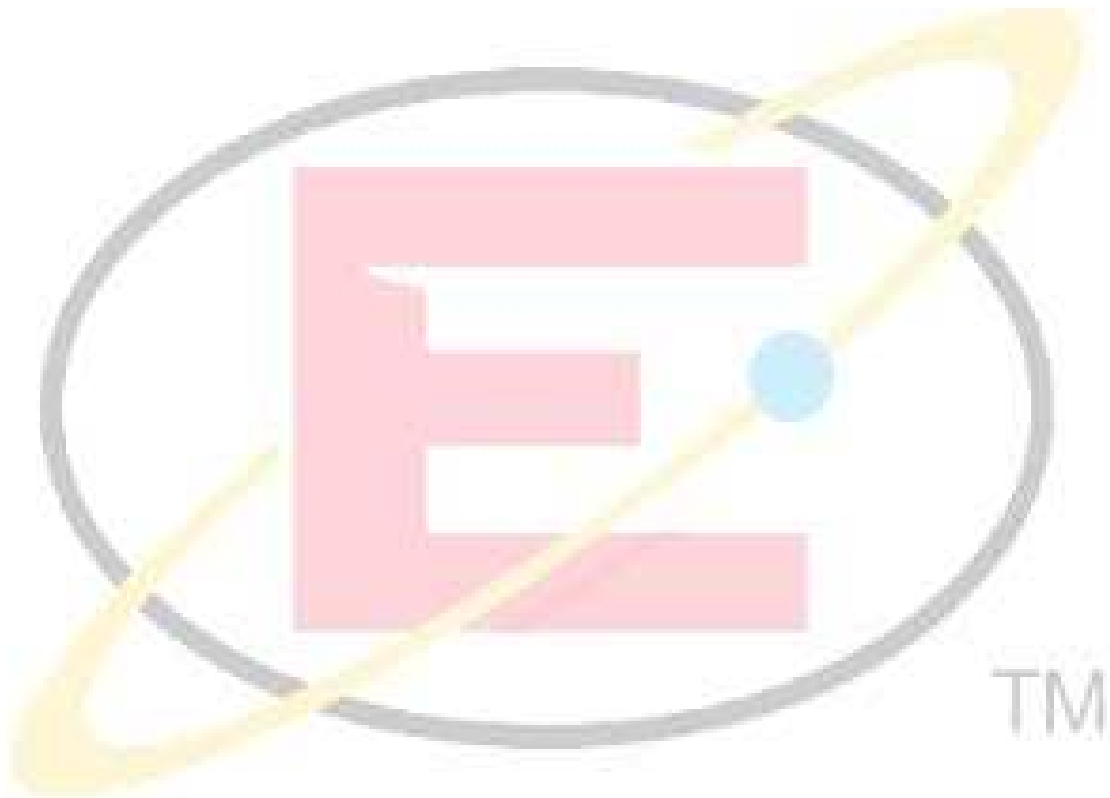


## APPENDIX C

### Quality Assurance / Quality Control Specifications



QA\_QC Parameters



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## APPENDIX D

### Organizational Charts



Billings Organization  
1-21-14.pdf



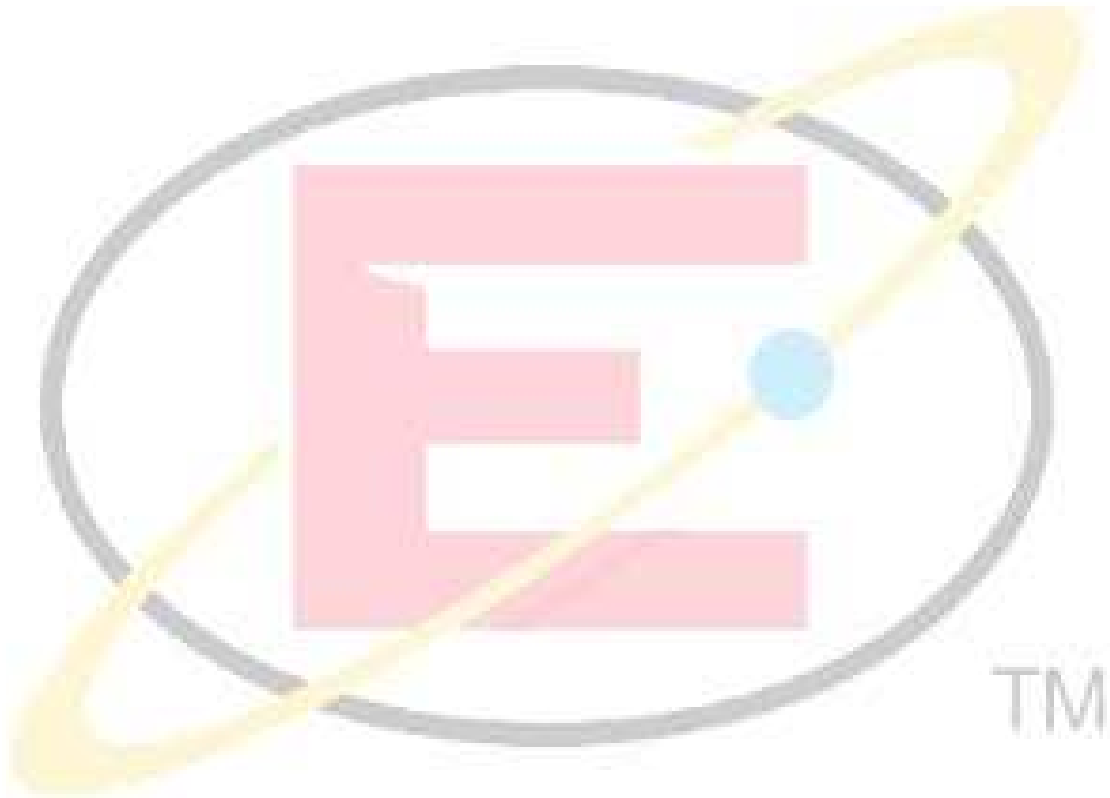
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## APPENDIX E

### *Curricula Vitae of Key Laboratory Personnel*



Curricula Vitae of Key  
Laboratory Personnel



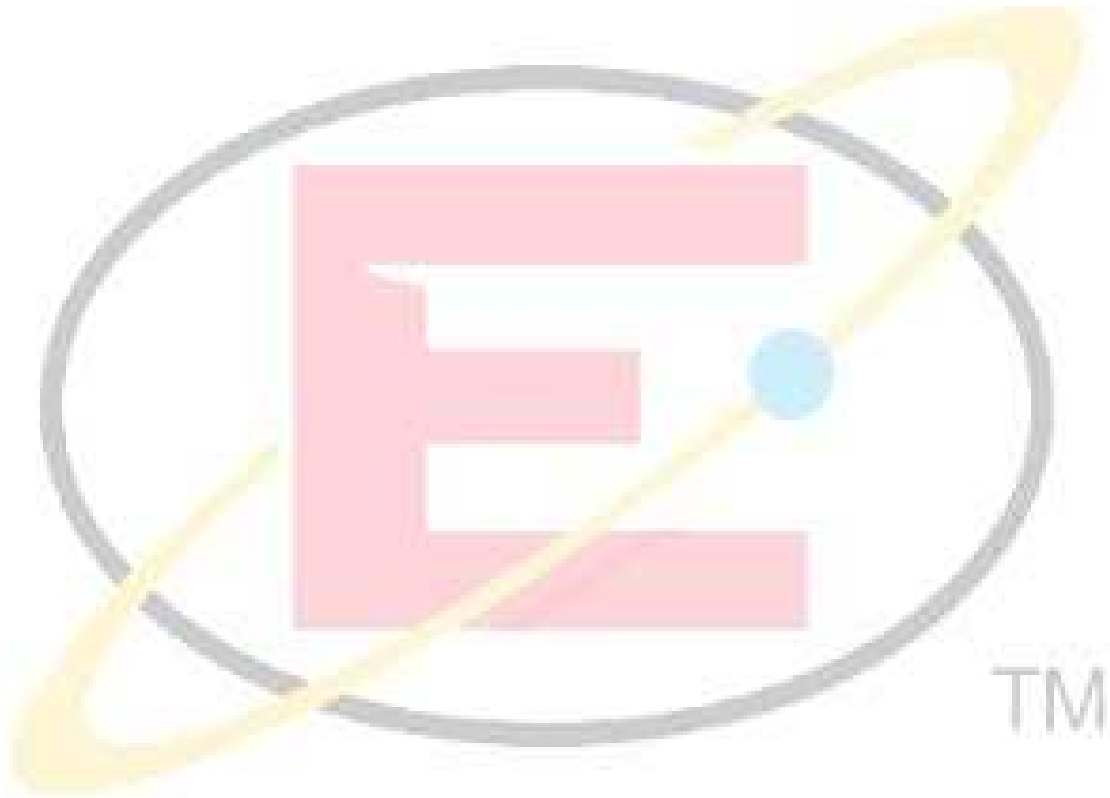
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## APPENDIX F

### Equipment and Methods List



Major Equipment and  
Methods List



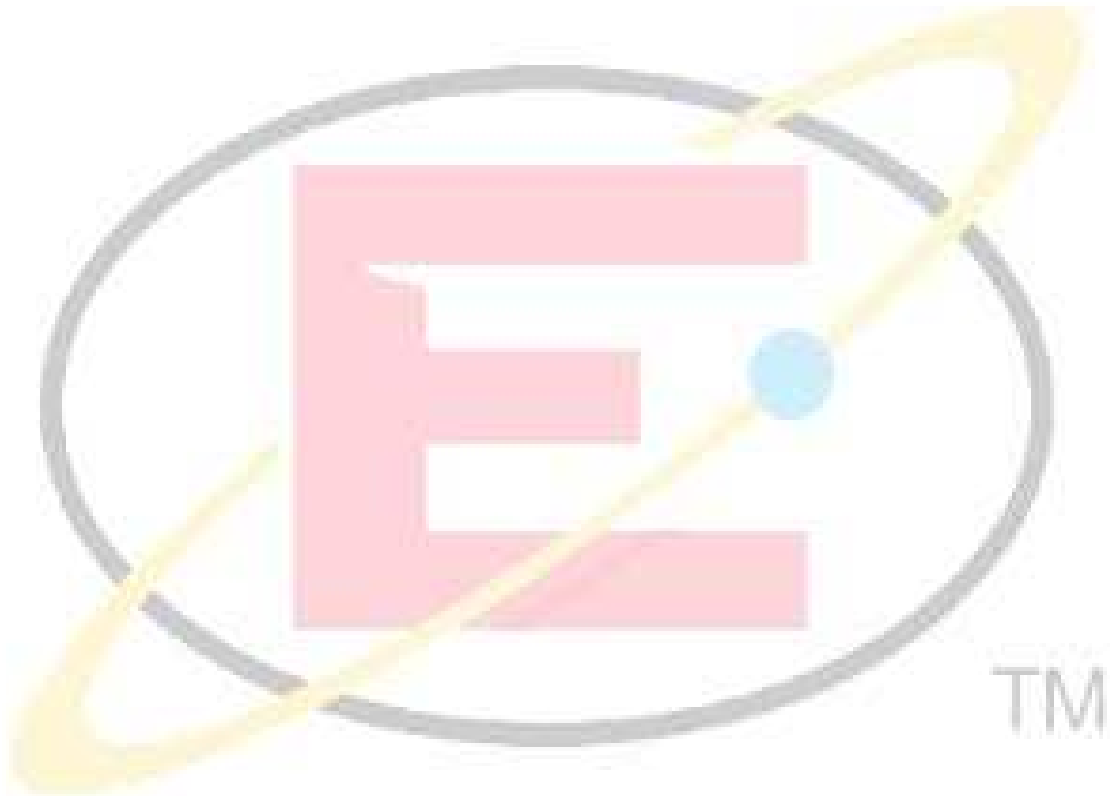
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# ATTACHMENT 1

## Record of Review/Revision Form



QA Manual Record  
Of Review



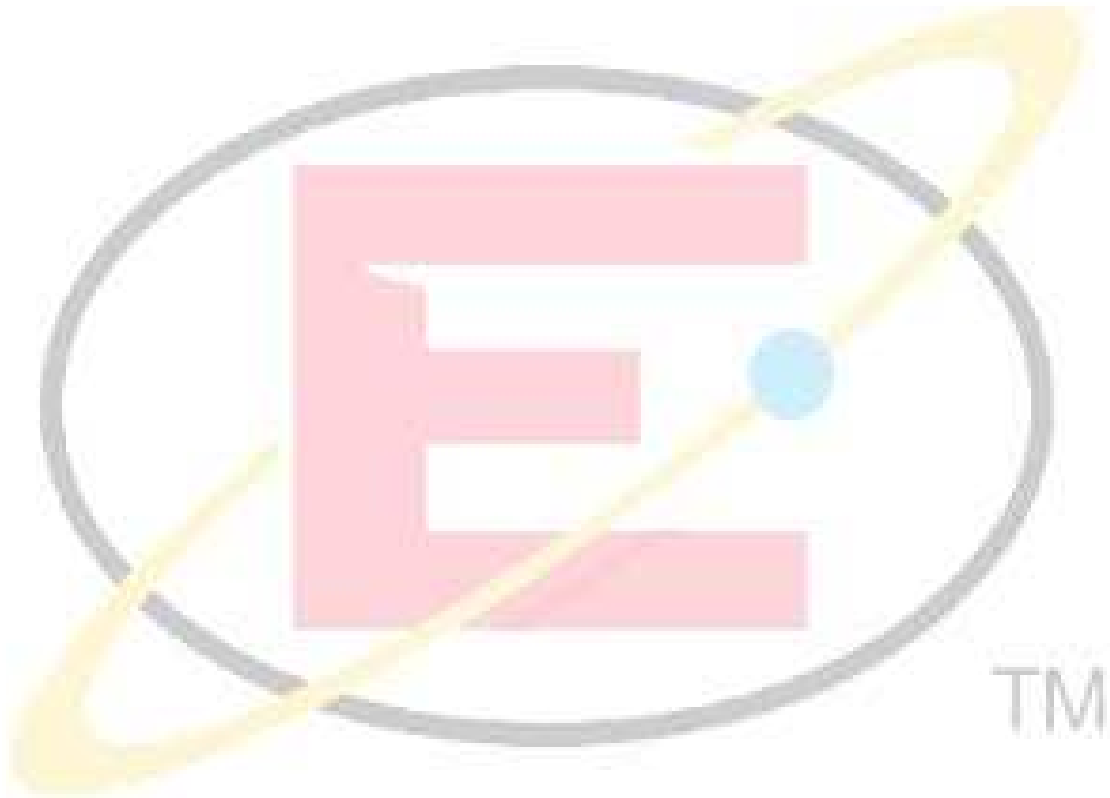
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## ATTACHMENT 2

### QA Manual Record of Acknowledgment



QA Manual  
Acknowledgement  
Form



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