

**ENERGY LABORATORIES, INC. – WYOMING REGIONAL
LABORATORIES
QUALITY ASSURANCE MANUAL**

Revision December 13, 2021

Casper Laboratory
2393 Salt Creek Hwy.
Casper, Wyoming 82601

Local: (307) 235-0515
Fax: (307) 234-1639
E-Mail: casper@energylab.com

Gillette Laboratory
400 West Boxelder Road
Gillette, Wyoming 82718

Local: (307) 686-7175
Fax: (307) 682-4625
E-Mail: gillette@energylab.com

Wyoming Regional Director, Gillette Laboratory Director
Terry L. Friedlan

Casper Laboratory Director, Casper Technical Director
Chrystal N. Sheaff, Ph.D.

Gillette Quality Assurance Officer
Julie L. Weisz

Casper Quality Assurance Officer
Donny C. Juarez



www.energylab.com

TABLE OF CONTENTS

Quality Assurance Manual 1

Table of Contents 2

ELI Commitment 4

Introduction 4

Chapter 1 – Quality Control Program 7

 Quality Policy Statement 7

 Quality Assurance Program 7

 Estimation of Uncertainty 10

 Maintenance of Performance Records 11

 Method Quality Control Specifications 11

Chapter 2 – Quality Assessment Program 12

 Proficiency Testing (PT) Samples 12

 Quality Control Check Samples 13

 Quality Assurance Audits 13

Chapter 3 – Laboratory Facilities 15

Chapter 4 – Personnel Requirements and Laboratory Organization 16

 Laboratory Organization 16

 Personnel Requirements 17

 Laborator Director 17

 Quality Assurance Officer 18

 Technical Director 18

 Laboratory Supervisor 18

 Analysts 18

 Laboratory Technicians 19

 Approved Signatories 19

Chapter 5 – Sampling Procedures 20

Chapter 6 – Sample Handling 22

 Sample Receipt 22

 Chain-of-Custody 22

 Sample Tracking 23

 Sample Disposal 23

 Subcontracting Policy 23

Chapter 7 – Instrument Operation and Calibration 25

Chapter 8 – Records and Reporting 27

 Document Management 27



Laboratory Notebooks..... 27

Records..... 28

Data Reduction 28

Validation 29

Reporting..... 29

Chapter 9 – General Laboratory Practices 31

 Chemicals and Reagents 31

 Reagent Interference 31

 Glassware Preparation..... 32

 Laboratory Pure Water..... 32

 Employee Training 32

 Data Integrity..... 33

 Standard Operating Procedures 34

 Client Confidentiality 34

Chapter 10 – Quality Control Monitoring 35

 Routine Monitoring..... 35

 Instruments/Methods..... 35

Chapter 11 – Corrective Action..... 37

 Procedure for Dealing with Complaints..... 38

 Penalty for Improper, Unethical or Illegal Actions..... 39

Chapter 12 – Management of Change..... 40

Chapter 13 – Major Equipment and Methods 41

Chapter 14 – Preventive Maintenance..... 42

Chapter 15 – References..... 44

Chapter 16 – Glossary of Terms..... 46

 Acronyms and Abbreviations 56

APPENDIX A..... 58

 Quality Assurance / Quality Control Specifications..... 59

APPENDIX B..... 66

 Corporate Organizational Chart..... 67

APPENDIX C 68

 Curricula Vitae of Key Laboratory Personnel..... 69

APPENDIX D 77

 Equipment and Methods List 78

Record of Review..... 80



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, 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, microbiology, soils and water physical parameters, and petroleum analysis.

Founded in 1952, Energy Laboratories currently incorporates four separate testing laboratories. The corporate headquarters are located in Billings, MT, with laboratories located in Casper, WY; Gillette, WY; and Helena, MT.

ELI, as a coordinated company of four participating laboratories, 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. Scientific approaches, Good Laboratory Practices, EPA Methods and Guidance documents, and accreditation audit guidance are used 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. The Casper and Gillette laboratories are certified under the Safe Drinking Water Act by Region VIII EPA. Individual state approval for SDWA is managed through reciprocal certifications when required by a specific state. ELI-Casper 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. To perform radon testing, ELI Billings is certified under the National Radon Proficiency Program administered by the National Environmental Health Association. ELI-Casper also maintains a United States Nuclear Regulatory Commission (USNRC) Materials License and therefore conducts all radiological effluent and environmental monitoring of licensed facility's samples in accordance with the guidelines set forth in *REGULATORY GUIDE 4.15 - QUALITY ASSURANCE FOR RADIOLOGICAL MONITORING*



www.energylab.com

PROGRAMS (INCEPTION THROUGH NORMAL OPERATIONS TO LICENSE TERMINATION) EFFLUENT STREAMS AND THE ENVIRONMENT. This Quality Assurance Manual contains the above guidance document's QA program elements that ensure the quality of the data for radiological effluent and environmental monitoring programs. Copies of ELI's certificates, including status of DOD/ISO17025 certification is maintained on ELI's website: www.energylab.com.

The ELI Quality Assurance Manual and the ELI Professional Services Guide together are used to outline the ELI Quality Assurance/Quality Control Program. This Quality Assurance Manual is appropriate to all departments of Wyoming Regional Laboratories. 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 Wyoming Regional, and all other ELI laboratories', applicable accreditations and certifications are maintained on the ELI website at www.energylab.com. 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, method validation criteria, quality control acceptance ranges, corrective action procedures, validation 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 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. Project samples requiring analysis under DOD accreditation are managed as having project specific requirements to meet client DQO requirements in addition to Quality System and method requirements as specified within the DOD Quality System Manual (QSM) 5.4.

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 Laboratory Director, or designee, will evaluate all new contracts to determine that the laboratory is capable of performing the requested work. This process includes ensuring that the



www.energylab.com

laboratory maintains the required accreditation, equipment and resources. In the event that sample analysis is not performed at one of the Wyoming locations, clients are notified on the laboratory analytical report that, the work was subcontracted to a qualified ELI laboratory or an outside laboratory (refer to Subcontracting Policy – Chapter 6 in this QA Manual).

This Quality Manual and related quality documentation meet requirements of the National Environmental Laboratory Accreditation Program (NELAP), which is an EPA approved accreditation program, and on a project specific basis include Department of Defense DOD accreditation requirements as specified in their Quality System Manual Version 5.4 (DOD QSM 5.4, 2021).



www.energylab.com

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, NELAP (TNI), and ANSI-ASQ National Accreditation Board (ANAB) for DOD and ISO-17025 accreditation. 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. ELI Quality Systems are designed to comply with the standards as defined by the most current version of the TNI accreditation standard, ISO 17025 standards and includes processes and procedures to manage risks and opportunities as discussed in the newest ISO 17025 version. 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, resources, 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. The Technical Director, or their designee, ensures that changes to the management system 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.

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, NELAP (TNI), and ANSI-ASQ National Accreditation Board (ANAB) for DOD and ISO-17025 accreditation.

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



www.energylab.com

- Performance of any analytical method requires that the proper equipment and instrumentation are available. A list of major equipment is listed in Appendix D. 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, calibration, analysis, and shut down. Chapter 13 of this manual includes recommended preventative maintenance, and/or a list of parameters used to identify other types of maintenance. Instrument specific preventative maintenance and routine maintenance is documented in Mirage and/or the Instruments Module of the LIMS. SOPs outline any special safety precautions for operation of the instrumentation.
- SOPs of detailed Standard Methods, EPA, ASTM, NIOSH, APHA, OSHA, or other 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.
- For radiochemical analysis performed at the Casper Laboratory, 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 where appropriate.
- The initial test method evaluation for applicable chemical analysis involves Method Detection Limit (MDL) studies including confirmation of the Limit of Detection (LOD) and Practical Quantitation Limit (PQL), also known as the Limit of Quantitation (LOQ) (refer to ELI SOP, *Determination of Method Detection Limits (MDL) and Limit of Quantitation (LOQ)*), an evaluation of method performance by successful completion of an Initial Demonstration of Capability (refer to ELI SOP, *Personnel Training and Training Records*), the successful completion of appropriate Performance Evaluation (PT) studies (when available), evaluation of the method selectivity and sensitivity, and any additional method or client specific requirements.
- ELI demonstrates that laboratory staff is 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 key management and supervisory personnel are described in Appendix C.



- 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 (QCS) appropriate to the analytical procedures they perform. These QCS samples may include LCS/LFB/ICV, MS/MSD, Duplicates, or proficiency testing samples. Competency in analyzing these control samples is documented in analysts' training files per NELAP requirements (for more information, refer to ELI SOP, *Personnel Training and Training Records*). For those methods that laboratory management has documented that an alternate approach to demonstrating competency is adequate, competency may be documented by a validated qualifying statement indicating that the analyst has been observed to be competent in performing the analysis.
- 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 at the required frequency or at least annually. For additional information on instrument calibration, refer to Chapter 7 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 2 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 σ 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. For most procedures, uncertainty at the reporting limit or Limit of Quantitation (LOQ) is determined by Limit of Quantitation spike recovery studies or by MDL study spike recovery evaluations. LOQ/MDL verifications are performed quarterly to verify ongoing method accuracy, precision and sensitivity when required by DOD certification. 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.



www.energylab.com

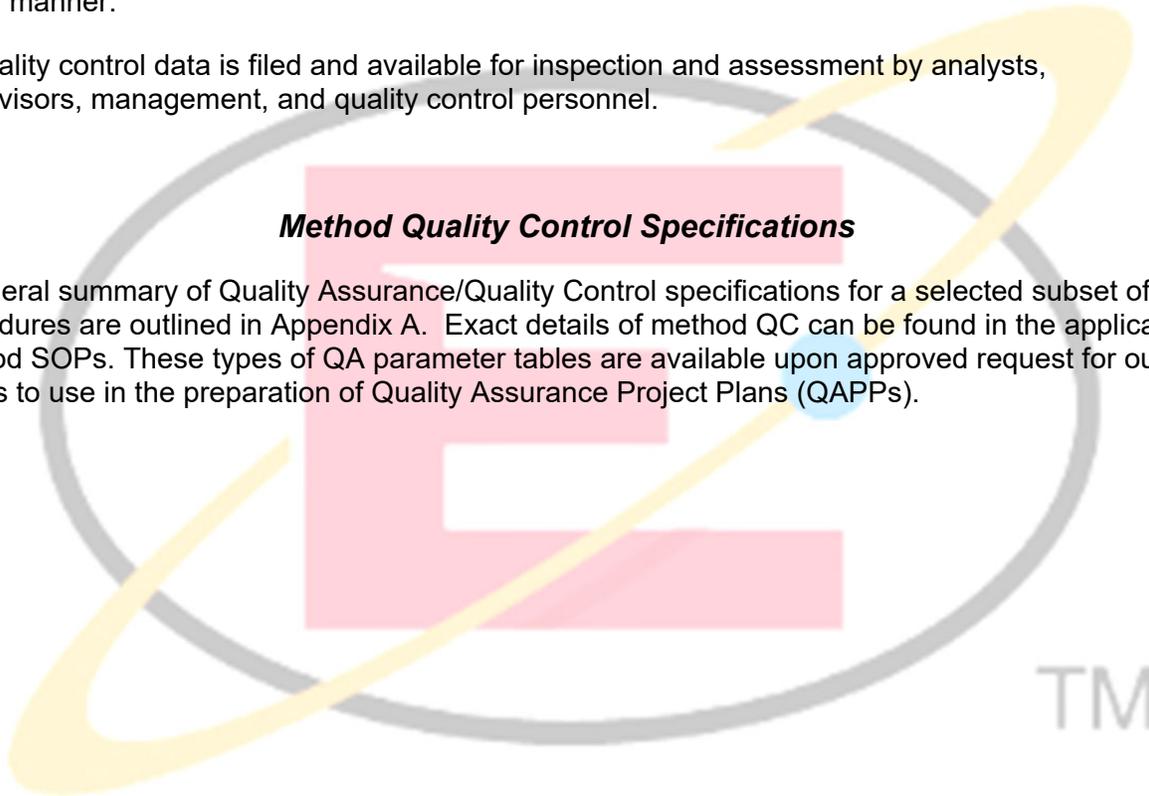
Maintenance of Performance Records

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

A general summary of Quality Assurance/Quality Control specifications for a selected subset of procedures are outlined in Appendix A. Exact details of method QC can be found in the applicable method SOPs. These types of QA parameter tables are available upon approved request for our clients to use in the preparation of Quality Assurance Project Plans (QAPPs).



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 samples required for various certifications are Water Pollution (WP or DMRQA), Water Supply (WS), and Soil (LPTP). These PT studies are provided by NELAP approved PT providers. Routine participation in these PT 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), Department of Defense (DOD), permit monitoring analyses, Resource Conservation and Recovery Act (RCRA) analyses, as well as for 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 based on multi-laboratory study results. The provider sends results to the appropriate certifying agencies as requested by the laboratory. PT study results are posted on the ELI website at www.energylab.com.

A copy of the laboratory's primary certifications issued by the USEPA and NELAP are maintained on the ELI website at www.energylab.com. The EPA certification includes a list of parameters/methods for which drinking water certification has been granted. In addition to drinking water parameters the NELAP certificate also includes RCRA methods used for hazardous waste characterizations and CWA parameters/methods which are used for NPDES monitoring permits. Reciprocal accreditation in other states is based on either of these, or both, depending on specific state certification requirements/parameters. ELI also participates in the Federal/State DMRQA programs for clients which require/request this with their NPDES permits. A list of current certifications is maintained on the ELI website at www.energylab.com.

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 routine environmental sample. The analysts do not know the analyte concentrations in 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 or unknown concentrations of analytes that are split and analyzed by more than one laboratory.



www.energylab.com

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 Officer of the laboratory. Refer to ELI SOP, *Internal 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 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 current NELAP/ISO 17025 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:

- Changes in internal and external issues that are relevant to the laboratory
- Fulfillment of objectives
- The suitability of policies and procedures
- Status of Actions from previous management reviews
- Reports from managerial and supervisory personnel
- The outcome of recent internal audits
- Corrective and preventative actions
- Assessments by external bodies
- The results of inter-laboratory comparisons or proficiency tests
- Changes in the volume and type of work
- Client and personnel feedback
- Complaints
- Recommendations for improvement and effectiveness of any implemented improvements

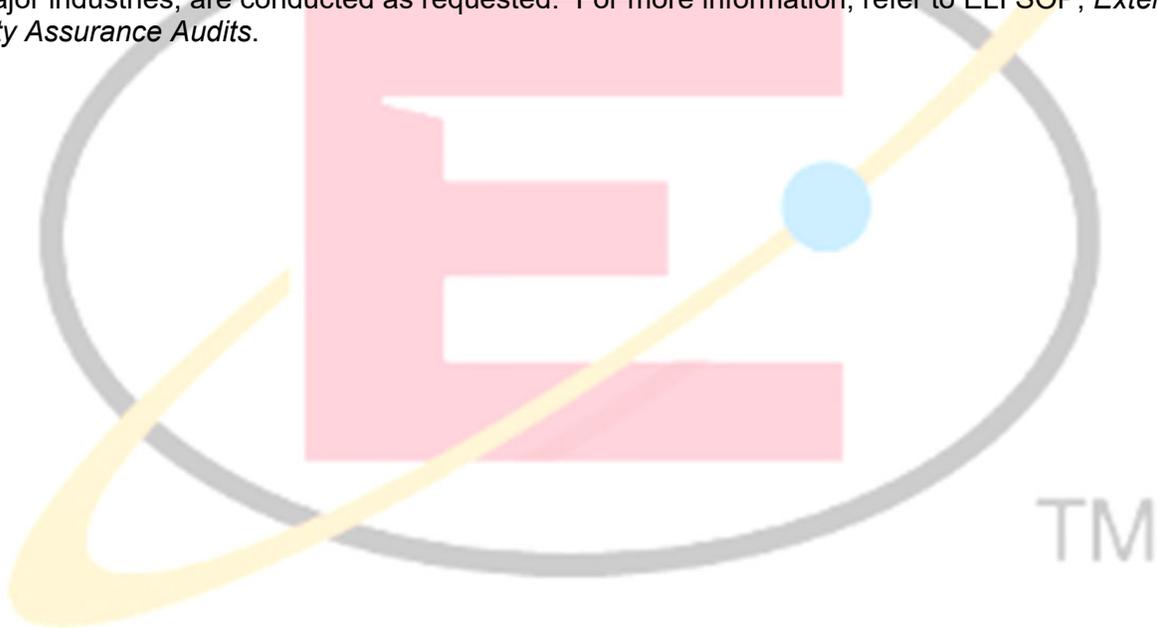


www.energylab.com

- Results of risk identification
- Other relevant factors, such as quality control monitoring activities, data integrity, data accuracy and precision, risks to impartiality, 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 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 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, refer to ELI SOP, *External Quality Assurance Audits*.



CHAPTER 3 – LABORATORY FACILITIES

The facility for Energy Laboratories, Inc. – Casper, WY consists of three buildings located at 2393 Salt Creek Highway, Casper, WY 82601.

The phone number for the Casper laboratory is (307) 235-0515, the fax number is (307) 234-1639, the email address is casper@energylab.com, and the website is www.energylab.com.

The facility for Energy Laboratories, Inc. – Gillette, WY consists of one building located at 400 West Boxelder, Gillette, WY, 82718.

The phone number for Gillette laboratory is (307) 686-7175, the fax number is (307) 682-4625, the email address is gillette@energylab.com, and the website is www.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, refer to 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, undergo safety awareness training, and are escorted when appropriate.

The laboratory has provisions for the disposal of chemical, radiochemical 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, refer to ELI SOPs, *General Laboratory Sample and Waste Disposal*.



www.energylab.com

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 four ELI laboratories located in Montana (2) and Wyoming (2), is provided in Appendix B. The Billings laboratory is the center for all corporate functions. Each laboratory is managed and operated individually under the supervision of a Laboratory Director. All ELI laboratories have fiscal and QA/QC responsibilities to the corporate office, as well as general operating policies and goals. Quality Assurance Manuals are prepared individually for the Billings and Helena laboratories and jointly for the Wyoming regional laboratories. All Quality Assurance Manuals follow the QA/QC program outlined in the ELI-Billings QA manual.

The Wyoming regional laboratory's organizational structure may be made available upon request. The Casper laboratory organizational structure is documented in [\\Cafle\qa\22 Org Charts](#). The Gillette laboratory organizational structure is documented in [\\ELIGL\Admin\QA\Gillette Admin\Org Charts](#). The corporate organizational chart can be found in Appendix B. Curricula vitae of key laboratory personnel maintained in Appendix C of this manual. Job descriptions are maintained by the Human Resources Department.

Quality Assurance receives direct support from senior management. Laboratory Quality Assurance Officers report directly to the Corporate Quality Assurance Officer as well as the appropriate Laboratory Director. Quality Assurance Officers provide independent oversight of Quality Systems within the overall Energy Laboratories structure. When Quality Assurance Officers fill more than one role within the organization, they operate independently of direct environmental data generation while fulfilling quality assurance responsibilities. Quality Assurance Officers facilitate development of and maintain the 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.

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 (refer to 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, Root Cause Analysis and Corrective Action Procedures*, 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



www.energylab.com

- 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 Director, Quality Assurance Officer or designee, shall assign specific persons to address management review findings and establish deadlines for their completion. The Technical Director, Laboratory Director, Quality Assurance Officer or designee, reviews and approves all QA 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. Any procedural deviations to the SOPs that are client or project-specific must receive approval either from the Technical Director, Laboratory Director, or the Quality Assurance Officer. 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 Director, Quality Assurance Officer, 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 are maintained by the Human Resources Department. Specific titles of employees are at the discretion of the Laboratory Director.

Laboratory Director

The Laboratory Director is required to have education and/or experience equivalent to a Bachelor of Science degree in Chemistry or a related science. Five years of relevant laboratory experience is required.

The Laboratory Director 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 Laboratory Director may delegate daily activities of these work aspects to appropriate personnel. The Laboratory Director reports directly to the Corporate Director of Operations. All Laboratory Directors have both technical and management responsibilities.



www.energylab.com

Quality Assurance Officer

The Quality Assurance Officer is required to have an education and/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 Assurance Officer is responsible for quality systems development, implementation, and management. The 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 Officer or his/her designee with the help of the Laboratory Director and Marketing Department manages the laboratory's certification programs to meet government regulatory and specific client requirements. The QA program is implemented in cooperation with all levels of management and staff. Quality Assurance Officers report directly to the Corporate Quality Assurance Officer. The Laboratory Director will direct daily laboratory-specific QA/QC requirements.

Technical Director

The Technical Director for any NELAP accredited Laboratory is required to meet the applicable educational requirements list in the current NELAP standard. Five years of relevant laboratory experience is preferred.

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 required standards and regulations. The Technical Director reports directly to the Laboratory Director.

The Technical Director may serve multiple roles. The Laboratory Director can also serve as one of the laboratory technical directors.

Laboratory Supervisor

A Laboratory Supervisor is required to have an education and/or experience 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 and client or project specific requirements. Laboratory Supervisors report directly to the Laboratory Director.

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 on-the-job training under direct supervision of a qualified analyst until authorized by management to perform assigned tasks. The training shall be relevant to the present and anticipated tasks required and the effectiveness of the training must be evaluated (for



www.energylab.com

more information, refer to ELI SOP, *Personnel Training and Training Records*). After the initial training period, and on a continuing basis thereafter, the analyst must 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 tasks assigned by the supervisor. 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 tasks assigned by the supervisor.

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

Approved Signatories

Signatures for policies are based on individual 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.

- Laboratory Director
- Technical Director
- Quality Assurance Officer
- Radiation Safety Officer (RSO)
- Corporate Officer – ELI Board of Directors

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



www.energylab.com

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, *Shipping, Sample Receiving and Login*.

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*.

The 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, 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. Container traceability is available upon pre-arranged request. Sample container type, sample volume, preservation requirements, and maximum holding times are detailed for each analyte/method in the ELI Professional Services Guide.

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

- Samples are out of temperature compliance
- 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
- 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.

Sample preservation should be performed immediately upon sample collection. For composite samples, each aliquot should be preserved at collection. Refer to ELI Professional Services Guide for detailed information on sample preservation requirements per applicable method and regulatory requirements.

The Laboratory will attempt to preserve any sample that has been determined to be improperly preserved during the sample receiving process. Samples for microbiological analysis are collected in pre-sterilized 120 mL plastic bottles containing sodium thiosulfate.



www.energylab.com

*NOTE: Samples that have not been properly preserved are noted on the Sample Work Order Receipt Checklist or in the Report Narrative.

Notification of sample receipt condition is available through the final report, Energy Source, Email, telephone and/or voice message.

The laboratory initiates a sample condition report, titled *Lab Receipt Chain of Custody*, 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, general comments concerning sample condition, and μR readings when screened for radioactivity. The sample condition report is provided with the analytical data report package. For more information, refer to ELI SOP, *Shipping, Sample Receiving and Login*.

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 Professional Services Guide, the Office of Hazardous Materials, Material Transportation Bureau, and Department of Transportation have 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_3) in water solutions of 0.15 % by weight or less (pH of 1.62 or greater).
- C) Sulfuric Acid - (H_2SO_4) 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 requirements for radiochemistry are met, the requirements for sample handling, preservation, and instrumentation for radiochemical analysis are included in ELI SOP, *Shipping, Sample Receiving and Login*. (For additional information, refer to "Manual for the Certification of Laboratories Analyzing Drinking Water", Table VI-2: Sample Handling, Preservation, and Instrumentation, EPA 5th Edition, January 2005).



www.energylab.com

CHAPTER 6 – SAMPLE HANDLING

All ELI laboratories utilize 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. Refer to 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, sample 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 during the sample receiving process to determine if the client correctly performed the preservation. If requested by the client, 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 encouraged.

Samples are stored per method specifications, or as method/parameter storage requirements are updated per later EPA guidance in Federal Regulations posted in 40CFR Part 136 and 40CFR Part 140.

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, when appropriate, 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. Refer to ELI SOP, *Shipping, Sample Receiving and Login*.



Energy Laboratories-Gillette does not accept evidentiary level chain of custody samples.

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, refer to ELI SOP, *Laboratory Records, Notebooks, and Document 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. Record is kept regarding all sample disposal including date and disposal method.

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. Refer to ELI SOPs, *General Laboratory Sample and Waste Disposal* for more information.

Subcontracting Policy

The Wyoming Regional ELI laboratories utilize the expanded ELI 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; or when the laboratory is not accredited for the particular analysis). Upon completion of the analyses, the subcontracted laboratories report the sample results, and their quality control package, to the primary laboratory. The results are reviewed before being reported.

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

To support Wyoming Regional ELI laboratory's analytical services, corporate ELI laboratories (which maintain specific instrumentation for specialized analysis) are utilized to provide complete analytical services. All ELI laboratory certifications are available on the Energy Laboratories website at www.energylab.com.

In the event that ELI is dependent on the service of an outside laboratory for analyses not available through our facility or ELI branch laboratories, the client is notified on the laboratory analytical report that their samples were 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



www.energylab.com

accredited for those parameters as required in the State from which the sample originated and/or to meet client specified required accreditation programs. All final reports indicate where the analyses were performed. Certification files of pre-approved subcontract laboratories are maintained by the ELI QA departments.



www.energylab.com

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 at the required frequency or at least annually. 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 Professional Services Guide. 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 considered acceptable. 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.

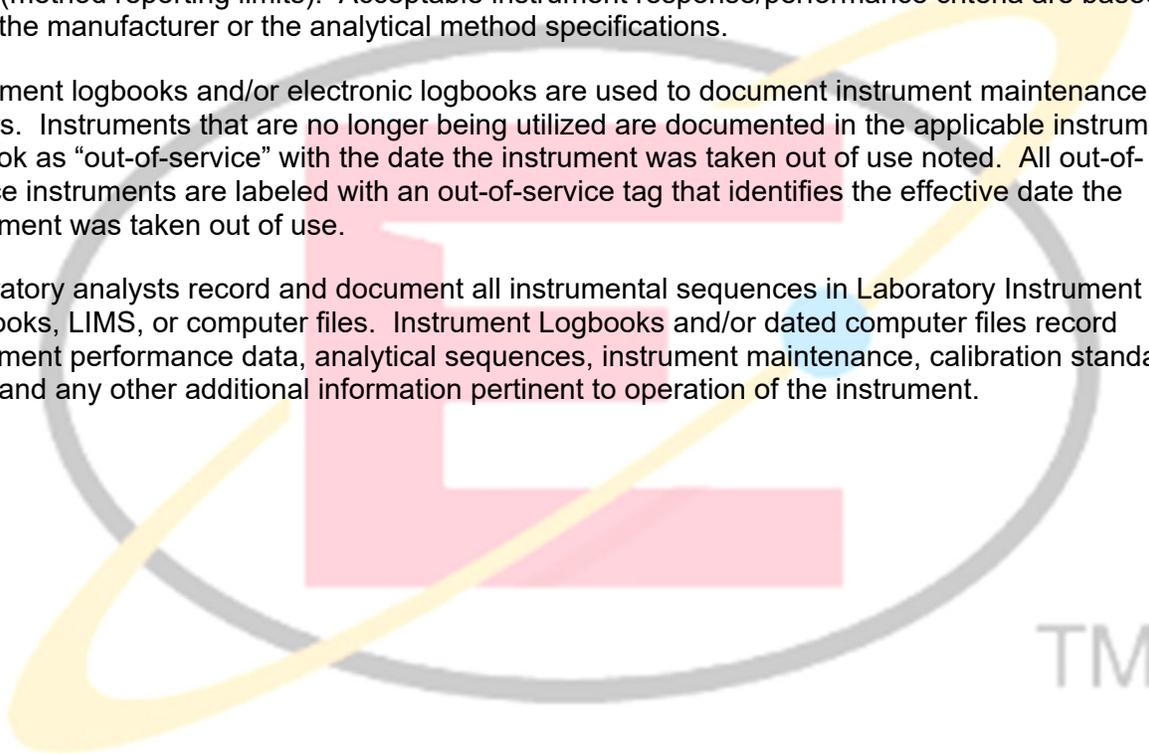
Use of measuring equipment and reagents (glassware, water, chemical reagents, and industrial gases) conform to Good Laboratory Practice guidelines. Good Laboratory Practices (GLPs) are laboratory guidelines which were established by the Food and Drug Administration and published in the Federal Register (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 and calibrated by certified technicians annually. Calibration checks of balances are performed each day of use, using ASTM Class 1 or 2 weights where appropriate. Laboratory thermometers are calibrated annually against a reference thermometer traceable to the International System of Units (SI) through a national metrological institute, such as NIST. 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, ISO/IEC 17034 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 calibration standards are documented in the analytical records 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 for general chemistry and 40 CFR 141.25 (c) for radiochemistry (except for the few methods that are not amenable to MDLs). Refer to ELI's Professional Services Guide for routine practical quantitation limits (method reporting limits). Acceptable instrument response/performance criteria are based upon the manufacturer or the analytical method specifications.

Instrument logbooks and/or electronic 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 sequences in Laboratory Instrument Logbooks, LIMS, 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. 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 or Management Systems. Controlled documents may be internal documents or external documents. Controlled documents are considered to be all documents issued to personnel in the laboratory as part of the management system such as regulations, standards, other normative documents, test and/or calibration methods, as well as drawings, software, specifications, instructions and manuals. All internal ELI controlled documents are written and reviewed by personnel technically competent to perform the procedure and approved for use by the Laboratory Director, Quality Assurance Officer or their designee(s).

An APPROVED document is one that has been reviewed and approved for use by authorized personnel prior to issue. Approval of these documents is indicated by the inclusion in the controlled document list.

An OBSOLETE document is one that has 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 Revision page, which details revisions. The Quality Assurance 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, *Laboratory Records, Notebooks, and Document 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



www.energylab.com

measurements, instrument operating parameters, preparation of calibration curves, analytical 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. Most 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. All physical laboratory notebooks are assigned a unique logbook control number and are assigned to an analyst and/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 from the date of last use. 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 an ELI 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, *Laboratory Records, Notebooks, and Document 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 Professional Services Guide.

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.



www.energylab.com

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. Data validation also includes review that client specific DQO's are met.

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.

The Laboratory Director, project managers, supervisors, Quality Assurance Officer 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 monitored on an on-going basis.

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, re-analyzing 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.



www.energylab.com

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 at <https://energysource.energylab.com>. For more information, refer to ELI SOP, *Laboratory Records, Notebooks, and Document 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 instruction on how to view/validate ELI's electronic signatures is available.



www.energylab.com

CHAPTER 9 – GENERAL LABORATORY PRACTICES

Chemicals and Reagents

When available and appropriate, chemicals used in the laboratory are analytical reagent grade 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 twenty years to be a reasonable expiration date for stable salts where the manufacturer does not supply such information. Reagents which are reactive or may be unstable should have an initial expiration date appropriate to the shelf life of the compound, with a suggested maximum of 1 year. 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.



www.energylab.com

Glassware Preparation

Glassware washing procedures for various analyses are described in specific ELI SOPs. 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.

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 are described in ELI SOP, *Use Maintenance and Calibration of Volumetric Glassware*.

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 method specific SOPs.

Disposable, glassware/plastic ware is preferred for many procedures in the laboratory. The cleanliness and suitability of disposable glassware/plastic ware 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 Purified 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 Laboratory Purified Water*.

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*.



www.energylab.com

All new and existing employees must demonstrate capability prior to performing an analytical procedure independently (refer to 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, for all applicable Manuals and SOPs, a Record of Acknowledgement Form that states they have read, understood, and agree to comply with the Manual/SOP.

Employees also receive training on general laboratory policies including ethics and conflict of interest. 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 an *Assessment of Data Integrity SOP*, which supplements the corporate manual and provides specific training on data integrity. All employees are required to read, understand and comply with the *Corporate Compliance & Ethics Manual* and the *Assessment of Data Integrity SOP*. 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 members 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 refer to ELI SOP, *Personnel Training and Training Records*.

Data Integrity

TM

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. For more information refer to ELI SOP, *Information Technology Operations*.

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.



www.energylab.com

Standard Operating Procedures

Laboratory operations and procedures are documented in Standard Operating Procedures (SOPs). SOPs provide information regarding the consistent and safe operation of the laboratory. SOPs provide details that may not be specified in the published analytical method(s). 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. All method SOPs follow NELAP and EPA requirements including the 12 QC elements listed in 40 CFR Part 136.7. Additionally, SOPs for DOD accredited methods follow additional DOD requirements. For more information on generation and distribution of SOPs, refer to 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 informed 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.

When the laboratory is required by law or authorized by contractual arrangements to release confidential information, the customer or individual concerns shall, unless prohibited by law, be notified of the information provided. As example, samples provided for Safe Drinking Water Act compliance monitoring, as per individual state regulatory requirements, may also need to be reported to the applicable state agency.

Individuals acting on the laboratory's behalf shall keep confidential all information. Information about the customer obtained from sources other than the customer (e.g. complainant, regulators) shall be confidential between the customer and the laboratory. The provider (source) of this information shall be confidential to the laboratory and shall not be shared with the customer unless agreed by the source.



www.energylab.com

CHAPTER 10 – QUALITY CONTROL MONITORING

Routine Monitoring

Temperatures of appropriate incubators, water baths, refrigerators, and ovens are checked and recorded according to a prescribed schedule using an automated monitoring system. In the event that the automated monitoring system is inoperable for more than twelve hours the appropriate temperatures will be recorded manually on instrument specific forms.

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

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.

Analytical balances are checked daily, when in use, against primary ASTM Class 1 or 2 reference weights traceable to the International System of Units (SI) through a national metrological institute, such as NIST or secondary weights with documented direct comparison to primary weights and are calibrated and serviced by certified technicians annually. For more information refer to ELI SOP, *Use and Maintenance of Analytical Balances*.

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 (Refer to Chapter 2 of this QA Manual).

Quality Control Check Samples are analyzed with each analytical batch.

Internal and external audits are performed as specified or requested (Refer to Chapter 2 of this QA Manual).

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 7 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 considered acceptable.



In most cases, the calibration stability is checked by analyzing 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 analyzed quarterly and calculated annually, or more frequently if changes in instrument performance are noted or per method requirements. Procedures for the determination of all applicable detection limits are described in ELI SOP, *Determination of Method Detection Limit (MDL) and Limit of Quantitation (LOQ)*. For all applicable procedures, ELI follows DOD QSM 5.4 guidance/requirements and definitions for performing MDL, LOQ, and LOD analysis. The detection limits for radiochemical analysis are calculated based on the requirements in 40 CFR 141.25(c).

Precision and accuracy requirements for each method applicable 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. (Refer to Chapter 1 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 or by client specific project requirements.
- 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 Quality Assurance 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 properly qualified.

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. Proper control must be reestablished before the instrument can continue analysis. Analysis of all samples that were analyzed while the procedure was considered to be out of control must be repeated. 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 and/or Technical Director 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.

A general summary of Quality Assurance/Quality Control specifications is outlined in Appendix A. Exact details of method QC requirements can be found in the applicable method SOPs.

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. Records are maintained regarding the complaint and of the investigation and corrective action(s) being taken.

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 corrective action report. This report should be completed with the intention of informing the affected staff about the problem so that all relevant staff can use it as a learning opportunity, change our procedures, and improve our service. A procedure to document corrective action reports is documented in ELI SOP, *Nonconformance, Root Cause Analysis and Corrective Action Reports*.

If an 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



www.energylab.com

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 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 these types of issues. Access to the program is available on the ELI internal website as well as through a 24-hour telephone hotline number (877-874-8416). Complaints, suggestions or comments from clients, vendors, auditors and other interested parties can be submitted directly to project management who will initiate resolution.

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.

TM



www.energylab.com

CHAPTER 12 – MANAGEMENT OF CHANGE

Management of change is the process used to review and manage proposed changes to materials, technology, equipment, procedures, personnel and facility operations. These changes may be permanent or temporary depending on circumstances. Change is managed, communicated, and documented as appropriate to the level of change, by the Laboratory Director and the Supervisors of each department. Significant revisions to controlled documents may require employees to sign a record of acknowledgement.

- New Equipment Validation – Documented in the Instrument Maintenance Module. Supporting studies are documented in the LIMS.
- Implementation of new test methods and method updates – Documented in the method SOP and the Instrument Maintenance Module. Supporting studies are documented in the LIMS.
- Manuals and SOPs – Documented in the Record of Revision and stored in the Document Control Software.
- Work order changes – Documented in the work order report and stored in the LIMS or Document Control Software.
- LIMS changes – Documented in a version control repository.
- Personnel changes – Documented in employee training records or personnel records.

TM

www.energylab.com

CHAPTER 13 – MAJOR EQUIPMENT AND METHODS

A summarized listing of major instrumentation and the corresponding certified methodology is included in Appendix D. Refer to the ELI Professional Services Guide, located on the ELI website at www.energylab.com, for a list of all methods and analyte parameters that Energy Laboratories, Inc. performs corporately.



www.energylab.com

CHAPTER 14 – PREVENTIVE MAINTENANCE

Preventive maintenance is performed on laboratory equipment according to the manufacturer's guidelines and laboratory 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.) Below is an example of maintenance performed.

| <u>Instrument</u> | <u>Maintenance</u> | <u>Frequency</u> -Daily is based on day of use. |
|--|---|--|
| Balances | Check with appropriate class or validated secondary weights | Daily |
| | Perform internal calibration | As needed – when daily check does not meet acceptance criteria |
| | Independent Service | Annually |
| Pipettes | Check volume | Quarterly |
| Thermometers | Calibrate | Annually |
| Gas Chromatograph | Change gas cylinders | At 200 psi |
| | Perform column bake-out procedure | As needed – indicated by poor chromatography |
| | Change column | As needed – indicated by poor chromatography |
| | Calibrate | As needed – indicated by poor QCS performance |
| | Change Inline Filter | Semi-annually |
| | Change Heated Sample-in Connector and O-ring | Annually |
| | Clean Detector | As needed – indicated by poor QCS performance |
| Ion Chromatograph | Replace guard column | As needed – indicated by poor QCS performance |
| | Replace analytical column | As needed – indicated by poor QCS performance |
| | Assign peak retention times | Monthly |
| | Edit anions program & run time | Monthly |
| | Change support beds in guard column | Monthly |
| | Calibrate | Semi-annually |
| | Clean/Change Stator Plate | As needed – indicated by poor performance |
| Change tubing | As needed – indicated by poor QCS performance or staining | |
| Man-tech auto-titrator | Change O-rings | As needed – indicated by poor performance |
| | Check pH probe fill level | Daily |
| | Clean pH probe | Monthly |
| | Change or clean tubing | Monthly |
| | Calibrate sample dosing pump | Quarterly |
| | Clean titration buret | Quarterly |
| | Clean dosing pump | Quarterly |
| | Change stirrer tubing | Semi-annually |
| | Change belt on dosing pump | Annually |
| | Change lip seals and gland washers on dosing pump | Annually |
| Replace tubing in peristaltic rinse pump | Annually | |



www.energylab.com

| | | |
|---|---|---|
| Metrohm | Check pH probe fill level | Daily |
| | Clean/flush probe | As needed – indicated by poor performance |
| | Replace tubing | As needed – indicated by poor performance |
| | Compare probe temperatures to reference thermometer | Annually |
| ICP-Atomic Emission | Check Pump Tubing | Daily |
| | Check Coolant Levels | Monthly |
| | Lubricate Autosampler | As needed indicated by continual faults |
| | Air Filter | Quarterly |
| | Optics Servicing | As needed – indicated by poor performance |
| ICP-Mass Spectrometry | Check Pump Tubing | Daily |
| | Check Coolant Levels | Monthly |
| | Lubricate Autosampler | As needed |
| | Air Filter | Quarterly |
| | Check Electron Multiplier | Daily |
| Radiochemistry Detection Equipment | Check Background | Daily |
| | Check Efficiency | Daily |
| | Clean Window | As needed – indicated by poor performance |
| | Change Gas Cylinders | At 200 psi |
| Liquid Chromatograph | Flush System | Daily |
| | Change Filters | As needed – indicated by poor performance |
| | Replace Seals | As needed – indicated by poor performance |
| TOXBOX | Replace sample chamber septa | As needed – indicated by poor performance |
| | Inspect/replace pyrolysis tube | Semi-annually |
| Solid-Phase extractors | Maintenance per manufacturer specification | As needed |
| Reagent Water Systems | System maintenance | Semi-annually |
| | Water quality monitoring | Daily – ongoing evaluation on appropriate method blanks for parameters done in-house Monthly – sub water to alternate branch laboratory for parameters not done in-house |
| Compressed Gases | Change gas cylinders | At 100 psi, monitor daily |
| YSI BOD probe/meter | Change oxygen membrane | As needed |
| | Check barometer pressure | Monthly |
| Microbiology | Quality Control and monitoring per EPA guidelines | EPA required frequency |
| Autoclaves | Check performance with spore ampoules | Monthly |
| | Check timing device w/stopwatch | Quarterly |
| | Outside service & calibration | Annually |
| Incubators / Water Bath / Refrigerators | Clean | Monthly |
| | Monitor temperature | Daily |
| Ovens | Clean | Monthly |
| | Monitor temperature | Daily |
| DAC System | Adjust DAC computer time | Every 2 weeks |
| | Calibrate | Annually |



www.energylab.com

CHAPTER 15 - REFERENCES

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

ANSI N13.30-2011, American National Standard Measurement and Associated Instrument, Performance Criteria for Radiobioassay

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 Professional Services Guide, 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 5th 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, 2016 or most current version approved by Florida NELAC Accreditation program.

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

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



www.energylab.com

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

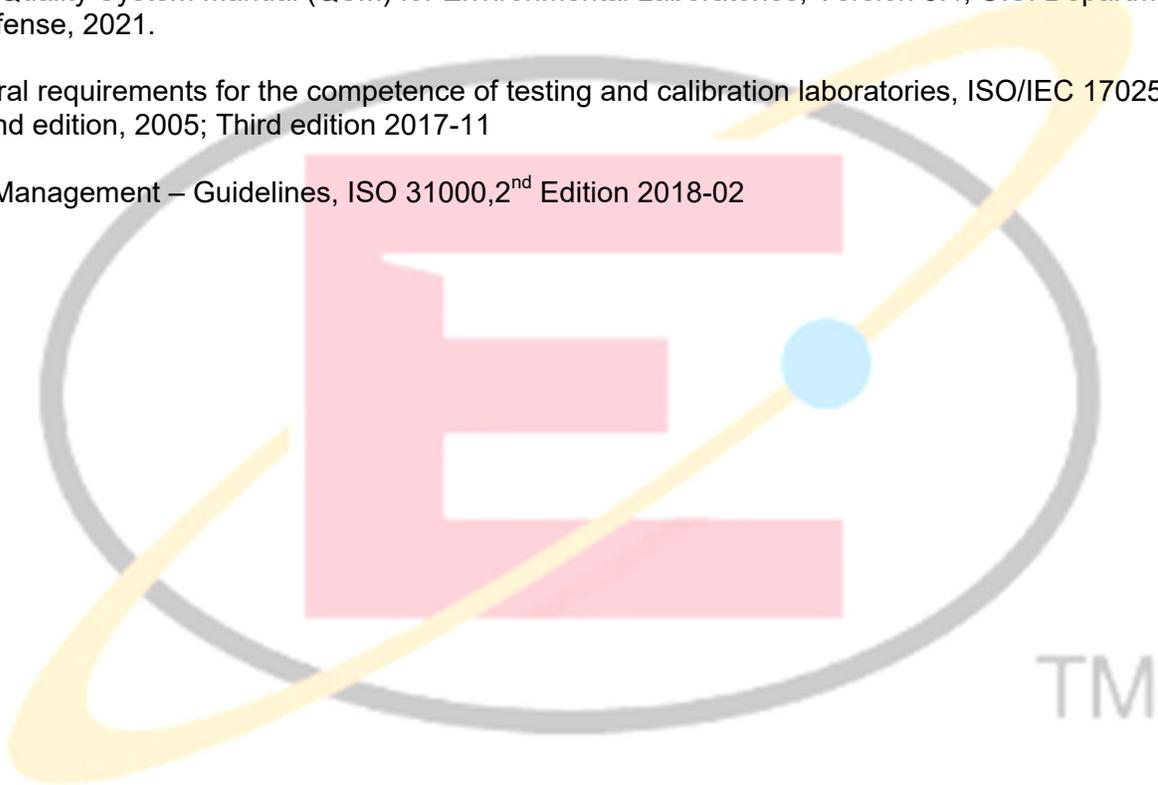
Test Methods for Evaluating Solid Waste, Physical/Chemical Methods (SW846), Environmental Protection Agency. <http://www.epa.gov/epawaste/hazard/testmethods/sw846/online/index.htm>

TNI Standard, Volume 1 (EL-V1-2016), The NELAP Institute.

DOD Quality System Manual (QSM) for Environmental Laboratories, Version 5.4, U.S. Department of Defense, 2021.

General requirements for the competence of testing and calibration laboratories, ISO/IEC 17025, Second edition, 2005; Third edition 2017-11

Risk Management – Guidelines, ISO 31000, 2nd Edition 2018-02



www.energylab.com

CHAPTER 16 – GLOSSARY OF TERMS

Acceptance Criteria - Specified limits placed on characteristics of an item, process, or service defined in requirement documents.

Accreditation - The process by which an agency or organization evaluates and recognizes a laboratory as meeting certain predetermined qualifications or standards, thereby accrediting the laboratory.

Accuracy - The degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components that are due to sampling and analytical operations; a data quality indicator.

Alpha Particle – A high-energy particle emitted from an atom's nucleus during radioactive decay that consists of two protons and two neutrons.

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.

Analyte - A substance, organism, physical parameter, property, or chemical constituent(s) for which an environmental sample is being analyzed.

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.

Assessment - The evaluation process used to measure or establish the performance, effectiveness, and conformance of an organization and/or its systems to defined criteria (to the standards and requirements of laboratory accreditation).

Audit - A systematic and independent examination of facilities, equipment, personnel, training, procedures, record keeping, data validation, data management, and reporting aspects of a system to determine whether QA/QC and technical activities are being conducted as planned and whether these activities will effectively achieve quality objectives.

Batch – A group of 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.

Beta Particle - A high-energy particle emitted from an atom's nucleus during radioactive decay that consists of either an electron or a positron, depending on the mechanics of the radioactive decay.

Blank (BLK) - A sample of clean matrix 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.



www.energylab.com

Blank Spike - Refer to 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 - A set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards.

- 1) In calibration of support equipment, the values realized by standards are established through the use of reference standards that are traceable to the International System of Units (SI).
- 2) In calibration according to methods, the values realized by standards are typically established through the use of Reference Materials that are either purchased by the laboratory with a certificate of analysis or purity, or prepared by the laboratory using support equipment that has been calibrated or verified to meet specifications

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 - Refer to Check Standard.

Calibration Curve – The mathematical 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 (Gillette Laboratory); 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.

Confirmation - Verification of the identity of a component through the use of an approach with a different scientific principle from the original method. These may include, but are not limited to:



www.energylab.com

Second column confirmation, Alternate wavelength, Derivatization, Mass spectral interpretation, Alternative detectors, or Additional cleanup procedures.

Constant Weight - The repeated process of drying, cooling, desiccating, and weighing a sample until readings are $\leq 4\%$ of the previous weight or does not vary more than $\leq 0.5\text{mg}$.

Continuing Calibration Blank (CCB) – A sample of laboratory purified water or matrix similar to calibration standards, in which no analytes of interest are present at concentrations that impact results, measured periodically throughout an analytical run. Evaluates baseline drift, contamination in the analytical system, and analyte carryover.

Continuing Calibration Verification (CCV) - A mid-range calibration standard measured periodically throughout an analytical run that evaluates instrument drift throughout analytical run.

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

Control Standard - Refer to 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.

CPM - Counts per minute; a unit of radioactivity.

Crosstalk – The re-classified identification of a count measured by a gas proportional counter. The degree and type of crosstalk (bleed-over) depends on which type of radiation whether alpha or beta, and how the discriminator is set after a plateau is run. This normally occurs at a proportional rate between 20 to 25 percent for alpha counts in the beta channel, while on the other hand beta into alpha crosstalk (bleed-over) occurs at a proportional rate of less than 1% in typical windowed gas proportional counters. Gas proportional counters must be set so crosstalk is either automatically corrected prior to the displaying of alpha and beta counts for a final result, or through the software corrections in ELI's Radiochem Database.

DAC System - Data Acquisition and Control System

Data Integrity - The condition that exists when data are sound, correct, and complete, and accurately reflect activities and requirements.

Data Reduction - The process of transforming the number of data items by arithmetic or statistical calculation, standard curves, and concentration factors, and collating them into a more useful form.

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

Decision Rule – Rule that describes how measurement uncertainty is accounted for when stating conformity with a specific requirement.

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 - Refer to 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.

DPM - Disintegrations per minute; a measure of radioactivity.

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 - Refer to Duplicate.

Efficiency – The ability of a detector to measure the radioactivity of interest using the following relationship:

$$\text{cpm/dpm} = \text{Efficiency}$$

Where:

cpm = Counts Per Minute Observed in the detection system

dpm = Disintegrations Per Minute determined for the calibrated source being measured

Field of Accreditation - Those matrix, technology/method, and analyte combinations for which the accreditation body offers accreditation.

Finding - An assessment conclusion referenced to a laboratory accreditation standard and supported by objective evidence that identifies a deviation from a laboratory accreditation standard requirement.

Fortified Sample - Refer to Matrix Spike.

Holding Times (Maximum Allowable Holding Times) - The maximum time that can elapse between two (2) specified activities. Sample holding time is based on Date/Time of Collection and Date/Time of the beginning of sample analysis. Time is based on hour/minute by default or by the accreditation requirements for a project. The maximum time is the longest time period that samples may be held prior to analysis and still be considered valid or not compromised.

Impartiality - The presence of objectivity which is managed by procedures and processes to avoid conflict of interest, freedom from bias, lack of prejudice, neutrality, fairness, open-mindedness, even handedness, detachment and balance so as not to adversely influence subsequent activities of the laboratory.

In-depth Data Monitoring - When used in the context of data integrity activities, a review and evaluation of documentation related to all aspects of the data generation process that includes



www.energylab.com

items such as preparation, equipment, software, calculations, and quality controls. Such monitoring shall determine if the laboratory uses appropriate data handling, data use and data reduction activities to support the laboratory's data integrity policies and procedures.

Initial Calibration Blank (ICB) - A sample of laboratory purified water, solvent or matrix similar to the calibration standards that has been treated exactly as a sample in which no analytes of interest are present at concentrations that impact results. Evaluates overall method including possible contamination in reagents and glassware.

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 - Refer to 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) – (however named, such as laboratory fortified blank, spiked blank, Initial calibration verification (ICV) or QC check sample) - A sample matrix, free from the analytes of interest, spiked with verified known amounts of analytes or a material containing known and verified amounts of analytes and taken through all sample preparation and analytical steps of the procedure unless otherwise noted in a reference method. It is generally used to establish intra-laboratory or analyst specific precision and bias or to assess the performance of all or a portion of the measurement system.

Laboratory Control Sample Duplicate (LCSD) - A second laboratory control sample of known concentration and similar matrix as samples. Evaluates overall method accuracy/bias and precision for the batch.

Laboratory Fortified Blank (LFB) – A sample of laboratory purified water or matrix similar to the calibration standards to which a known amount of target analyte(s) is added. Evaluates spiking technique and when prepared from a source independent of the calibration standards can also be used to measure method performance.

Laboratory Inter-comparison Sample - A sample, typically a performance evaluation sample of same or similar composition, analyzed by two or more laboratories in accordance with predetermined conditions. Acceptance criteria are often based statistically on the analysis results.

Laboratory Intra-comparison Sample - A sample, of same or similar composition, analyzed within the same laboratory with predetermined conditions. Sample may be used for evaluation of new instruments or methodology.

Legal Chain of Custody Protocols - Procedures employed to record the possession of samples from the time of sampling through the retention time specified by the client or program. These procedures are performed at the special request of the client and include the use of a Chain of Custody Form that documents the collection, transport, and receipt of compliance samples by the laboratory. In addition, these protocols document all handling of the samples within the laboratory.



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 with 99% confidence. At the LOD the false negative rate (type II error) is 1%. An LOD is analyte and matrix specific and may be laboratory-dependent. Generally, the LOD is assigned as 1-3X of the MDL. Refer to LOD Verification for DOD certified methods.

Limit of Detection Verification - This is an analysis of a sample spiked with a concentration near the calculated MDL. The spike concentration should be at a level of 1-4 times the calculated MDL for multiple analyte tests and 2-3 times the calculated MDL for single analyte tests. Lower spike concentration may be used if LOD verification criteria are met.

Limit of Quantitation (LOQ) – For chemical analysis, the LOQ is the smallest concentration that produces a quantitative result with known and recorded precision and bias. The LOQ must be equal to or greater than the LOD, typically set at 2 to 10 times the calculated LOD, and the LOQ shall be set at or above the concentration of the lowest initial calibration standard and within the calibration range. The LOQ is comparable to the PQL or RL as defined by the laboratory. The lowest LOQ available is the lowest limit of quantitation (LLOQ).

LIMS - Laboratory Information Management System.

Mass Attenuation - Refer to Solids Self-Attenuation

Matrix – The substrate of a test sample.

Matrix Duplicate - A replicate matrix prepared in the laboratory and analyzed to obtain a measure of precision. (Also see MSD)

Matrix Spike - (MS, spiked sample or fortified sample) – A sample prepared, taken through all sample preparation and analytical steps of the procedure unless otherwise noted in a referenced method, by adding a known amount of target analyte to a specified amount of sample for which an independent test result of target analyte concentration is available. Matrix spikes are used, for example, to determine the effect of the matrix on a method's recovery efficiency. Generally, for valid recovery calculations the parameter spike level should be greater than 1-4X of the sample parameter level.

Matrix Spike Duplicate (MSD, spiked sample or fortified sample duplicate) – A replicate matrix spike prepared in the laboratory and analyzed to obtain a measure of the precision of the recovery for each analyte.

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

Method - A body of procedures and techniques for performing an activity (e.g., sampling, chemical analysis, quantification), systematically presented in the order in which they are to be executed.

Method Blank (MBLK) - A sample of laboratory purified water, solvent or matrix similar to samples that has been treated exactly as a sample in which no analytes of interest are present at concentrations that impact results. Evaluates overall method including possible contamination in reagents and glassware.



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. The MDL is the minimum concentration of a substance that can be reported with 99% confidence that the measured concentration is distinguishable from method blank results. At the MDL the false positive rate (Type I error) is 1%. This MDL is referred to as the DL (Detection limit) by DOD.

Method Reporting Limit (MRL) – Refer to Report Limit.

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).

Metrological Traceability – Property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty.

NELAC - National Environmental Laboratory Accreditation Conference.

NELAP - National Environmental Laboratory Accreditation Program.

National Institute of Standards and Technology (NIST) - A federal agency of the US Department of Commerce's Technology Administration that is designed as the United States national metrology institute (NMI). SI is the international metrological traceability term which NIST includes.

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 acceptance limits.

Physical Parameter - A measurement of a physical characteristic or property of a sample as distinguished from the concentrations of chemical or biological components.

Practical Quantitation Limit (PQL) – Refer to Limit of Quantitation.

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

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

Preventative Action – A proactive process to identify opportunities for improvement rather than a reaction to the identification of problems or complaints.

Proficiency Testing - A means of evaluating a laboratory's performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by an external source.



www.energylab.com

Proficiency Testing Program - The aggregate of providing rigorously controlled and standardized environmental samples to a laboratory for analysis, reporting of results, statistical evaluation of the results and the collective demographics and results summary of all participating laboratories.

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.

Protocol - A detailed, written procedure for field and/or laboratory operation (e.g., sampling, analysis) which must be strictly followed.

Quality Assurance (QA) – An integrated system of management activities involving planning, implementation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the client.

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 (QC) – The overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer; operational techniques and activities that are used to fulfill requirements for quality; also the system of activities and checks used to ensure that measurement systems are maintained within prescribed limits, providing protection against “out of control” conditions and ensuring that the results are of acceptable quality.

Quality Control Sample – A sample used to assess the performance of all or a portion of the measurement system. One of any number of samples, such as Certified Reference Materials, a quality system matrix fortified by spiking, or actual samples fortified by spiking, intended to demonstrate that a measurement system or activity is in control.

Quality Manual - A document stating the management policies, objectives, principles, organizational structure and authority, responsibilities, accountability, and implementation of an agency, organization, or laboratory, to ensure the quality of its product and the utility of its product to its users.

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

Quality System Matrix - These matrix definitions are to be used for purposes of batch and QC requirements:

Air and Emissions: Whole gas or vapor samples including those contained in flexible or rigid wall containers and the extracted concentrated analytes of interest from a gas or vapor that are collected with a sorbant tube, impinger solution, filter, or other device.



Aqueous: Any aqueous sample excluded from the definition of Drinking Water or Saline/Estuarine. Includes surface water, ground water effluents, and TCLP or other extracts.

Biological Tissue: Any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origin.

Chemical Waste: A product or by-product of an industrial process that results in a matrix not previously defined.

Drinking Water: Any aqueous sample that has been designated a potable or potential potable water source.

Non-Aqueous Liquid: Any organic liquid with <15% settleable solids.

Saline/Estuarine: Any aqueous sample from an ocean or estuary, or other salt water source such as the Great Salt Lake.

Solids: Includes soils, sediments, sludges, and other matrices with >15% settleable solids.

Raw Data - The documentation generated during sampling and analysis. This documentation includes, but is not limited to, field notes, electronic data, magnetic tapes, untabulated sample results, QC sample results, print outs of chromatograms, instrument outputs, and handwritten records.

Raw Method Reporting Limit (RMRL) – MRL usually in the default units of the analytical instrument before any preparation or dilution factors are applied.

Raw Practical Quantitation Limit (RPQL) – PQL usually in the default units of the analytical instrument before any preparation or dilution factors are applied.

Reference Material - Material or substance, one or more of whose property values are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials

Reference Method - A reference method is a published method issued by an organization generally recognized as competent to do so. (When the ISO language refers to a “standard method”, that term is equivalent to “reference method”). When a laboratory is required to analyze an analyte by a specified method due to a regulatory requirement, the analyte/method combination is recognized as a reference method. If there is not a regulatory requirement for the analyte/method combination, the analyte/method combination is recognized as a reference method if it can be analyzed by another reference method of the same matrix and technology.

Reference Standard - Standard used for the calibration of working measurement standards in a given organization or at a given location.

Replicate - Refer to 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.



www.energylab.com

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

Sampling - Activity related to obtaining a representative sample of the object of conformity assessment, according to a procedure.

Selectivity - The ability to analyze, distinguish, and determine a specific analyte from another component that may be a potential interferent or that may behave similarly to the target analyte within the measurement system.

Sensitivity - The capability of a method or instrument to discriminate between measurement responses representing different levels (e.g., concentrations) of a variable of interest.

Solids Self-Attenuation – The scattering or absorption of radioactive particles by solid material that contains the radioactive elements under measurement so that the particles cannot be correctly detected. Alpha particles are attenuated (also described as being absorbed) much more strongly than beta particles in typical solids. Also referred to as mass attenuation.

Spiked Sample – Refer to Matrix Spike.

Standardization - Refer to 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 ability to trace the history, application, or location of an entity by means of recorded identifications. In a calibration sense, traceability relates measuring equipment to national or international standards, primary standards, basic physical constants or properties, or reference materials. In a data collection sense, it relates calculations and data generated throughout the project back to the requirements for the quality of the project.

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.

Validation – The confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled.

Verification - Confirmation by examination and objective evidence that specified requirements have been met. In connection with the management of measuring equipment, verification provides a means for checking that the deviations between values indicated by a measuring instrument and corresponding known values of a measured quantity are consistently smaller than the maximum allowable error defined in a standard, regulation or specification peculiar to the management of the measuring equipment.

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 |
| DoD | - Department of Defense |
| 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 |
| PT | - Proficiency Testing |
| QA/QC | - Quality Assurance / Quality Control |
| QS | - Quality Systems |

TM



www.energylab.com

- QAM - Quality Assurance Manual
- QAPP - Quality Assurance Project Plan
- 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



www.energylab.com

APPENDIX A

QUALITY ASSURANCE / QUALITY CONTROL SPECIFICATIONS



www.energylab.com

INSTRUCTIONS: These are general QA/QC parameters. The table must be tailored for each specific method, as not all sample types, frequency, or acceptance criteria may apply. Sample types that are not applicable may be deleted. Insert method requirements in place of "X" or "Per method requirements" where needed for frequency and acceptance criteria. Use the verbiage and formatting of this table wherever possible.

| Method QA/QC Parameters | | | | |
|---|--|--|--|--|
| QA SAMPLE/ SAMP TYPE CODE | FREQUENCY | ACCEPTANCE CRITERIA | CORRECTIVE ACTION | COMMENTS |
| Instrument Calibration (ICAL) | At least X (Per method, annually at minimum) After maintenance or when needed due to peak shifts or QC failures. | R or $R^2 \geq X$ (As specified by method) RE = Generally same as CCV requirements. Lowest point may be set statistically. Number of Calibration points: Ave RF = 4 Linear = 5 Quadratic = 6 Cubic = 7 Polynomial = 3 + #equation factors (min 7) | 1) Re-pour standards and recalibrate 2) Prepare/purchase new standards 3) Perform instrument maintenance 4) Calibration points can be removed per specific guidance in the Calibration SOP. | Establishes calibration curve over a range of analyte concentrations to quantify analytes of interest. The zero concentration (blank) point in the curve is not included in the required number of calibration points. RE (Residual Error) = Calculated as % Recovery in Omega |
| Linear Calibration Range (LCR) | Initially, then every 6 months, as required by method. | RE = Generally same as CCV requirements. | 1) Evaluate alternate non-linear calibration models, especially for lowest and highest calibration points. | LCR is the linear portion of a calibration curve. Must use a minimum of a blank and 3 standards RE (Residual Error) = Calculated as % Recovery in Omega |
| Linear Dynamic Range (LDR) | Initially, then every 6 months. | RE = Generally same as CCV requirements. | 1) Re-establish/verify LDR 2) Dilute samples within the calibration range. | Sets the upper limits of the calibration range. Must include at least 3 points, with one outside the upper range of the curve. RE (Residual Error) = Calculated as % Recovery in Omega |
| Retention Time (RT) window position establishment | Initially with instrument set up. Recommend verifying annually. | Position shall be set using the midpoint standard of the ICAL curve when ICAL is performed. On days when ICAL is not performed, the initial CCV is used. | 1) For shifting retention times, adjust according to initial CCV (mid-range). 2) Follow method requirements. | Calculated for each analyte. |



Method QA/QC Parameters

| QA SAMPLE/ SAMP TYPE CODE | FREQUENCY | ACCEPTANCE CRITERIA | CORRECTIVE ACTION | COMMENTS |
|--|--|---|--|--|
| Retention Time (RT) window width | Initially with instrument set up. Recommend verifying annually. | IC: RT width is $\pm 3x$ standard deviation for each analyte RT from the 24-hour period. GC and HPLC: RT width is $\pm 3x$ standard deviation for each analyte RT from the 72- hour period. GC/MS: RT of each reported analyte within ± 0.06 RT units. | 1) For shifting retention times, adjust according to initial CCV (mid-range). 2) Follow method requirements. | Calculated for each analyte. |
| Initial Calibration Verification (ICV) | Immediately following calibration, daily when used as Analytical Sequence LCS for analyses without prep. | %Rec = X (Limits may be set statistically depending on method.) | 1) Re-pour or re-inject. 2) Re-digest/re-prepare all QC and samples. 3) Recalibrate. | Evaluates calibration accuracy and method performance. Must be prepared from second source standard. |
| Initial Calibration Blank (ICB/MBLK) | Immediately follows ICV | < Lowest reporting limit | 1) Re-pour or re-inject. 2) Re-digest/re-prepare all QC and samples. 3) Qualify sample data. | Evaluates calibration accuracy, reagent/ glassware contamination, and instrument carryover. |
| Continuing Calibration Verification (CCV) | Run every 10 samples and at end of run. (Methods with internal standards do not require and ending CCV.) | %Rec = X (Limits may be set statistically depending on method.) | 1) Re-pour or re-inject if CCV failure impacts only the CCV, the reason for the failure is known and documented and a second acceptable CCV is analyzed immediately. 2) Re-digest/re-prepare all QC and samples since last valid CCV 3) Recalibrate. | Evaluates instrument drift throughout analytical sequence. Concentration must be equal to or less than half the highest calibration concentration. |
| Continuing Calibration Blank (CCB) | Run after every CCV | < Lowest reporting limit | 1) Re-pour or re-inject. 2) Re-digest/re-prepare all QC and samples. 3) Qualify sample data. | Evaluates baseline drift, contamination in the analytical system, and analyte carryover. |

| Method QA/QC Parameters | | | | |
|---------------------------------------|---------------------------------|--|--|---|
| QA SAMPLE/ SAMP TYPE CODE | FREQUENCY | ACCEPTANCE CRITERIA | CORRECTIVE ACTION | COMMENTS |
| Instrument Blank | Daily prior to sample analysis. | < Lowest reporting limit | 1) Re-pour and rerun. 2) Perform instrument maintenance. | Evaluates baseline drift, contamination in the analytical system, and analyte carryover. The method blank may be substituted; not required for methods with CCB criteria. Generally necessary for organics methods. Not necessarily imported to Omega. |
| Method Blank (MBLK) | 1/batch | < Lowest reporting limit | 1) Re-pour or re-inject. 2) Re-digest/re-prepare all QC and samples. 3) Qualify sample data. | Evaluates overall method including possible contamination in reagents and glassware utilized in preparatory batch. |
| Laboratory Control Sample (LCS/LCSD) | 1/ batch | %Rec = X (Limits may be set statistically depending on method.) | 1) Re-pour or re-inject. 2) Re-digest/re-prepare all QC and samples since last valid CCV 3) Recalibrate. | Evaluates overall method accuracy/bias for the Preparatory Batch. Must be second source. If prepared the same as MS/MSD will evaluate the spiking technique. |
| Laboratory Fortified Blank (LFB/LFBD) | 1/daily sequence | %Rec = X (Limits may be set statistically depending on method.) | 1) Re-pour or re-inject. 2) Re-digest/re-prepare all QC and samples since last valid CCV 3) Recalibrate. | If prepared the same as MS/MSD will evaluate the spiking technique. Can be primary or secondary source depending on the method. LCS or ICV are preferred QC Types. |
| Duplicate Sample (DUP) | 1/X samples | % RPD ≤ X (Appropriate limits must be evaluated for each method.) | 1) Rerun sample pair, evaluate for sample homogeneity or 2) Report with qualifiers.*** | Evaluates method precision. MSD duplicate analyses preferred on some methods. |



Method QA/QC Parameters

| QA SAMPLE/ SAMP TYPE CODE | FREQUENCY | ACCEPTANCE CRITERIA | CORRECTIVE ACTION | COMMENTS |
|--|-------------------------|-------------------------------------|---|---|
| Matrix Spike (MS/MSD) | 1/X samples | %Rec = X %RPD \leq X | LCS/LFB/ICV must be passing. 1) If matrix interference suspected report as found, or 2) Re-analyze and re-spike if no matrix interference suspected, or 3) Use "A" qualifier for sample amount > 4X spike level. | Evaluates effect of matrix on method performance. MSD also evaluates method precision. |
| Post Digestion Spike (PDS/PDSD) | 1/X samples | %Rec = X %RPD \leq X | LCS/LFB/ICV must be passing. 1) If matrix interference suspected report as found, or 2) Re-analyze and re-spike if no matrix interference suspected, or 3) Use "A" qualifier for sample amount > 4X spike level. | Evaluates effect of matrix on method performance. PDSD also evaluates method precision. Use the same solution and concentration as LFB. |
| Internal Standards (IS) | All samples and QC | Per method and analyte requirements | Per method and analyte requirements. | Mimics the analyte of interest without interfering. Used for some GC, GC/MS, HPLC, ICP/MS analyses to help quantify analytes of interest. |
| Surrogates (organics) or Tracers (radiochemistry) | All samples and QC | Per method and analyte requirements | Per method and analyte requirements. | Evaluates method performance in each sample. |
| Laboratory Performance Check Sample (LPC) | Per method requirements | Per method requirements | Per method requirements. | Monitors instrument sensitivity, column performance, and chromatographic performance. |
| Tune | Per method requirements | Per method requirements | Per method requirements. | Evaluates mass sensitivity, mass resolution, isotope ratio, and baseline threshold. |
| Batch Definition | 20 samples | Must pass all method QC criteria | Re-analyze batch or qualify results. | A group of samples and associated QC |



www.energylab.com

| <u>Method QA/QC Parameters</u> | | | | |
|---------------------------------------|--|--|--|--|
| QA SAMPLE/ SAMP TYPE CODE | FREQUENCY | ACCEPTANCE CRITERIA | CORRECTIVE ACTION | COMMENTS |
| MDL | <p>Initial MDL: <u>Samples:</u></p> <p>Analyze at least 7 MDL samples over at least 3 calendar days.</p> <p><u>Study:</u></p> <p>Initial study required for new method and whenever method changes might reasonably be expected to affect sensitivity.</p> <p>Ongoing MDL: <u>Samples:</u></p> <p>Analyze at least 2 ongoing MDL spikes for each quarter samples are analyzed. Must have at least 7 MDL spikes per year.</p> <p><u>Study:</u></p> <p>Annually, recalculate MDL spike and MDL blank from overall historical data.</p> | <p>MDL Samples:</p> <p>All results are quantitative (above zero and meet the qualitative identification criteria of the method; e.g., recognizable spectra, signal to noise requirements, and presence of qualifier ions).</p> <p>MDL Studies:</p> <p>MDL = whichever is higher of MDL spike or MDL blank.</p> <p>< PQL</p> | <p>1) If the result for any individual analyte from the MDL spiked samples does not meet the method qualitative criteria or does not provide a numerical result greater than zero, repeat the spiked samples at a higher concentration.</p> <p>2) Repeat initial MDL spike and MDL blank study or adjust reporting limit to > 2X of calculated MDL.</p> | <p>Per CFR Part 136</p> <p>The minimum measured concentration of a substance that can be reported with 99% confidence that the measured concentration is distinguishable from method blank results.</p> <p style="text-align: right; font-size: 2em; opacity: 0.5;">TM</p> |



| <u>Method QA/QC Parameters</u> | | | | |
|---|--|---|---|---|
| QA SAMPLE/ SAMP TYPE CODE | FREQUENCY | ACCEPTANCE CRITERIA | CORRECTIVE ACTION | COMMENTS |
| LOQ Verification | <p>Initial LOQ: <u>Samples:</u></p> <p>Analyze at least 7 LOQ samples over at least 3 calendar days.</p> <p><u>Verification:</u></p> <p>Initial verification required for new method and whenever method changes might reasonably be expected to affect sensitivity.</p> <p>Ongoing LOQ: <u>Samples:</u></p> <p>Analyze at least 1 ongoing MDL spikes for each quarter samples are analyzed.</p> <p><u>Study:</u></p> <p>Annually, verify that acceptance criteria is met.</p> | <p>LOQ Sample:</p> <p>Quantitative (above zero and meet the qualitative identification criteria of the method; e.g., recognizable spectra, signal to noise requirements, and presence of qualifier ions).</p> <p>% Rec = Statistical or set</p> <p>LOQ Verification:</p> <p>> Calculated MDL</p> | <p>1) Correct method or instrument performance and repeat the verification.</p> <p>2) Evaluate and correct established statistical acceptance criteria.</p> <p>3) Adjust reporting limit.</p> | <p>If MDL samples meet the LOQ acceptance criteria, the MDL samples can be used as LOQ Samples.</p> |
| LOD Verification (for DOD certified methods only) | <p>Required for each analyte/method certified by DOD to verify calculated MDL. Annually based on MDL Study Frequency.</p> | <p>Positive result, (Above background.</p> | <p>1) Examine method or preparatory steps.</p> <p>2) Verify MDL study.</p> <p>3) Repeat analysis.</p> <p>4) Consult QA.</p> | <p>Spike at 2-3 times the calculated MDL.</p> |
| External PT Samples | <p>WS, WP, and LPTP studies performed biannually.</p> | <p>PT sample defined acceptance limits (Must pass 2 out of last 3 PT studies.)</p> | <p>1) Complete corrective action report</p> <p>2) Repeat with another make-up study (for failure of 2 out of 3).</p> | <p>External review of analytical method accuracy.</p> |
| Control Charting | <p>Annual statistical review of method.</p> | <p>Data statistically within control limits.</p> | <p>1) Trend Analysis/ Method Review</p> <p>2) Correct method/instrument problem.</p> <p>3) Replace analyst.</p> | <p>For statistical process control.</p> |



Method QA/QC Parameters

| QA SAMPLE/ SAMP TYPE CODE | FREQUENCY | ACCEPTANCE CRITERIA | CORRECTIVE ACTION | COMMENTS |
|--------------------------------------|---|---|---|--|
| Demonstration of Capability (DOC) | Initially for each new analyst, annually thereafter | 4 passing LCS (or other second source QC), passing PT study results, or qualifying statement from supervisor. Method requirements for initial DOCs and ongoing DOCs must be met. | 1) Provide additional training 2) Replace analyst. | Demonstrates proficiency to perform the method and obtain acceptable results for each analyst. |

The 12 QC elements per 40 CFR Part 136.7, if not applicable or required per method, are deleted from the table in individual SOPs.

*** DUP Qualifier (Canned Comment) for use when values are low and the % RPD criteria does not apply.

Since the difference between the analytical result for the sample and its duplicate is less than the reporting limit, the RPD variance is not considered significant.

TM



www.energylab.com

APPENDIX B

ORGANIZATIONAL CHARTS

Corporate Organizational Chart

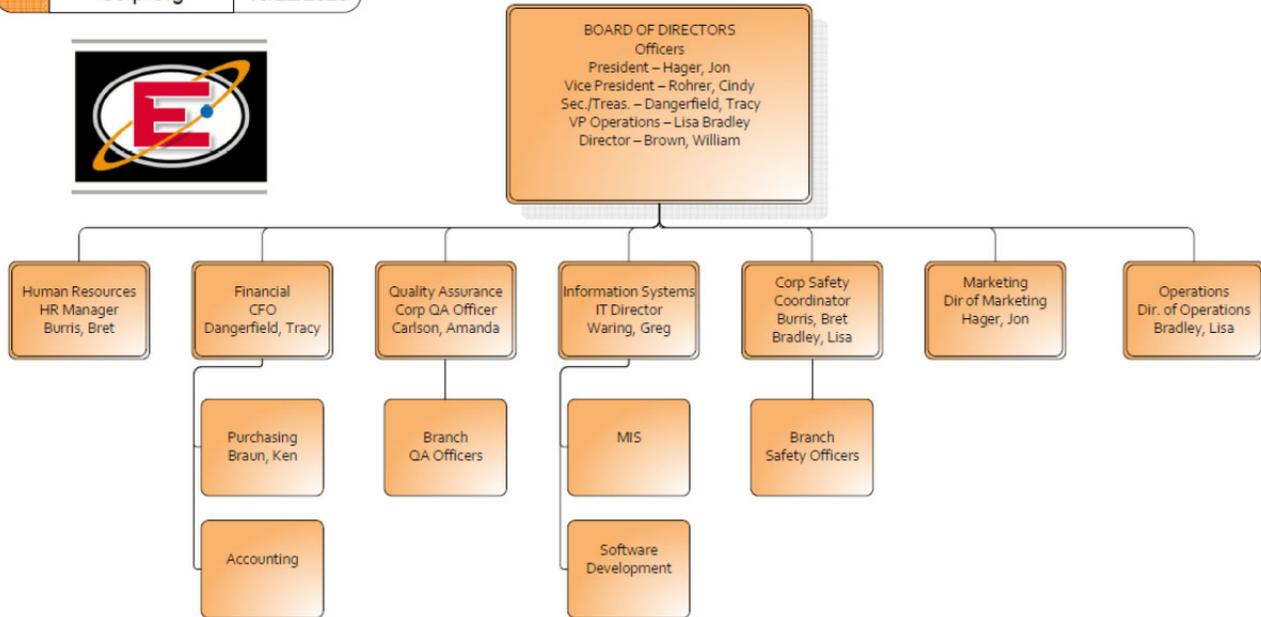


www.energylab.com

Energy Laboratories
Corp Org | 10/22/2020



Energy Laboratories / Corporate Structure



www.energylab.com

APPENDIX C

CURRICULA VITAE OF KEY LABORATORY PERSONNEL



www.energylab.com

JONATHAN D. HAGER

President / Helena Laboratory Manager

Academic Training

Bachelor of Arts in Biology, Chemistry Minor, Carroll College, Helena, MT, May 2003

GC/MS Training Seminar, Restek 8 hour seminar, Sept 2005.

Interaction Management, 40 hr class, Billings, MT, 2008.

Professional Experience

May, 2001-Present: Laboratory Manager -Energy Laboratories, Inc., Helena, Montana.

Responsible for ensuring work is performed with ethics, quality and safety as a primary concern. Encourages a quality-oriented and cooperative atmosphere that promotes collaboration and company-wide success.

Coordinates laboratory analysis with client contracts. Responsible for direction, training, and supervision of the analytical laboratory staff. Involved in new procedural and equipment development, quality assurance program, client relations, and report preparation.

Experienced in the analysis of soils and water in a variety of applications.

Technical Training:

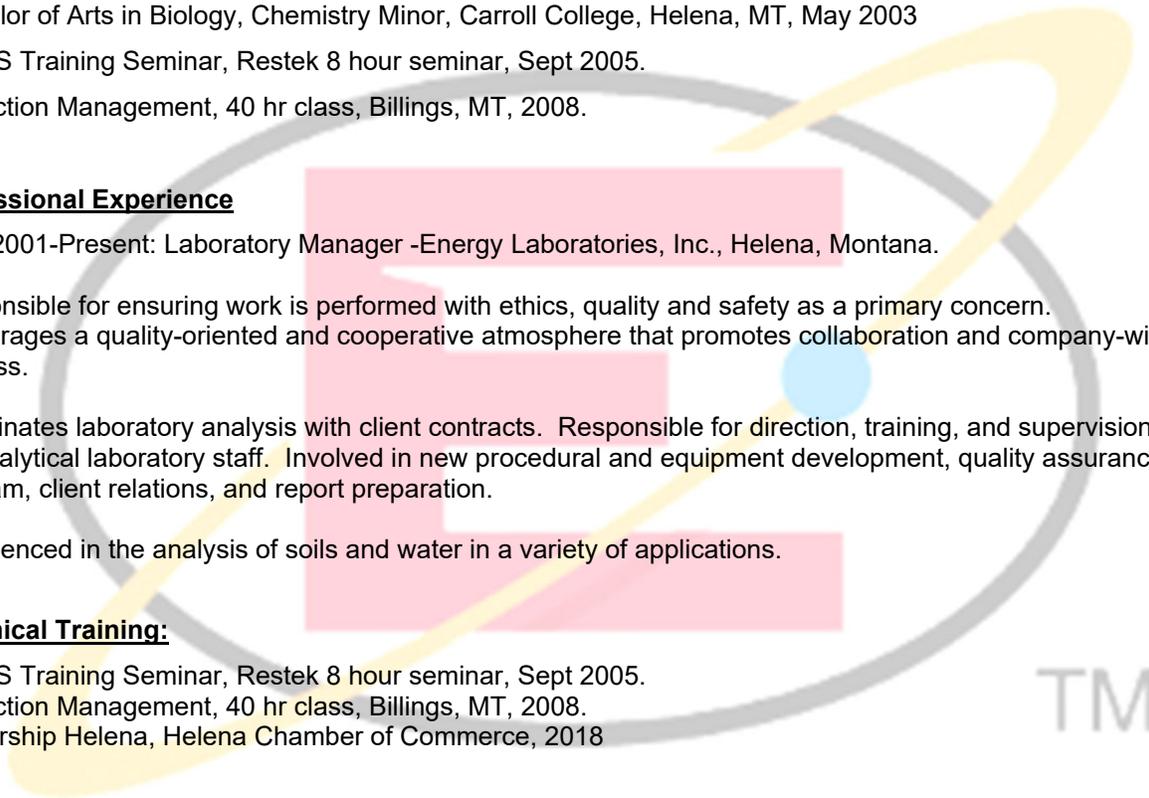
GC/MS Training Seminar, Restek 8 hour seminar, Sept 2005.

Interaction Management, 40 hr class, Billings, MT, 2008.

Leadership Helena, Helena Chamber of Commerce, 2018

Professional Organizations

American Chemical Society
Treasure State Resource Industry Association
Alaska Miners Association
Soil Society of America



www.energylab.com

CINDY ROHRER

Vice President/Laboratory Manager

Academic Experience

Bachelor of Science, Rocky Mountain College, Billings, Montana, 2000

Professional Experience

Experienced in supervision and management of staff, training analysts, technical review of data reports, and performing the following analyses: anion, alkalinity, acidity, metals analysis (ICP-MS), mercury analysis, metals digestions, Flame FAA, UV, solids and pH.

2020 – Present: Vice President, Energy Laboratories, Inc. - Responsible for development and oversight of operations for Energy Laboratories, Inc.

2014 – Present: Laboratory Manager, Energy Laboratories, Inc., Billings, MT
Supervises department operation, staff training, and maintains QA/QC criteria. Oversees audits, coordinates tasks with other departments, and performs data validation.

2011 – 2014: Inorganics and Aquatic Toxicology Supervisor, Energy Laboratories, Inc., Billings, MT
Responsible for daily operations and management of Inorganics and aquatic toxicology department. Responsibilities include supervision of Inorganics and Aquatic Toxicology staff, maintain QA/QC criteria, oversee audits, review and improve Inorganics and Aquatic Toxicology department operations, coordinate tasks with other departments, and proofing data.

2008 – 2014: Inorganics Supervisor, Energy Laboratories, Inc., Billings, MT
Responsible for daily operations and management of Inorganics department. Responsibilities include supervision of Inorganics staff, maintain QA/QC criteria, oversee audits, review and improve Inorganics department operations, coordinate tasks with other departments, and proofing data.

2006 – 2007: Inorganics Assistant Supervisor, Energy Laboratories, Inc., Billings, MT
Responsibilities included training of new analysts, QC method development, oversee audits, and management of samples.

1999: Montana State University, Billings, MT
Researched SOD mimetics, studied SOD mimetic activity of Copper Kinetin. Ran UV Spectrometry, pH meter, Mass Spec, and Flame AA.

Technical Training

Radon Measurement Provider Certification 2019

Interaction Management Training 2008

Dale Carnegie Course 2004



www.energylab.com

TRACY A. DANGERFIELD, CPA, MBA

Treasurer and Chief Financial Officer

Experienced in business leadership, management and strategic development. Extensive background in accounting, finance and organizational development.

Education

Master of Business Administration, University of Montana, Missoula, MT 2013

Certified Public Accountant, 1992

Bachelor of Science, Business Administration, Minor in Accounting, Eastern Montana College, Billings, MT 1989

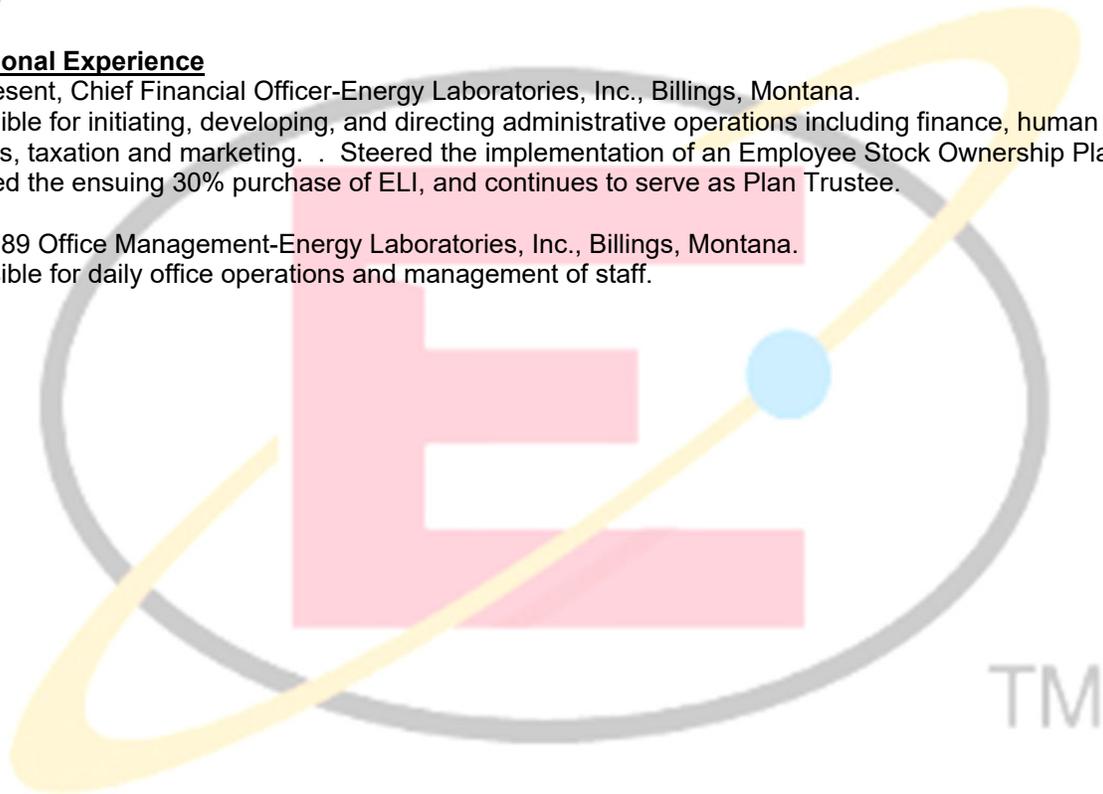
Professional Experience

1989-Present, Chief Financial Officer-Energy Laboratories, Inc., Billings, Montana.

Responsible for initiating, developing, and directing administrative operations including finance, human resources, taxation and marketing. . Steered the implementation of an Employee Stock Ownership Plan, transacted the ensuing 30% purchase of ELI, and continues to serve as Plan Trustee.

1985 -1989 Office Management-Energy Laboratories, Inc., Billings, Montana.

Responsible for daily office operations and management of staff.



www.energylab.com

AMANDA B. CARLSON

Corporate Quality Assurance Officer/Assistant Laboratory Manager (Helena)

Academic Experience

Bachelor of Arts in Chemistry, Carroll College, Helena, MT, May 2004

Professional Experience

June 2019-Present Corporate Quality Assurance Officer, Energy Laboratories, Inc.. Responsible for Quality Assurance procedures and monitoring. Assists with method development, prepares and updates standard operating procedures, performs technical training, and involved with special projects.

Jan 2013-Present Assistant Laboratory Manager-Helena, Montana. Assists in the supervision of the daily operations of the laboratory while promoting collaboration and communication between analysts. Supervise Inorganics Department.

January 2008-Present-Quality Assurance Manager Helena, Montana

Ensures the laboratory maintains client satisfaction by meeting quality requirements. Maintains training records for employees and provide ongoing training of QAQC topics. Maintains a general knowledge of methods performed in the laboratory and the appropriate method corrective actions.

Coordinate client relations from bottle preparation and sample receipt through reporting and invoicing, and data review of technical reports issued to clients.

May 2004-2008 Inorganics and Organics Analyst-Energy Laboratories, Inc. Helena Montana. Certified analyst for total coliform and E.Coli in both public and private water samples.

Professional Organizations

American Water Works Association
American Chemical Society
TNI

Technical Training

GC/MS Training Seminar, Restek 8 hour seminar, Sept 2005.
Interaction Management, 40 hr class, Billings, MT, 2008.
Contaminant Vapor Migration and Intrusion, 13 hr class, Helena, MT, Feb 2013.
Small Laboratory TNI Standard Implementation, 21 hour course, 2017
Basic Assessor Training-TNI Standard 2016, 3 day course, 2019



CHRystal N. SHEAFF PH.D.

Casper Laboratory Director

Education

University of Idaho, Moscow, ID
Ph.D., Chemistry, 2008

Black Hills State University, Spearfish, SD
B.S., Chemistry and Biology, 2004

Professional Experience

2016- Present ENERGY LABORATORIES, INC., Casper, Wyoming
Laboratory Director - Supervises laboratory operation, facilitates staff training, maintains QA/QC criteria, conducts internal assessments, and performs data validation.

2015 - 2016 ENERGY LABORATORIES, INC., Casper, Wyoming
Organics Department Manager – Supervise the daily operation and management of the volatiles, semi-volatiles, HPLC, soil, and microbiology departments. Leads staff training sessions within the department as well as across departments. Responsible for maintaining quality control/assurance compliance within the department. Technical reviewer of standard operating procedures.

2012 – 2014 ENERGY LABORATORIES, INC., Casper, Wyoming
Chemist – Performed HPLC analysis for determination of pesticides and herbicides in drinking water. Performed analysis for gasoline range organics using a purge and trap system. Perform instrument maintenance and repair on HPLC and GC-PID/FID. Responsible for sample management; including, turn-around-times, sample disposal, and waste disposal. Writer, editor, and reviewer of standard operating procedures.

2008 – 2012 ALTURAS ANALYTICS, INC., Moscow, Idaho
Scientist – Performed sample analysis on various biological matrices using HPLC-MS/MS. Developed analytical methods to support drug discovery under regulatory criteria. Followed SOPs, method protocols, analytical test methods, and EPA regulations. Performed troubleshooting, repairs, and maintenance on HPLC-MS/MS instruments.

2004 – 2008 UNIVERSITY OF IDAHO, Moscow, Idaho
Research Assistant – Researched fluorescent methods to detect and identify explosives, determine effectiveness of catalytic hydrogenation, and determining uranium extraction from aqueous solutions. Used synchronous spectroscopy, derivative spectroscopy and excitation-emission matrices (EEM) to identify explosives bases on their impurities and associated tagging agents.

2004 – 2006 UNIVERSITY OF IDAHO, Moscow, Idaho
Teaching Assistant – Taught laboratory classes for General Chemistry and Quantitative Analysis. Tutored chemistry students across all disciplines. Instructed recitation classes and review sessions.

Technical Training

GLPs for Study Directors-West Coast Quality Control Training-2011.
Testing Requirements in EPA Regulations, TNI Webinar, 10/9/2015



TERRY L. FRIEDLAN

Wyoming Regional Director/Gillette Laboratory Director

Experienced in the examination of many types of environmentally related samples including water, natural gas and crude petroleum.

Education

Associate of Science, University of Wyoming, 1982

Engineering courses in Petroleum Engineering, University of Wyoming, 1982-1983

Organic chemistry, Northeastern Wyoming Community College, 1998

PC Repair and Operation, Northeastern Wyoming Community College, 1994

Visual Basic Programming, Northeastern Wyoming Community College, 2000

Professional Experience

2017 to Present, Wyoming Regional Director Energy Laboratories, Inc., Gillette, WY and Casper, WY. Responsible for leading the management teams of the Wyoming branches of ELI. Responsibilities include ensuring accountability, leading by example, improving technical knowledge and quality of work, and aiding in strategic direction and development.

1987 to Present, Laboratory Director Energy Laboratories, Inc., Gillette, WY.

Responsible for routine analysis and quality control of water, natural gas and petroleum products.

Develop test methods, select equipment, train and supervise all laboratory staff.

1983 – 1987, Laboratory and Field Technician, Energy Laboratories, Inc., Gillette, WY.

Responsible for water, natural gas, and petroleum products' sampling and testing. Responsible for natural gas meter calibrations in the field.

Professional Organizations

Society of Petroleum Engineers, 1982 to present

Society of Metallurgical and Mining Engineers, 2005 to present



www.energylab.com

JULIE L. WEISZ

Gillette Laboratory Quality Assurance Officer

Education

Bachelor of Science, Zoology & Physiology, University of Wyoming, Laramie, WY – 1999
Bachelor of Science, Molecular Biology, University of Wyoming, Laramie, WY – 2000

Professional Experience

2011 – Present, Quality Assurance Officer - Energy Laboratories, Inc., Gillette, Wyoming
Responsible for enforcing quality standards. Implement and maintain quality initiatives. Assess quality system performance. Maintain laboratory certification in drinking water, responsible for demonstration of capabilities and MDL studies. Responsible for review of inorganic, organic, and microbiological data.

2009 – 2011, QA Coordinator - Energy Laboratories, Inc., Gillette, Wyoming
Responsible for review of inorganic, microbiological and natural gas data. Assist with SOP updates. Participate in internal and external PE studies and audits. Assist in maintaining quality systems.

2007 – 2008, Office Assistant - Urgent Care, Gillette, Wyoming
Responsible for filing insurance claims and general office duties. Check patients in and out of a busy walk-in clinic. Answer phones.

2000 – 2004, Laboratory Technician - University of Utah, School of Medicine, Salt Lake City, Utah
Responsible for research on a B cell marker found in acute rheumatic fever patients and patients with Tourette's Syndrome. Responsible for isolating bacteria, measuring streptococcal antibody levels, isolating DNA and RNA from whole blood, maintaining cell lines, measuring B cell markers using flow cytometry, performing phlebotomy, analyzing research data and preparing manuscripts, reagent preparation, instrument maintenance and writing protocols.

1997 – 2000, Editorial Assistant - Alumni Association, University of Wyoming, Laramie, Wyoming
Responsible for writing the Wyograms (class notes) sections of the Alumnews and UWyo magazine.



www.energylab.com

Donny C. Juarez

Casper Laboratory Quality Assurance Officer

Education

Casper College, Casper, Wyoming
A.S., Chemistry, 2017

Professional Experience

June 2014 – Present Quality Assurance Manager, Energy Laboratories, Inc., Casper, Wyoming
Maintains laboratory certifications, quality assurance and control criteria. Responsible for annual employee ethics training. Maintains employees training folders. Manages Quality Systems of laboratory including annual reviews of Standard Operating Procedures, QA Manual and employee training folders. Technically reviews data and reports. Well-versed in NELAC, EPA, SW-846, Clean Water Act, and Safe Drinking Water Act regulations and guidelines.

2012 – May 2014 Quality Assurance Assistant, Energy Laboratories, Inc., Casper, Wyoming
Assisted in management of quality and client service standards, implemented and maintained quality initiatives, and assessed quality system performance. Was actively involved with peer auditing of branch laboratories and assisted with the development of internal test method assessments.

2006 – 2012 Soils and Semi-Volatile Organics Dept. Supervisor, Energy Laboratories, Inc., Casper, Wyoming. Performed supervisory duties pertaining to the Agronomic Soils and Semi Volatile Organics Departments. Responsibilities included; prioritization of sample analyses, sample scheduling, ordering, data review and report generation. Managed sample loads, maintained quality assurance and control criteria, and performed method development and improvements.

1995 – 2006 Semi-Volatile Organic and Agronomic Soils Analyst, Energy Laboratories, Inc., Casper, Wyoming. Responsibilities included analysis of samples for semi-volatile organics using Gas Chromatographs, routine maintenance, optimization of instrument performance, data documentation and review, and report generation. Instrumentation included various HP Gas Chromatographs equipped with FIDs to include automated injectors, trays, and controllers. Proficient in analytical and preparation methods including EPA 8015B DRO, 3510, 3550, 1010A, and 1664. As Soil Analyst, responsibilities included analysis, and data review for agronomic and mining samples utilizing various agronomic testing methods.

SPECIAL TRAINING

Supervisor Interaction Management Training, 2009 Energy Laboratories, Inc., Lean Training, 2012
Manufacturing-Works, Environmental Laboratory Assessment
Basic Assessor Training – TNI Standard
Testing Requirements in EPA Regulations, TNI Webinar, 10/9/2015



APPENDIX D
EQUIPMENT AND METHODS LIST



ENERGY LABORATORIES, INC – CASPER, WYOMING

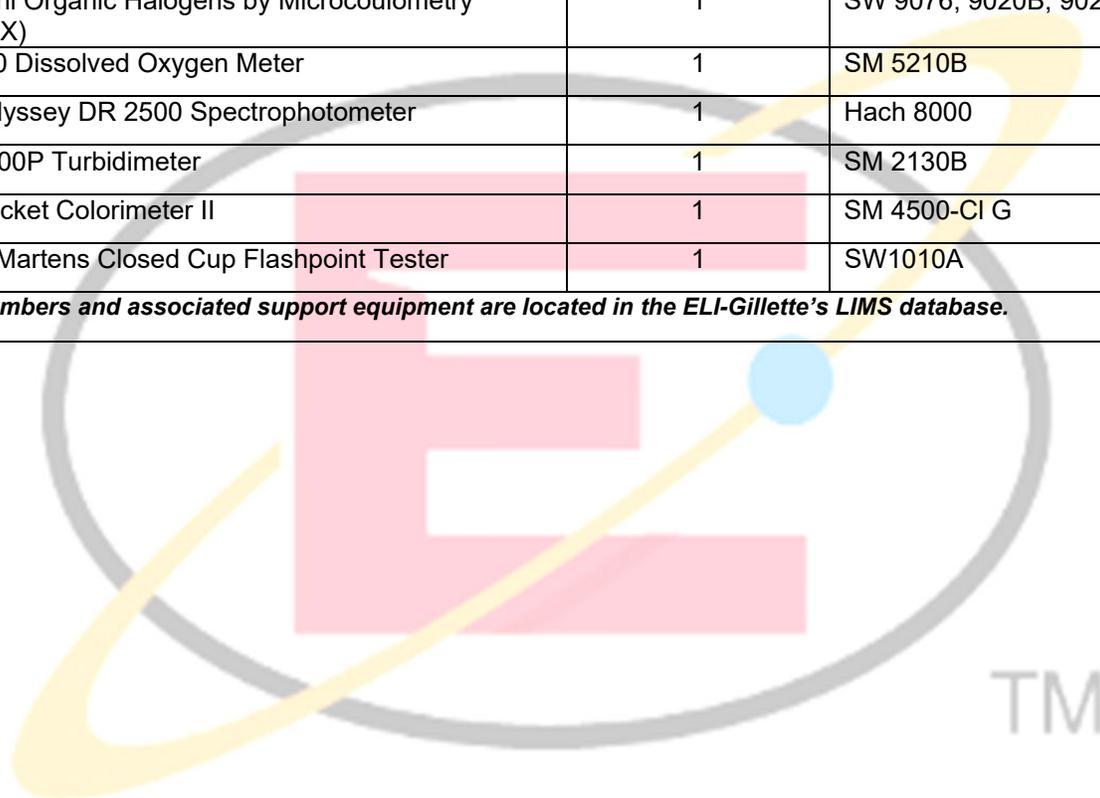
| Equipment | Quantity | Methods |
|---|-----------------|--|
| Gas Chromatograph-FID with auto sampler | 4 | EPA 8015 DRO, GRO |
| Inductively Coupled Argon Plasma Spectrophotometer | 1 | EPA 200.7, EPA 6010 |
| Inductively Coupled Argon Plasma Spectrophotometer-Mass Spectrometer | 1 | EPA 200.8, EPA 6020 |
| Ion Chromatograph | 1 | EPA 300.0 |
| Conductivity and pH | 1 | SM 2510 B, SM 4500-H+- B |
| Turbidimeter | 1 | SM 2130 B |
| Auto Titrator / ISE | 1 | SM 2320B, SM 4500-F C |
| Manual Solid-Phase Extractor | 1 | EPA 1664 A |
| Spectrophotometer | 2 | SM 4500-NO2 B |
| Autoanalyzer (FIA) | 1 | EPA 353.2, EPA 365.1, EPA 350.1 |
| TOC Analyzer | 2 | SM 5310 C |
| Liquid Chromatography (HPLC) | 4 | EPA 549.2, EPA 531.1, EPA 547 |
| Liquid Scintillation Counter | 2 | EPA 906.0, EPA 909.0, ASTM D5072 92 |
| Alpha / Beta Gas Proportional Counters Detectors | 5 80 | EPA 900.0, EPA 903.0, EPA 905.0, EPA Ra-05 |
| Gamma Ray Spectrometers (2 HPGe, 3 NaI(Tl)) | 5 | EPA 901.1 |
| Alpha Spectrometers Detectors | 6 48 | EPA 908.0, SM 7500-U C |
| BOD/DO Analyzer | 1 | SM 5210 B |
| Serial numbers and associated support equipment are located in the ELI-Casper's LIMS database. | | |
| Additional Methods: SM 2330 B, SM 2340 B, SM 2540 C, SM 2540 D | | |

ENERGY LABORATORIES, INC – GILLETTE, WYOMING



www.energylab.com

| <u>Equipment</u> | <u>Quantity</u> | <u>Methods</u> |
|---|-----------------|---------------------------------|
| Dionex Anion Chromatograph | 2 | EPA 300.0 |
| Man-Tech Auto-Titrator | 1 | SM 2320B |
| Horizon Solid Phase Extractors | 7 | EPA 1664A |
| Metrohm 855 Robotic Titrosampler | 1 | SM 2510B, 4500-H ⁺ B |
| Varian CP-4900 GC | 1 | GPA 2261 |
| Mitsubishi Organic Halogens by Microcoulometry (TOXBOX) | 1 | SW 9076, 9020B, 9023 |
| YSI 5100 Dissolved Oxygen Meter | 1 | SM 5210B |
| Hach Odyssey DR 2500 Spectrophotometer | 1 | Hach 8000 |
| Hach 2100P Turbidimeter | 1 | SM 2130B |
| Hach Pocket Colorimeter II | 1 | SM 4500-CI G |
| Pensky-Martens Closed Cup Flashpoint Tester | 1 | SW1010A |
| Serial numbers and associated support equipment are located in the ELI-Gillette's LIMS database. | | |



TM


www.energylab.com

RECORD OF REVIEW/REVISION

| Date of Review/ Revision | Revision Number | Performed By | Action (Review with no changes/ Detailed modifications) |
|--------------------------|-------------------|--------------|--|
| 10/20/2018 | October 20, 2018 | D Juarez | New Wyoming Regional Quality Assurance Manual replacing Casper revision January 23, 2018, and Gillette revision 10.26.2017. For specific changes see previous branch specific revisions. |
| 10/28/2019 | October 31, 2019 | D. Juarez | Refer to ELI-C-SOP-700 WY Regional QAM October 31 2019 REDLINE.pdf |
| 11/10/2020 | November 10, 2020 | D. Juarez | Refer to ELI-C-SOP-700 WY Regional QAM November 10 2020 REDLINE.pdf |
| 12/13/2021 | December 13, 2021 | D. Juarez | Refer to ELI-C-SOP-700 WY Regional QAM December 13 2021 REDLINE.pdf |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

