QUALITY ASSURANCE PLAN

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1.0 Organization and Responsibility

1.1 Introduction

Basic Laboratory is committed to the production of analytical data of the highest quality in all environmental analyses. Basic Laboratory recognizes that quality data is a function of an effective and consistent quality assurance program. It is in support of Basic Laboratory's commitment to data integrity that this Quality Assurance Plan was prepared. It is our goal to produce data that is scientifically valid, legally defensible, and of known and documented quality in accordance with nationally recognized standards.

The different elements of the Quality Assurance Plan are discussed in the remainder of this manual. The detailed procedures for how each element of the plan is carried out can be found in the Standard Operating Procedures (SOP). All analyses are performed using promulgated reference methods for which the laboratory has demonstrated competency prior to its use.

Basic Laboratory provides microbiological, bioassay, general chemical, organic chemical, and metals analysis for water and soil. Radiological, electron microscopy, and other testing services are provided through state certified subcontractor laboratories with established quality assurance plans. Basic Laboratory analyzes blind Performance Testing samples annually for all methods and analyses for which we are certified.

The implementation of the Quality Assurance Plan is achieved through a laboratory-wide effort of the entire staff. The laboratory organization and personnel are geared toward carrying out the objectives of the Quality Assurance Plan. This may be seen in the organization chart in section 1.3 and in the descriptions of the staff duties, responsibilities, and qualifications provided in the remainder of this section and in *Appendix A*. As the lab grows, additional staff may be added to the organizational structure.

To strengthen its commitment to the production of quality data, Basic Laboratory has established high qualification standards for employment and provides a specific and documented training program for all its employees. The result is a laboratory staff who offer a unique blend of scientific and technical expertise, highly capable of serving a wide range of analytical needs in the environmental arena.

1.2 Code of Ethics

All employees are to adhere to the following code of ethical business practices. Any ethical infraction by an employee is grounds for immediate termination of employment, and also for legal action against the offending employee.

I. Basic Laboratory and employees thereof will perform all work in a manner that merits full confidence and trust.

II. Basic Laboratory and employees thereof, will not engage in illegal practices, or cooperate with anyone so engaged.

III. Basic Laboratory and employees thereof, will ensure the integrity of their data by complete adherence to the laboratory QA/QC Manual and Standard Operating Procedures, and will be diligent to expose and correct any errors that may be brought to light.

IV. Basic Laboratory and employees thereof, will maintain as their first priority the common needs of the community, and will at all times contribute as responsible and profitable members of our society.

V. Basic Laboratory and employees thereof, will work and act in a strict spirit of honesty and fairness to clients, and in a spirit of personal helpfulness and fraternity toward fellow employees.

VI. Basic Laboratory and employees thereof, will not accept any of the following practices:

- Fabrication of data
- Misrepresentation of QC samples
- Non-acceptable instrument calibration procedures
- Unapproved modification of samples to alter their characteristics
- Improper and unethical manual integrations
- Manipulation or misrepresentation of analytical results
- Substitution of samples, files, or data
- Falsification of records or instrument readings
- Any other form of fraud or intentional misrepresentation

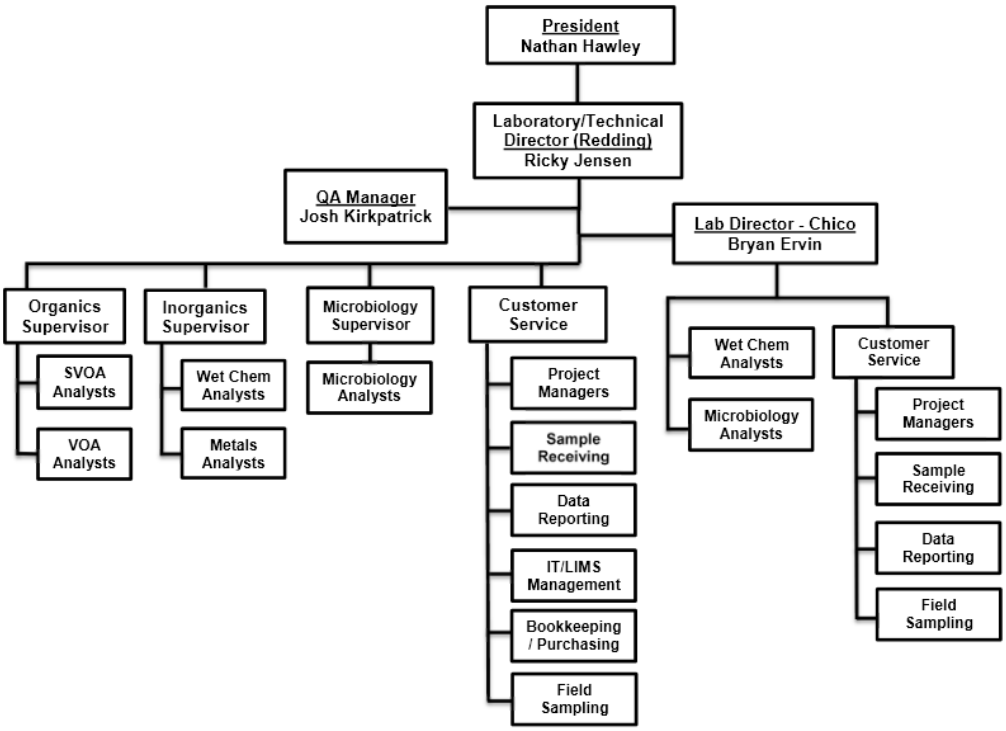
VII. Basic Laboratory and employees thereof, will advise clients of the probability of success before undertaking a project, and will not accept work that would constitute a conflict of interest.

VIII. Basic Laboratory and employees thereof will ensure the confidentiality of all data and information provided by their clients.

IX. Basic Laboratory and employees thereof will only perform testing services for which they have consistently demonstrated full compliance with high quality, legally defensible performance standards.

X. Basic Laboratory and employees thereof will seek to consistently demonstrate the positive qualities of enthusiasm, diligence, responsibility, initiative, integrity, honesty, kindness, and patience in dealing with both clients and fellow employees.

1.3 Organizational Structure



1.4 Duties and Responsibilities of Personnel

- The **Laboratory Director** has the responsibility for the overall management and supervision of the laboratory and its personnel. He will interface with clients on all aspects of their projects including progress, problems, and recommended solutions. He will also work with the President, Quality Assurance Manager, and laboratory personnel in reviewing progress reports, analytical reports, financial reports, and QC reports. He is primarily responsible to ensure that all employees have received the necessary level of training to make them capable of properly executing their duties.

- The **Quality Assurance Manager (QAM)** assists the Laboratory Director in assuring the production of accurate, valid, and reliable data by continuously monitoring the implementation of the laboratory quality assurance program. The QAM administers all inter-laboratory QA efforts,

schedules and reviews performance evaluation results, takes corrective actions, and prepares quality assurance reports for management. He also conducts annual internal audits of the overall laboratory operation, and is responsible for the management and annual review of this QA manual.

- The **Department Supervisors** are responsible for each task identified in their scope of work. They are responsible for organizing and directing the technical activities within their assigned sections(s). They are involved in daily laboratory operations and are responsible for verifying that laboratory QC and analytical procedures are being followed as specified for each project. They are responsible for organizing, assembling, disseminating, and filing all documents pertinent to the analysis for each set of samples. They may also be responsible for the review of data generated in their departments for accuracy. They also advise the Laboratory Director of progress, needs, and potential problems in their assigned section(s).

- The **Analysts** or Technical Staff are responsible for sample analysis and data processing in accordance with this laboratory QAP and established SOPs. They are responsible for calibration and preventive maintenance of instrumentation, data reduction, data review, and reporting of all out-of-control situations, as well as for initial corrective actions whenever necessary. Well documented training records are kept on file for each Analyst in order to provide proof of proper training for each method they perform.

- The **Sample Custodians** are responsible for the proper preparation, shipment, and receipt of samples. When the samples are received into the laboratory, the sample custodian is responsible for checking and documenting the chain-of-custody by checking sample descriptions, labels, and parameters requested against the chain of custody record. If any discrepancies are noted, the sample custodian or their designee contacts the client, and coordinates with laboratory staff and management until the discrepancy is resolved and the resolution is documented. This information is recorded on the COC and into the Laboratory Information Management System (LIMS). All samples are logged into the LIMS and are tracked within the LIMS for the remainder of their journey through the laboratory. Audit trails are available for each sample.

1.5 Personnel Training

To ensure that all personnel involved in analytical activities are able to carry out their duties, they are required to undergo a training program. Training is administered by trainers designated by the Laboratory Director or by the QA Manager, and is normally a senior analyst.

The program is presented to new employees upon employment and must be completed prior to assumption of assigned duties. It includes orientation, review of the job description and how the position integrates with the overall organization, overview of the QA program, overview of the safety program, and initial on-the-job training for the employee's initial job assignment. Each

employee has read, understood, and is using the latest version of the laboratory's QAP and the SOPs that relate to their job responsibilities.

The readiness of the new employee to assume initial job assignment is assessed by the area supervisor. Acceptable performance is determined by conducting an Initial Demonstration of Capability (IDC). Each acceptable performance of analysis is noted on the employee's training record. After final approval by the QAM, the employee is allowed to begin initial assignments. All completed documentation is kept in the employee's permanent training record.

1.6 Laboratory Capabilities

Basic Laboratory is capable of testing aqueous and solid samples for a wide variety of parameters. *Visit our website www.basiclab.com for a complete listing of all certified methods.*

2.0 Quality Assurance Objectives

The overall QA objectives for Basic Laboratory are to develop and implement procedures for laboratory analysis, chain-of-custody, and reporting that will provide results which are of known and documented quality. Data Quality Indicators (DQIs) are used as qualitative and quantitative descriptors in interpreting the degree of acceptability or utility of data. The principal DQIs are precision, bias (accuracy), representativeness, comparability, completeness and detection limits. DQIs are used as quantitative goals for the quality of data generated in the analytical measurement process. This section summarizes how specific QA objectives are achieved. The specific application of these various activities are contained in the method SOPs.

The laboratory's quality assurance objectives of precision and accuracy are listed in *the laboratory's SOPs*. These objectives are based on the laboratory's capabilities as well as method specified criteria.

2.1 Precision

Precision is a measure of the degree to which two or more measurements are in agreement. Precision is assessed through the calculation of relative percent differences (RPD) and/or relative standard deviations (RSD) for replicate samples. For inorganic analyses, laboratory precision is usually assessed through the analysis of a sample/sample duplicate pair, although some methods require the use of matrix spike/matrix spike duplicate. For organic analyses, precision is usually assessed through the analysis of matrix spike/matrix spike duplicate (MS/MSD) and field duplicate samples.

Precision is a measurement of the mutual agreement among individual measurements of the same parameters under prescribed similar conditions.

If calculated from duplicate measurements:

$$RPD = \frac{(C_1 - C_2) \times 100}{(C_1 + C_2)/2}$$

where: RPD = relative percent difference
C_1 = larger of the two observed values
C_2 = smaller of the two observed values

If calculated from three or more replicates, use relative standard deviation (RSD) rather than RPD:

$$RSD = (s/\bar{y}) \times 100\%$$

where: s = standard deviation
$\bar{y}$ = mean of replicate analysis

Standard deviation(s) is defined as follows:

$$s = \sqrt{\sum_{i=1}^{n} \frac{(y_i - \bar{y})^2}{n-1}}$$

where:

y_i = measured value of the *i*th replicate
$\bar{y}$ = mean of replicate measurements
n = number of replicates

2.2 Accuracy

Accuracy is the degree of agreement between an observed value and an accepted reference or true value. Accuracy is first assessed by the analysis of blanks and through the adherence to all sample handling, preservation and holding times. Laboratory accuracy is further assessed through the analysis of MS/MSD, quality control check samples, laboratory control samples (LCS) and surrogate compound spikes.

For measurements where matrix spikes are used, the percent recovery (%R) is calculated:

$$\%R = 100 \times \frac{S - U}{C_{sa}}$$

where: S = measured concentration in spiked aliquot
U = measured concentration in un-spiked aliquot
C_{sa} = actual concentration of spike added

For situations where a standard reference material (SRM) is used instead of, or in addition to, a matrix spike, the percent recovery (%R) is calculated:

$$\%R = 100 \times \frac{C_m}{C_{srm}}$$

where: C_m = measured concentration of SRM
C_{srm} = actual concentration of SRM

2.3 Representativeness

Representativeness expresses the degree to which data accurately and precisely represent a characteristic of a population, parameter variations at a sampling point, a process condition, or an environmental condition within a defined spatial and/or temporal boundary. Representativeness is ensured by using the proper analytical procedures, appropriate methods, meeting sample holding times and analyzing field duplicate samples.

2.4 Completeness

Completeness is a measure of the amount of valid data obtained from a measurement system compared to the amount that was expected to be obtained under normal conditions. Laboratory completeness is a measure of the amount of valid measurements obtained from all the measurements taken in the project.

$$\%\ C = \frac{\text{No. of Acceptable parameters}}{\text{Total number analyzed}} \times 100$$

2.5 Comparability

Comparability is an expression of the confidence with which one data set can be compared to another. Comparability is achieved by the use of routine analytical methods, achieving holding times, reporting results in common units, use of consistent detection limits, and consistent rules for reporting data.

2.6 Detection Limits

Method Detection Limits (MDLs) are determined for all analytes as specified by recognized EPA standards. From these, a Reporting Limit (RL), normally around 3-5 times the MDL, is also established. The RL is the minimum concentration of an analyte that can be identified and quantified within specified limits of precision and bias during routine analytical operating conditions. The RL is never lower than the lowest standard in the calibration curve, unless the method specifically requires it.

3.0 Sample Collection Procedures

3.1 Sample Collection

Special consideration is given to the procurement, storage, and transportation of samples to be analyzed. Procedures ensure that the analyte(s) originally present in the sample matrix has not undergone degradation or concentration, and that contaminants which might interfere with the analysis have not been added. Plastic containers are not used for samples to be analyzed by electron capture detector. Use of metal containers is discouraged since they may contain trace impurities such as oil films, lacquers, or rosin from soldered joints, which cause interference during gas chromatographic analysis. In general, glass jars or bottles with Teflon-lined lids or aluminum foil are the most suitable sample containers for organic analysis. In certain cases, the analyte of interest may be unstable because of its chemical nature and/or interaction with the sample matrix, and special preservatives need to be added during sample collection. Sample collection, preservation, and storage should always be done in accordance with the established method (where available) as well as in compliance with regulatory authorities when applicable.

It is the responsibility of the client to ensure the proper collection and delivery of their sample. Basic Laboratory will provide whatever support possible to assist the client in this endeavor, such as providing proper supplies and instructions.

3.2 Sampling Kit Preparation

Sampling kits to be used by client field personnel are prepared by Basic Laboratory sample custodians following instructions indicated on the Bottle Order Form (BOF). The BOF is generated when the client contacts a Basic Laboratory representative about analyzing samples. The instructions on the BOF are therefore unique to the client's requirements.

If required, preservatives are added to the sample containers by the sample custodians according to the instructions on the BOF. These preservatives are prepared by various laboratory personnel according to the appropriate written Standard Operating Procedure, or bottles are purchased pre-preserved and certified from an outside supply company. The type of preservative added is indicated on the sample container labels Sampling kits are then assembled in appropriately sized ice chests for shipping or transportation.

3.3 Field Sampling

Field sampling personnel are trained by our certified laboratory to follow the specific sampling procedures required within each analytical method for which they are collecting samples. Documentation of any formal off-site training is kept in the employee's permanent training record. At least once per year, field sampling personnel attend a refresher class performed by the QAM and/or the Laboratory Director (or their designee) to ensure that proper field sampling techniques are being used at all times. At a minimum, each of the primary field sampling methods are covered during the class. All training is documented and records are maintained.

All equipment used for field measurements (pH, temperature, DO, conductivity) are high quality, field specific instruments that can produce data of laboratory

quality. Field instruments are calibrated according to the manufactures recommendations, and according to the requirements of the method being performed. Calibration records are maintained at all times.

4.0 Sample Custody

4.1 Sample Tracking

Basic Laboratory uniquely identifies each sample to be tested to ensure that there is no confusion regarding identity. A unique identification code is placed on each sample container. The identifier used by Basic Laboratory is referred to as the Work Order number, and is trackable at all time using the LIMS. Each analyst is also required to maintain laboratory benchsheets to provide sufficient detail to enable others to reconstruct the analysis should the analyst not be available to do so.

In summary, the system for tracking samples consists of the Chain of Custody, the LIMS work order, subcontract work orders (if applicable), laboratory bench sheets, laboratory notebooks, instrument operation logbooks, instrument printouts (raw data), and final analytical reports. This tracking system ensures that the Laboratory's records can be used as valid evidence should such data become the subject of litigation or any other type of review or investigation.

4.2 Sample Acceptance

For sample acceptance Basic Laboratory requires proper, full, and complete documentation, including the sample identification, the location, date and time of collection, collector's name, preservation type, sample type and any special remarks concerning the sample; Unique identification of samples using durable labels completed in indelible ink; use of appropriate sample containers; receipt within holding times; adequate sample volume are required. Samples that do not meet these requirements are noted on the COC defining the nature and substance of these variations and clients are contacted for further clarification.

4.3 Sample Receipt and Login

All samples submitted to Basic Laboratory are delivered to the laboratory's central sample receiving area and are received by the Sample Custodians. The temperature (and pH when required) of the sample are checked and recorded on the Chain of Custody and in the LIMS. The sample custodian compares the samples received against the Chain of Custody

If a sample discrepancy, such as a broken or missing sample is observed at check-in by the sample custodian, a statement to that effect is written in the remarks section of the Chain of Custody. The client must be notified and approve of any changes made to the COC. At this time, the Laboratory Director, the Project Manager, or the QAM may also need to be notified so that any technical problems can be addressed.

All samples received are recorded into the LIMS with the following minimum information: client name, client address, analytical parameters requested, sample

collection date and time, and laboratory work order number. The laboratory work order number is a sequential number that is unique to each sample. Samples are processed through the laboratory by their unique laboratory Work Order numbers. Special instructions about the samples are written onto the Chain of Custody (COC) and are entered into the LIMS in the comments section. A copy of the COC and work order is given to each laboratory section.

Samples are taken by the sample custodian to the designated storage areas. Access to these areas is limited to authorized laboratory personnel only.

4.4 Sample Preservation

Samples that require preservation by the laboratory are preserved after completion of the login process, but before transfer to the laboratories. The preservatives used by the sample custodians are prepared by the respective laboratories and are analyzed before use to ensure that they are free from contamination. After preservation, the sample custodian or laboratory analyst verifies the pH of each sample to ensure that an adequate amount of preservative has been added to the sample.

4.5 Sample Storage

Samples which require thermal preservation are stored under refrigeration. Storage at a temperature above the freezing point of water to 6^{o}C is considered acceptable. Samples are stored in a manner that prevents cross contamination. Laboratory standards and reagents are never stored in the same refrigeration units as client samples.

4.6 Sample Disposal

All original samples, digestates, leachates and extracts or other sample preparation products are disposed of in accordance with Federal and State laws and regulations. If the sample is part of litigation, disposal of the physical sample occurs only with the concurrence of the affected legal authority, sample data user and/or submitter of the sample. Otherwise, all samples are disposed of 30 days after the final report is mailed to the client, unless prior arrangements are made to maintain the samples for a longer period.

5.0 Calibration Procedures and Frequency

This section deals with the systems that are in place in the laboratory to ensure that all conditions are in a state of control at the time of analytical data generation. The operation of each system is documented in written Standard Operating Procedures (SOPs) to ensure consistent execution and compliance at all times. Analytical procedures used are based on approved and published methods. All Standard Operating Procedures are readily available at the analysts' bench.

5.1 Traceability

Wherever applicable, calibration of analytical support equipment and instruments

is traceable to national standards of measurement.

5.2 Reference Standards

Reference standards of measurement, such as Class S or higher weights, or traceable thermometers, are used for calibration only. Reference standards are subjected to in-service checks between calibrations and verifications.

5.3 General Requirements

Each calibration is dated and labeled with or traceable to the method, instrument, analysis date, and each analyte name, concentration and response (or response factor). Sufficient information is recorded to permit reconstruction of the calibration. Acceptance criteria for calibrations comply with method requirements or are established and documented.

5.4 Analytical Support Equipment

Analytical support equipment include, but are not limited to: balances, ovens, refrigerators, freezers, incubators, water baths, temperature measuring devices and volumetric dispensing devices (if quantitative results are dependent on their accuracy, as in standard preparation and dispensing or dilution into a specified volume). All such support equipment is maintained in proper working order. The records of all activities including service calls are kept. Re-calibration occurs at least annually, using NIST traceable references whenever available, over the expected range of use. The results of such calibration must be within the specifications required of the application for which the equipment is used; otherwise the equipment is removed from service until repaired.

Prior to use on each working day, balances, ovens, refrigerators, freezers, incubators and water baths are checked with NIST traceable thermometers (where possible) in the expected use range. The acceptability for use or continued use is according to the needs of the analysis or application for which the equipment is being used. The acceptance limits for each piece of equipment is located in the front of the daily logbook associated with it. Mechanical volumetric dispensing devices (except Class A glassware) are checked for accuracy semi-annually and documented.

5.5 Instrument Calibration

Calibration procedures for a specific laboratory instrument will consist of an initial calibration and secondary source calibration verification. The SOP for each analysis performed in the laboratory describes the calibration procedures, their frequency, acceptance criteria and the conditions that will require recalibration. In all cases, the initial calibration is verified using an independently prepared calibration verification solution. Basic Laboratory maintains records for each instrument which contains the following information: instrument identification, serial number, date of calibration, analyst, calibration solutions run and the samples associated with these calibrations. This record may be automatically created by the software used to run the instrument, and if so, is saved to the hard drive and routinely backed up. This does not replace the necessary hard copy

logbook used to record maintenance data.

All results are calculated based on the response curve from the initial calibration and are bracketed by the calibration standards or reported as having a lower confidence level. If the initial calibration fails, the analysis procedure is stopped and evaluated. For example, a second standard may be analyzed and evaluated or a new initial calibration curve may be established and verified. In all cases, the initial calibration must be fully acceptable before analyzing any samples.

When a full initial instrument calibration is not required or performed on the day of analysis, a calibration verification check standard is analyzed at the beginning and end of each batch. An exception to this policy may be for internal standard methods (e.g. most organic methods). For these analyses, the calibration check is only required at the beginning of the analytical sequence. The concentration of this calibration check varies as described in each method SOP. If a calibration check standard fails, and routine corrective action procedures fail to produce a second consecutive calibration check within acceptance criteria, a new initial calibration curve is required. If the continuing calibration acceptance criteria are exceeded high (i.e., high bias), and there are non-detects for the corresponding analyte in all environmental samples associated with the continuing calibration check, then those non-detects may be reported, otherwise the samples affected by the unacceptable check are reanalyzed after a new calibration curve has been established, evaluated and accepted.

Below is listed a brief synopsis of calibration procedures for various primary instrument types within the laboratory. These are not intended to be complete. For complete details on each instrument calibration, please consult the appropriate SOP.

5.6 CVAA / GFAA / ICP Calibration Procedures

CVAA, GFAA, and ICP are calibrated for the metals of interest by the analysis of calibration standards of known concentrations.

For atomic absorption by cold vapor AA the instrument is calibrated using a minimum set of three standards which are prepared by diluting a stock solution of known concentration and a blank. For atomic absorption by graphite furnace, a minimum of four concentrations and a blank are used for initial calibration. For ICP, the calibration is performed according to the instrument manufacturer's specifications and each individual EPA Method Protocol. Linear range studies are performed in order to accurately establish the valid range for each analyte.

Each instrument is calibrated at the beginning of each series of samples analyzed. The concentration of the calibration standards is chosen so as to cover the working range of the instrument. Subsequently, all sample measurements are made within this working range, unless a linear range has been established (for ICP only) above the highest calibration standard. An EPA reference standard or a second source initial calibration verification standard (ICVS) of known concentration is analyzed to verify initial calibration. A continuing calibration verification standard (CCVS) is analyzed after every 10 samples to verify continuing instrument calibration. Analytes in the continuing calibration standard

must be within ±10 percent of the true value. A continuing calibration blank (CCB) is also run after every 10 samples. For each analytical batch, a preparation (method) blank and a laboratory control sample (LCS) are also analyzed to verify overall method performance.

5.7 ICP/MS Calibration Procedures

Calibration is performed strictly according to the instrument manufacturer's specifications and each individual EPA Method Protocol. Interference correction calculations are included for all required analysis. Full initial calibration of each element is performed daily before running samples, and stability is verified with CCV and CCB analysis every 10 samples in each run sequence.

5.8 UV-VIS Spectrophotometer Calibration Procedures

UV-VIS spectrophotometers are checked and calibrated with an approved standard color solution yearly. For sample analyses, a blank and at least four standard concentrations over the linear range are used for calibration. The curve must meet the minimum criteria for correlation coefficient of 0.995. Each curve is validated using an EPA reference standard or a secondary source initial calibration verification standard (ICVS) independently purchased or prepared from a different lot number or vendor than the calibration standards.

Mirror, grating alignment, and wavelength alignment is checked if warranted, such as when deviations of the standard color solutions are noted.

5.9 GC AND GC/MS Calibration Procedures

Calibration and integration is performed strictly according to the instrument manufacturer's specifications and each individual EPA Method Protocol. Full calibrations are performed whenever check standards failures occur, and whenever any instrument maintenance has been performed.

5.10 Radiation Instrument Calibration Procedures

The geiger-muller detection instrument is sent to a certified calibration service company annually for re-certification and calibration of all measurement ranges. Routine calibration of the internal proportional counter is performed according to the manufacturer's specifications and Standard Methods 7030B and 7110B.

5.11 Other Calibration Procedures (Support Equipment)

Regular periodic calibrations are performed for equipment such as balances, thermometers, ovens, incubators, pipettes, and D.O. meters that are required in analytical methods, but that are not routinely calibrated as part of the analytical procedure. All the calibration measurements are recorded in a dedicated QA instrument log or on a laboratory benchsheet.

- Balances - Calibration is checked using certified Ultra or Class 1 weights daily or before each use, whichever is less frequent. Each balance is cleaned, calibrated, and re-certified yearly by a certified technician.

Certificates of traceability are provided for each balance at that time.

- Incubators and Refrigerators - Temperatures are checked daily using a traceable thermometer and the results are recorded in a logbook.

- Ovens, Heat/Digestion Blocks, and Water Baths - Temperatures are checked daily or during each use, whichever is less frequent. The temperatures are recorded in a laboratory logbook and necessary adjustments are made as required.

- Thermometers - All thermometers in the laboratory are calibrated annually against a certified NIST traceable thermometer. The NIST thermometers are sent to the manufacturer annually to be re-calibrated and re-certified.

- Pipettes - All automatic pipettes are calibrated to the manufacturer specifications semi-annually. The results are recorded in a logbook.

- Meters - each instrument is checked for calibration before each use, using pre-established standards described in the method and SOP.

6.0 Analytical Methods and Standard Operating Procedures

Basic Laboratory maintains Standard Operating Procedures (SOPs) that accurately reflect all laboratory activities such as assessing data integrity, corrective actions, sample handling, and all analytical procedures. Copies of SOPs are readily accessible to all personnel. Each SOP indicates the effective date, the revision number, and the signatures of the QA Manager and Laboratory Director.

SOPs are used to ensure consistency, quality, and comparability of all data. Any approved deviation from an established procedure during an analysis is documented.

The laboratory uses written in-house Standard Operating Procedures that are based on published and approved methods from USEPA, APHA, AWWA, NIOSH and others. New procedures are validated according to an established protocol prior to implementation. Each SOP is reviewed for changes or necessary revisions annually.

6.1 SOP for Sample Custody

Basic Laboratory maintains a comprehensive SOP for the receipt, handling, storage, preservation, and disposal of all samples.

6.2 SOP for Reagent and Standard Preparation

Details for standard and reagent preparation are found in the SOPs specifically written for each analytical method.

6.3 SOPs for General Laboratory Techniques

These SOPs describe all essentials of laboratory operations that are not addressed elsewhere. These techniques may include, but are not limited to, glassware cleaning procedures, operation of analytical balances, pipetting techniques, and use of volumetric glassware.

6.4 SOPs for Analytical Test Methods

Procedures for test methods describing how the analyses are actually performed in the laboratory are specified in method SOPs. These SOPs are based on approved reference methods published by EPA, Standard Methods, ASTM, AWWA, and other organizations as well as internally developed methods validated according to EPA's Performance Based Measurement System. Each method SOP should normally include or discuss details for the following items:

1) Scope and Application
2) Summary of the Method
3) Matrices
4) Detection Limit
5) Method Performance (Precision and Accuracy)
6) Definitions
7) Interferences
8) Safety
9) Equipment and Supplies
10) Reagents
11) Standards
12) Sample Collection, Preservation, Shipping, and Storage
13) Quality Control and Acceptance Criteria
14) Calibration and Standardization
15) Procedures
16) Calculations
17) Waste Management and Pollution Prevention
18) Data Assessment and Review
19) Corrective Actions and Contingencies for Out of Control Data
20) Deviations
21) References

6.5 SOPs for Equipment Calibration and Maintenance

These SOPs describe how to ensure that laboratory equipment and instrumentation are in working order. These procedures include calibration procedures and schedules, maintenance procedures and schedules, maintenance logs, service arrangements for all equipment, and spare parts available in-house. Calibration and maintenance of laboratory equipment and instrumentation are in accordance with manufacturers' specifications or applicable test specifications. In most cases, these procedures will be covered in the specific analytical method SOP and will not be a separately written procedure.

7.0 Internal Quality Control Checks

The laboratory employs quality control samples to assess the validity of the analytical

results of all samples. Determination of the validity of all sample results is based on the acceptance criteria being met by the control samples. The methods used to determine quality control acceptance criteria and frequency should be the most recent EPA approved method revision. The acceptance criteria and frequency for each type of control sample are delineated in the appropriate standard operating procedures. These acceptance criteria are usually based on the method requirements and/or EPA's CLP acceptance criteria, unless the specific method requires the use of control charts to establish the acceptance limits. Control charts are then usually prepared annually using the laboratory's statistical process capabilities determined from historical data. The control samples are analyzed in the same manner as the samples. They are interspersed with the samples at frequencies that are specified by the appropriate standard operating procedure. The frequencies may be altered to comply with client-specific requirements.

7.1 Laboratory Quality Control Samples

The data acquired from QC procedures is used to estimate the quality of analytical data, to determine the need for corrective action in response to identified deficiencies, and to interpret results after corrective action procedures are implemented. Each method SOP includes a specific QC section that addresses the minimum QC requirements for the procedure. The internal QC checks may differ slightly for each individual procedure but a general description of the various types of QC checks are listed below.

7.1.1 Method Blank (MB) Analysis

A method blank is a "clean" sample (i.e., containing no analyte of concern), most often deionized water or nanopure water, to which all reagents are added and all analytical procedures are performed. Method blanks are analyzed at a rate of one per sample lot or at least every 20 samples. The blank is analyzed in order to assess possible contamination from the laboratory, and corrective actions are taken, if necessary.

Corrective Action: The method blank results should not exceed the reporting limits (RL). If high blank values >RL are observed, laboratory glassware and reagents are checked for contamination and the analysis halted until the system is brought under control.

7.1.2 Laboratory Control Sample (LCS) Analysis

A laboratory control sample is a blank water sample to which a known amount of the analyte of concern has been added. The sample then undergoes all the same preparatory procedures as the sample batch prior to analysis. They are analyzed at least 1 per batch of 20 or fewer samples. The LCS is used for all analysis, except for any method for which no check standards are available.

Corrective Action: If the LCS recovery does not meet the criteria specified by the method and SOP, analysis is halted; the batch is re-prepared from the beginning of the prep procedures and re-analyzed.

7.1.3 Matrix Spike/Matrix Spike Duplicate (MS/MSD) Analysis

To evaluate the effect of the sample matrix on the analytical methodology, a matrix spike is analyzed, and in some cases, a matrix spike/matrix spike duplicate is analyzed. The matrix spike/matrix spike duplicate (MS/MSD) is analyzed at a frequency of 10% for drinking water and 5% for other matrices. The percent recovery for the spiking compounds is calculated. The relative percent difference (RPD) between the MS/MSD is also calculated.

Whenever a new spike solution is prepared for an instrumental analysis, the preparation will be logged in the appropriate logbook or LIMS. A blank spike will then be prepared, usually in DI water, and analyzed for the relevant constituents. For the Inorganic Departments, the percent recoveries of all the analytes in the spike solution must fall between 90-110%. The Organic Department's recoveries must fall within their pre-established control limits. The acceptable results are then documented and maintained.

Corrective Action: The observed percent recoveries and RPD between the MS/MSD are used to determine the accuracy and the precision of the analytical method for the sample matrix. If the percent recovery and RPD results exceed the control limits as specified for each spiking compound, the sample is not reanalyzed, but the data is qualified. Poor recovery in matrix spike samples does not necessarily represent an analytical system out of control. It is possible that unavoidable interference and matrix effects from the sample itself preclude efficient recoveries.

For samples with interfering matrices, a special analytical technique called the method of standard addition may have to be employed. It consists of adding known incremental amounts of the target analytes to equal aliquots of the sample, and establishing a calibration curve from the responses. The native sample concentration is then calculated from the curve, and the interference is thereby eliminated.

7.1.4 Duplicate Sample Analysis

Duplicate analyses are performed to evaluate the precision and reproducibility of the method. Results of the duplicate analyses are used to determine the relative percent difference (RPD) between replicate samples. Duplicates are analyzed at a frequency of 10% for drinking water (5% for metals) and 5% for other matrices.

Corrective Action: If the precision value exceeds the control limit for the given parameter, the entire sample batch must be re-prepared and re-analyzed.

7.1.5 Check Standard Analysis (ICV, CCV)

Analysis of a second source check standard (ICV) is used to verify the

initial calibration curve and is performed immediately after each calibration. Preferably, the secondary source standard is obtained from a different vendor than the calibration standards. If no reliable secondary vendor is available, a separate lot number standard from the same vendor is allowed. Continuing Calibration Verification (CCVs) standards are analyzed after every 10 sample analyses, and at the close of each analytical run. Results of these data must be within the specified limits of the method, normally 90-110% of the true value. Some methods may allow for greater deviation.

Corrective Action: Check standard results that fall outside the method control limits require the re-analysis of all preceding samples, back to the last acceptable check standard. ICV failures require re-calibration.

7.1.6 Surrogate Analysis

Surrogate compounds are added to all samples, standards, and blanks for all organic chromatography test methods except when the matrix precludes its use or when a surrogate is not available. Poor surrogate recovery generally indicates a problem with the sample composition and are qualified and reported to assist in data assessment.

7.1.7 LCS and Matrix Spike Components (Organic Chromatography)

In general, all reportable components are in the spike mixes. However, in cases where the components interfere with accurate assessment (such as simultaneously spiking chlordane, toxaphene, and PCBs in Method 608), or the test method has an extremely long list of components (such as Methods 8270 or 8260) or components are incompatible, a representative number (10%) of the listed components are used as specified by the method. The selected components of each spiking mix represent all chemistries, elution patterns and masses and include permit specified analytes and other client requested components. No one component or components dominate the spike mixture. Poor spike recovery generally indicates a problem with the sample composition and is qualified and reported to assist in data assessment.

7.2 Detection Limits

For analytes where spiking is a viable option, detection limits are determined by a Method Detection Limit (MDL) study as described in 40 CFR Part 136. The method detection limit is initially determined for the compounds of interest in each method in laboratory pure reagent water, pre-cleaned sand, or glass beads.

MDL studies are generally performed according to the procedure in 40 CFR Part 136. MDL studies may also be performed by procedures specified in the reference method.
MDLs may also be established at higher concentrations than those determined in the MDL studies. MDL studies do not always provide an MDL that is reasonable,

and it is always better to establish an MDL that is reasonable than to report a false positive sample concentration.

An MDL study is not performed for any component for which the analytical technique relies on more direct measurement, such as (but not limited to) solids/residue testing, titrimetric methods, pH, color, odor, temperature, or dissolved oxygen. For these types of analytes, the detection limit is based on instrument capabilities and/or method specifications.

The Method Reporting Limit (MRL) is never established as lower than the lowest point in the calibration curve, unless specifically allowed or required by the method.

7.3 Selectivity

Absolute and relative retention times aid in the identification of components in chromatographic analyses and help evaluate the effectiveness of a column to separate constituents. Acceptance criteria for retention time windows are documented in each method SOP.

A retention time confirmation may be performed to verify a compound identification when positive results are detected on a sample from a location that has not been previously tested. Such confirmations are performed on organic tests except when the analysis involves the use of a mass spectrometer. Acceptance criteria for mass spectral tuning are contained in the various method specific SOPs.

7.4 Demonstration of Method Capability

Prior to acceptance and use of any method, satisfactory initial demonstration of method performance is required. This initial demonstration of method performance is performed each time there is a significant change in instrument type, personnel, or test method. The accompanying data is filed and available at all times for review if necessary.

8.0 Data Reduction, Review, Reporting, and Records

8.1 Data Reduction and Review

Data resulting from the analyses of samples is reduced according to protocols described in the laboratory SOPs. Computer programs used for data reduction are validated before use and checked regularly by manual calculations. All information used in the calculations (e.g., raw data, calibration files, tuning records, results of standard additions, interference check results, sample response, and blank or background-correction protocols) are recorded in order to enable reconstruction of the final result at a later date. Information on the preparation of the sample (e.g., weight or volume of sample used, percent dry weight for solids, extract volume, dilution factor used) is also maintained in order to enable reconstruction of the final result at a later date.

All data is reviewed according to laboratory procedures to ensure that

calculations are correct and to detect transcription errors. Spot checks are performed on computer calculations to verify program validity. Errors detected in the review process are referred to the analyst(s) for correction.

The analyst has the initial responsibility for proper instrument conditions and calibration, for the data meeting all method acceptance criteria, and for all calculations to be accurate. If this is not the case, the analyst has the responsibility to correct all deficiencies at the time they are discovered. When acceptance criteria are not met, appropriate corrective action is taken.

Before analytical results are reported to the client, they are subjected to a multi level data validation process. All data is validated against the acceptance criteria specified by the appropriate method. When data validation is finished, a Quality Assurance Audit checklist is completed. The Laboratory Director, QAM, or their designee approves all reports. All out-of-control conditions are reviewed by the Laboratory Director, the QAM, or their designee.

A complete SOP titled *Procedures for Data Management and Review* contains detailed information regarding the steps that all data is subjected to before being permitted to be reported to the client. The remainder of this section will discuss how data validation is performed for broad parameter categories. The requirements that are checked during validation are listed below:

- Holding Times - Sample holding times are verified by comparing the analysis dates with the sampling dates.

- Calibration - Daily instrument calibration using the correct number of standards and blank is verified. The correlation coefficient for standard curves is verified to be acceptable. Random recalculation of percent recoveries in the initial and continuing calibration verification standards is done to verify that acceptance criteria are met.

- Blanks - Contaminants are verified to be absent or at acceptable levels.

- Laboratory Control Sample (LCS) - One or more percent recoveries are recalculated to verify that the acceptance criteria are met.

- Duplicate Sample Analysis – Percent recoveries and relative percent difference are randomly recalculated to verify that they fall within the method specified control limits.

- Matrix Spike / Matrix Spike Duplicate - Percent recoveries and RPDs are randomly recalculated to verify that they meet acceptance criteria.

- Sample Results - Results are randomly recalculated to verify that all dilutions were factored in. The raw data is randomly checked to verify that the results fall within the linear range.

8.2 Report Formats and Contents

The results of each test, or series of tests, are normally compiled into a report which includes all the information necessary for the accurate interpretation of the results. Each report typically includes the following parameters:

1) The name and address of the laboratory, with the phone number.

2) The unique identification number and the total number of pages, with all pages sequentially numbered.

3) The name and address of the client.

4) The description and unambiguous identification of the sample(s) including any client identification code.

5) Qualifiers for results for any sample that did not meet method acceptance requirements, or for which any deviations or alterations from the SOP occurred during analysis.

6) Date and time of receipt of sample and sample collection, and date of sample preparation and analysis.

7) Identification of the test methods used.

8) Identification of whether data is calculated on a dry or wet weight basis.

9) Identification of the reporting units such as mg/l, ug/l, or mg/kg.

10) Clear identification of all test data provided by outside sources, such as subcontracted laboratories.

11) Clear identification of results with values below the Reporting Limit. (J flags)

12) Method Detection Limits and Reporting Limits

Exceptions and additions to this standard approach for reporting are allowed with approval of the Laboratory Director at the request of the client.

Material amendments to a test report after issue are made only in the form of a further document, or data transfer including the statement "Amended" with the appropriate date of amendment. Clients are notified promptly of any event such as the identification of defective measuring or test equipment that casts doubt on the validity of results given in any test report or amendment to a report.

8.3 Records

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

maximum of ten years.

Laboratory records generally consist of bound notebooks with pre-numbered pages, personnel qualification and training forms, equipment maintenance and calibration forms, chain-of-custody forms, work order forms, and analytical change request forms. All records are recorded in indelible ink and retained for five years. Records that are stored or generated by computers have hard copy or write-protected backup copies.

Any documentation errors are corrected by drawing a single line through the error so that it remains legible and is initialed by the responsible individual, along with the date of change. The correction is written adjacent to the error. An electronic audit trail is kept for all computerized changes in the LIMS.

Laboratory records include the following:

8.3.1 Standard Operating Procedures

Any revisions to laboratory procedures are written, dated, and distributed to all affected individuals to ensure implementation of changes.

8.3.2 Equipment Maintenance Documentation

Documents detailing the receipt and specification of analytical equipment are retained. A history of the maintenance record of each system serves as an indication of the adequacy of maintenance schedules and parts inventory. As appropriate, the maintenance guidelines of the equipment manufacturer are followed. When maintenance is necessary, it is documented in either standard forms or in logbooks.

8.3.3 Calibration Records & Traceability of Standards / Reagents

The frequency, conditions, standards, and records reflecting the calibration history of a measurement system are recorded.

8.3.4 Sample Management

A record of all procedures to which a sample is subjected while in the possession of the laboratory is maintained. These include records pertaining to:

a) Sample preservation including appropriateness of sample container and compliance with holding time requirement
b) Sample identification, receipt, acceptance or rejection and login
c) Sample storage and tracking including shipping receipts, transmittal forms, and internal routing or assignment records
d) Disposal of hazardous samples including the date of disposal

8.3.5 Original Data

The raw data and calculated results for all samples are maintained in

laboratory notebooks, logs, benchsheets, files or other sample tracking or data entry forms. Instrumental output is stored in a computer file or a hard copy report. These records include:

a) Laboratory sample ID code
b) Date of analysis
c) Instrumentation identification and instrument operating conditions
d) Analysis type and sample preparation information, including sample aliquots processed, cleanup, and separation protocols
e) All manual, automated, or statistical calculations
f) Confirmatory analysis data, when required to be performed
g) Review history of sample data
h) Analysts or operators initials/signature

8.3.6 QC Data

The raw data and calculated results for all QC samples and standards are maintained in the manner described in the preceding paragraph. Documentation allows correlation of sample results with associated QC data. Documentation also includes the source and lot numbers of standards for traceability. QC samples include, but are not limited to, laboratory control samples, method blanks, matrix spikes, and matrix spike duplicates.

8.3.7 Correspondence

Correspondence pertinent to a project is kept in the client project files.

8.3.8 Deviations

Any deviations from approved laboratory SOPs are reviewed and approved by the QA Manager or Laboratory Director. Data is properly qualified before release to the client.

8.3.9 Final Report

A copy of any report issued and all supporting documentation is maintained for 10 years.

8.3.10 Administrative Records

The following records are maintained:
1) Personnel qualifications, experience and training records;
2) Initial and continuing demonstration of proficiency for each analyst;
3) A log of names, initials and signatures for all individuals who are responsible for signing or initialing any laboratory record.

8.3.11 Radiation Safety Records

All documentation necessary to comply with CFR Title 10, Part 20 and California Code of Regulations, Title 17 are described in the laboratory's

radiation safety plan document. All radiation safety records and documentation are maintained for 10 years.

8.4 Document Control

A document control system is used to ensure that all staff have access to current policies and procedures at all times. Documents that are managed by this system include this Quality Manual and all SOP's. The system consists of a document review, revision and approval system, and document control and distribution.

All quality documents are reviewed and approved by the QA Manager and the Laboratory Director. Such documents are revised whenever the activity described changes significantly. All documents are reviewed annually, and originals are controlled by the QA Manager. Original copies are provided to the Lab Director and QAM for approval and wet signature. Electronic (PDF) or hardcopies are distributed to the appropriate staff after final approval. The QA Manager ensures that all revisions are distributed and implemented appropriately. The QAM maintains a control document listing all SOPs currently in use.

8.5 Confidentiality

All laboratory results and associated raw data are kept in confidence to the customer who requested the analyses. Access to laboratory records and LIMS data is limited to laboratory personnel except with the permission of the QA Manager or Laboratory Director. Certification related records are made available to authorized accrediting authority personnel. Where clients require transmission of test results by phone, fax, email, or other electronic means, staff will ensure confidentiality is preserved at all times.

9.0 Performance and System Audits

Systems are in place to monitor the effectiveness of the laboratory in carrying out the Quality Assurance Plan. These are described below.

9.1 Performance Evaluation Sample Program

The laboratory performs yearly studies in all required performance evaluation programs, such as the Water Supply, Water Pollution, UST, and Soil/Hazardous Waste studies. The laboratory only uses PT providers who are on the approved provider list. Studies are conducted on all analytes in the Fields of Testing for which the laboratory is certified and for which performance samples are available.

The results of all performance evaluation samples are reported to management and the staff by the QAM. The QAM also coordinates investigations and corrective actions on the deficiencies noted.

9.2 Regulatory Laboratory Audits

The laboratory undergoes a complete audit by our regulatory authority at least

every two years. Other external independent audits are performed at various intervals by other agencies and clients as required for their various QC programs.

9.3 Internal Laboratory Audits

At least annually, internal audits are performed to verify that laboratory operations continue to comply with the requirements of the quality system. Such audits are performed by the Quality Assurance Manager or his designee. Where the audit findings cast doubt on the correctness or validity of the laboratory's results, an immediate corrective action is initiated and any client whose work may have been affected is notified.

The internal system audits includes an examination of laboratory documentation on sample receiving, sample log-in, sample storage, chain-of-custody procedures, sample preparation and analysis, instrument operating records, etc. A standardized checklist system is employed to ensure that specific items are consistently reviewed for compliance. Copies of the final internal audit report, along with an associated corrective action report, are distributed to all laboratory personnel, including management.

For the radiological testing department, semi-annual audits to meet the RAM license safety requirements (as specified in the laboratory's Radiation Safety Plan) are performed by the Radiation Safety Officer and are documented.

9.4 Control Chart Monitoring

The Laboratory uses standard EPA CLP and EPA method criteria for all QC acceptance limits unless control charts are mandated by the specific method. The QAM periodically checks to see that each section is complying with any applicable control charting requirements.

All radiological analysis quality control limits are determined by control charting based on a minimum of 20 data points. 2 standard deviations are used to determine the warning limits, and 3 standard deviations are used to establish the out-of-control limits. These control charts are generated for the instrument detector performance, the background stability, and the precision and accuracy of the laboratory control samples.

9.5 Quality Assurance Management Report

Periodically, the laboratory QAM conducts a full review of the quality system to ensure its continuing suitability and effectiveness and to introduce any necessary changes or improvements in the quality system and laboratory operations. The review takes account of reports from managerial and supervisory personnel, the outcome of recent internal audits, assessments by external bodies, the results of proficiency tests, any changes in the volume and type of work undertaken, feedback from clients, corrective actions, and any other relevant factors. The QAM prepares a written report for all management and ownership personnel after completing the review.

10.0 Facilities, Equipment, Reagents, Computers, and Preventative Maintenance

10.1 Facilities

Basic Laboratory occupies a 7500+ square foot building in the City of Redding, California. The building has been customized to meet the ever growing needs of the laboratory, and includes semi-clean and clean room facilities for ultra low level analysis. All rooms are separated for proper segregation of operations that are not compatible with each other. Access to certain rooms in the laboratory is limited to authorized personnel only in order to decrease the possibility of cross contamination. Food and open drinks are prohibited in the laboratories at all times, and are limited to the break room area only. Basic Laboratory also operates a smaller facility in Chico, California of approximately 2500 square feet.

Adequate housekeeping measures are maintained in order to ensure that physical contamination does not negatively affect the quality of data.

10.2 Equipment

Records are maintained for each piece of major equipment. These records may include following information:

1) Name of the equipment
2) Manufacturer's name, type identification, and serial number
3) Date received and date placed in service (only if available)
4) Current location, where appropriate
5) Condition when received if available. (e.g. new, used, reconditioned)
6) Copy of the manufacturer's instructions, wherever available
7) Dates and results of calibration (scales, balances, pipettes, etc.)
8) Details of manufacture maintenance
9) History of any damage, malfunction, modification or repair.

10.3 Documentation and Labeling of Standards and Reagents

Records are kept for all standards, including the manufacturer/vendor, the manufacturer’s Certificate of Analysis or purity (if supplied), the date of receipt, recommended storage conditions, and an expiration date after which the material is not used unless it can be re-verified. After being verified and logged into the appropriate logbooks or LIMS, the original containers provided by the vendor are labeled with an expiration date and in-house identification number.

Detailed records are maintained on reagent and standard preparation. These records indicate traceability to purchased stocks or neat compounds, reference to the method of preparation, date of preparation, expiration date and preparer's initials. All containers of prepared reagents and standards bear a unique identifier and expiration date and are linked to the documentation requirements above.

1) Reagents - In methods where the purity of reagents is not specified, analytical reagent grade or better shall be used. Reagents of lesser purity are never used. The labels on the container are checked to verify that the purity of the reagents meets the requirements of the particular method.

2) Water - The quality of reagent grade water sources is monitored and documented to meet method specified requirements. In general, de-ionized or water with a resistivity of at least 18 megaohms is used.

10.4 Computers and Electronic Data Related Requirements

Where computers or automated equipment are used for the capture, processing, manipulation, recording, reporting, storage or retrieval of test data:

- Section 8.1 through 8.11 of the EPA Document "2185 - Good Automated Laboratory Practices" (1995), is used as the standard;
- Computer software is documented to be adequate for use;
- Procedures are established and implemented for protecting data integrity;
- Computer and automated equipment are maintained to ensure proper functioning;
- Appropriate procedures are used for the maintenance and security of data including the prevention of unauthorized access to, and the unauthorized amendment of, computer records.

10.5 Preventative Maintenance

Regular preventive maintenance, such as lubrication, source cleaning, and detector cleaning, is performed according to the procedures delineated in the manufacturer's instrument manual, including the frequency of such maintenance. Precision and accuracy data are examined for trends and excursions beyond control limits to determine evidence of instrument malfunction. Maintenance is performed when an instrument begins to degrade as evidenced by the degradation of peak resolution, shift in calibration curves, decreased ion sensitivity, or failure to meet one or another of the quality control criteria.

Instrument maintenance logbooks are maintained in the laboratory at all times. The logbook contains a complete history of past maintenance, both routine and non-routine. The nature of work performed, the date, and the initials of the person who performed the work are recorded in the logbook. Preventive maintenance is scheduled according to each manufacturer's recommendation. Instrument downtime is minimized by keeping adequate supplies of all expendable items, where expendable means an expected lifetime of less than one year. The instrument operator handles routine instrument preventive maintenance. All intensive repair and/or maintenance are generally performed by a specialized instrument technician.

11.0 Routine Procedures for Evaluating Data Quality

As discussed in previous sections, quality control acceptance criteria are used to determine the validity of the data based on the analysis of internal quality control check (QC) samples. The specific QC samples and acceptance criteria are found in the laboratory SOPs. Typically, acceptance criteria are taken from published EPA methods. Where no EPA criteria exist, laboratory generated acceptance criteria are established. Acceptance criteria for bias are based on the historical mean recovery plus or minus three standard deviation units, and acceptance criteria for precision range from zero (no

difference between duplicate control samples) to the historical mean relative percent difference plus three standard deviation units.

Analytical data generated with QC samples that fall within prescribed acceptance criteria indicate the laboratory was in control. Data generated with QC samples that fall outside the established acceptance criteria indicate the laboratory was "out-of-control" for the failing tests. These data are considered suspect and the corresponding samples are reanalyzed or reported with qualifiers.

Some published methods do not contain recommended acceptance criteria for QC sample results. Generally In these situations, Basic Laboratory uses 80-120% or 75-125% as standard acceptance criteria for recoveries of spiked analytes, unless in-house limits are developed. In-house limits are based on a 95% confidence interval and must include a minimum of 20 data points to be considered valid.

11.1 Laboratory Control Samples

A laboratory control sample (LCS) is analyzed with each batch of samples to verify that the accuracy of the analytical process is within the expected performance of the method. The results of the laboratory control sample are compared to acceptance criteria to determine usability of the data. Data generated with LCS samples that fall outside the established acceptance criteria are judged to be out-of-control. These data are considered suspect and the corresponding samples are reanalyzed. In some cases the data may be reported with qualifiers, but only if addition sample for re-analysis is unavailable.

11.2 Matrix Spikes / Matrix Spike Duplicates

Results from MS/MSD analyses are primarily designed to assess data quality in a given matrix, and not laboratory performance. In general, if the LCS results are within acceptance criteria, performance problems with MS/MSD results may either be related to the specific sample matrix or to an inappropriate choice of extraction, cleanup, or determinative methods. If any individual percent recovery in the matrix spike (or matrix spike duplicate) falls outside the designated acceptance criteria, Basic Laboratory will determine if the poor recovery is related to a matrix effect or a laboratory performance problem. A matrix effect is indicated if the LCS data are within acceptance criteria but the matrix spike data exceed the acceptance criteria. Data associated with a failed MS/MSD are reported with the appropriate qualifiers.

11.3 Surrogate Recoveries

Surrogates are normally used in organic analyses. Surrogate recovery data from individual samples are compared to surrogate recovery acceptance criteria in the methods, or to established limits based on control charts. Along with the MS/MSD results, surrogate recoveries are used primarily to evaluate data quality based on sample matrix, and not necessarily laboratory performance. Data associated with failed surrogate recoveries is normally reported with the appropriate qualifiers.

11.4 Method Blanks

Method blank analyses are used to assess acceptance of sample results. If method blank results are detected above the reporting limit, the source of contamination is investigated and measures taken to correct, minimize or eliminate the problem. Under most circumstances the entire sample batch is re-prepared and re-analyzed, unless:

- The blank contamination is less than 1/10th the measured concentration of any sample in the associated sample batch or

- The blank contamination does not exceed the concentration present in the samples, and is less than 1/10th of the specified regulatory limit.

Each sample in the affected batch is assessed against the above criteria to determine if the sample results can be reported with qualifiers. All samples associated with the contaminated blank are reprocessed for analysis or the results are reported with appropriate data qualifying codes.

12.0 Corrective Actions

The laboratory has a Corrective Action Program that ensures the proper documentation and dispositions of conditions requiring corrective action. The system also ensures that the proper corrective action is implemented to prevent recurrence of the condition.

The Corrective Action Program applies to all situations that impact data quality. Any QC sample result outside of acceptance limits requires corrective action. Once the problem has been identified and addressed, corrective action may include the reanalysis of samples, or appropriately qualifying the results. These situations may include, but are not limited to, quality control criteria being exceeded, statistically out-of-control events, deviations from normally expected results, suspect data, deviations from the standard operating procedure, and special sample handling requirements.

The procedure consists of documenting the condition requiring corrective action on a simple Corrective Action Report and implementing corrective action based on the results of the investigation performed to determine the cause of the condition.

Most batch QC failures (MB, LCS, CCV, etc.) are immediately corrected by the analyst through re-analysis and do not require a written corrective action report. When a significant condition requiring written corrective action arises such as reoccurring QC failures or SOP deviation, a Corrective Action Report is initiated. The initiator describes the condition requiring corrective action. An investigation, if necessary, is conducted to determine the cause of the condition. A corrective action is recommended based on the results of the investigation.

The Corrective Action Report is reviewed by the supervisor and QAM who either approve the recommended corrective action or indicate the appropriate corrective action.

The Quality Assurance Manager has the responsibility of following up and making sure that the corrective action is implemented. Implementation of the corrective action is documented by the Corrective Action Report being signed and dated by the person who implemented the corrective action, along with the appropriate department supervisor,

and also by the QAM.

13.0 Subcontracting and Support Services

13.1 Subcontracting Laboratory Services

Clients are advised before or upon sample receipt if any analyses will be subcontracted to another laboratory. Any subcontracted work is placed with another accredited laboratory for the tests to be performed. The following records of all subcontracted analyses are maintained:

- A copy of the subcontracted laboratory's scope of accreditation
- A copy of the report from the subcontracted laboratory

Each report package that is sent to the client clearly identifies which data was performed in-house, and which data was sent to a subcontracting laboratory. In most cases the entire original report from the subcontracted laboratory is sent to the client with all supporting documentation. Copies are maintained in our files.

13.2 Outside Support Services and Supplies

Basic Laboratory only uses those outside support services and suppliers that are of adequate quality to sustain confidence in the laboratory's tests. Records of all suppliers for support services or supplies required for tests are maintained.

14.0 Laboratory Information Management System (LIMS)

14.1 General Information

Basic Laboratory uses ELEMENT Datasystem, developed by Promium LLC, as our electronic database and reporting system, know as our LIMS. Promium LLC is located in Bothell, Washington, and can be contacted by phone at 425-286-9200, or by visiting their website: www.promium.com.

14.2 Security

Access to the LIMS is strictly monitored at all times. Each employee is given a unique username and password, which they must use to login to the system. Varying levels of access and priority are set for different types of employees. Analysts are not able to update their own data to reviewed status, only managers have this privilege. Only certain management employees can update work order status to Completed. These levels of access to the database allow us to maintain multiple crosschecks to ensure that all data is properly reviewed and processed.

The computer system that hosts the LIMS is kept up to date with the latest anti-virus protection available. Diagnostics are regularly performed on the system to ensure that problems do not develop that could undermine its integrity.

14.3 Updates

Occasionally Promium provides us with software updates that are designed to enhance performance or correct problems with the system. These updates are applied whenever they are received from Promium in order to keep our software as current as possible. Only the database administrator has access to the update website from which the updates are downloaded to our server.

14.4 Backup

The computer server that hosts the laboratory network and LIMS is designed with the latest backup technology available. First, each physical server is “mirrored” using virtualization software to another physical server to eliminate the possibility of physical hardware downtime. Second, snapshot backups of all data are recorded every 2 hours. Third, a full backup is uploaded and stored offsite every night on a secure remote server.

14.5 Audit Trail

All actions performed by any person logged into our LIMS is recorded and kept indefinitely in the database. Each action can be traced to time, place, and person, along with details of the action performed.

15.0 References

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