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QUALITY ASSURANCE MANUAL

of

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E.S. Babcock & Sons, Inc. has no parent corporation or subsidiaries and is located at 6100 and 6110 Quail Valley Court, Riverside, CA 92507.

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1 INTRODUCTION

This document outlines the Quality Assurance procedures implemented by **Edward S. Babcock and Sons, Inc.**, a privately owned environmental laboratory involved primarily in the testing of drinking water, wastewater, soils, and other matrices (http://www.babcocklabs.com/). This document describes the framework by which the laboratory establishes and maintains a documented quality system appropriate to the type, range, and volume of environmental activities it undertakes. This document outlines the laboratory's policies and procedures established in order to meet the requirements set by the National Environmental Laboratory Accreditation Conference (NELAC, http://www.epa.gov/ttn/nelac/) for National Environmental Laboratory Accreditation Program (NELAP) accreditation. Other documents and procedures will be referenced and should be consulted for specific details. The quality system is maintained to provide accurate and dependable data for the laboratory's clients. It is the responsibility of each employee to be familiar with and implement the quality control practices of the laboratory. Additionally, management is responsible for maintaining Quality Assurance (QA) in all aspects of the operation.

2 MISSION STATEMENT

The goal of Edward S. Babcock & Sons, Inc. is to produce the highest-quality, most reliable environmental services and analytical data possible.

3 OBJECTIVES

In order to achieve the goal of Edward S. Babcock & Sons, Inc. (ESB), the corporate officers, board of directors, and managers are committed to the following objectives:

A) To provide professional service to our clients and the community, drawing on the many years of experience in the analytical testing industry.

B) To produce scientifically valid and legally defensible data.

C) To promote ethical standards and professional integrity within our organization and the environmental community.

4 FLOW OF RESPONSIBILITY:

The flow of responsibility within the laboratory is as follows:

A) President, General Manager, and Laboratory Technical Director.
B) Quality Assurance Manager and Assistant QA Manager.
C) Supervisors.
D) Chemists.
E) Technicians.

The President is responsible for the business functions of the laboratory. The General Manager oversees the office and the generation of all final reports. The Director is in control of the operations of the laboratory. The QA Manager and Assistant QA Manager have access to the President, General Manager, and Director and are responsible for the system to review all quality control data generated by the laboratory. The Supervisors are accountable for the smooth operation of their sections, meeting holding time deadlines, reviewing data, and troubleshooting problems. The chemists and technicians are held responsible for following prescribed protocols in the performance of their assigned analyses, and keeping their supervisors apprised of any difficulties that could affect the accuracy of results or the smooth operation of the laboratory.

The President and General Manager are named as Deputy Technical Directors and fulfill that responsibility when the Laboratory Technical Director is absent. The Assistant QA Manager and Project Manager are named as Deputy QA Officers and fulfill that responsibility when the QA Manager is absent.

Job descriptions for the Laboratory Technical Director and the QA Manager are attached to this document in appendices. Job descriptions for all positions are maintained in the personnel files.

When laboratory documentation refers to the QA Managers, these are the QA Manager and Assistant QA Manager. The QA Department includes the QA Managers and their designees performing tasks under the direction of the QA Managers. The members of the QA Department may also be referred to as QA Officers. The QA Office is the location of the QA Managers desks and where they maintain their files.

5 LABORATORY CAPACITY

It is the responsibility of the Laboratory Technical Director to ensure adequate capacity for all new projects prior to commencing work. The system used to determine laboratory capacity is based on the time taken to analyze a batch of samples for a given analyte, the number of analysts and labor hours available, and the equipment at hand. Each test is monitored for frequency of request on a weekly basis. When new work is contemplated, workloads are reviewed to determine what number of samples can be added while remaining within the laboratory capacity to perform the work.

6 CONFIDENTIALITY

Laboratory reports and accompanying documents contain confidential information intended for use by the individual or entity requesting and

purchasing the analytical services. Except when required by law, no information relating to a report is released to another person or party without permission from the paying client.

Permission to release information may be given by telephone or in writing. Documentation of consent, including the name of the person and the date/time of consent, is recorded in the client file.

Faxes clearly identify the intended recipient. The fax coversheet utilized by Edward S. Babcock & Sons contains a statement at the bottom of the sheet stating that the contents of the fax are confidential and intended only for the recipient.

Employees are informed of this policy during new employee orientation.

7 EXCEPTIONAL CIRCUMSTANCES

In the event that it is necessary to deviate from a documented policy, procedure or specification, several steps must be taken for approval of the exception. The QA Manager and Laboratory Technical Director meet to discuss and research the proposed exception. When circumstances are such that the QA Manager and Lab Technical Director agree that permission to deviate from policy, procedure or specification is warranted, the following steps must be taken.

A) Where applicable, the client is contacted for approval of the proposed change in procedure and written approval is requested and receipt verified.
B) The agreed upon change in policy, procedure, or specification is documented and kept in the QA files.
C) Copies of the change are attached to the analytical records, where applicable.

D) Copies of the change are attached to the review reports for any analyses directly related to the change.
E) Copies of the change are filed in the client report file.

8 COMPLAINTS

Client concerns regarding any aspect of laboratory services are directed to the Client Services Manager, the Marketing Director, or their designee. Questions or concerns from representatives of regulatory agencies are directed to the Laboratory Technical Director or a manager designated as a Deputy Technical Director. For any question or concern, the problem is first researched and the circumstances surrounding the incident are ascertained.

Where analytical results are at issue, the data is re-verified by the QA Manager or Supervisor. If the sample is still available a re-analysis may be requested to verify the original data. Where an error is identified, an amended report is issued.

If the investigation of any question raises doubt about compliance with the established laboratory policies, procedures or the quality of calibrations or test, the area of concern is audited in accordance with the audit section of this document. For more information on the forms, refer to the Quality Control Follow-Up Forms SOP (Q24).

9 RECORD KEEPING

All Analyses:

The laboratory information management system (LIMS) maintains records of Quality Control (QC) performance data and client samples data. An analytical run (listed in the laboratory information management system as a “Batch”) contains calibration standards, blanks, lab control samples, replicate analyses, matrix spikes, matrix spike duplicates, and sample data

analyzed as a group and may contain one or more analytical batches. For more information on data records, refer to the Records Management SOP (A02). It is the responsibility of the QA Manager to periodically review LIMS-generated records of QC performance data and to update acceptance criteria, as needed. For more information on the QC data review, refer to the Statistical Evaluation of Quality Control Data SOP (Q03).

Chemical Analyses:

Analytical runs are recorded in a notebook for that particular analysis. Other information included in the notebooks is:

A) Sample preparation.
B) Method of analysis.
C) Name of analyst.
D) Date of analysis.
E) QC results and acceptance criteria.

10 RECORDS MANAGEMENT

All hard copy and electronic records are stored on-site, or at an independent archive facility, for at least 5 years. After the archive period, the records are destroyed by a reputable records archiving and disposal company. Records maintained for at least five years include:

A) LIMS electronic files.
B) Raw analytical data files, hard copy and electronic.
C) QC data files including standard verification, control charts and corrective action reports.
D) Analytical data review reports
E) Client files including all final reports, Chain of Custody forms, Analysis Request Forms, and other correspondence.

F) Personnel files including:
   a. Personnel qualifications, experience, and training records.
   b. Initial demonstration of capability (IDOC) and demonstration of continuing proficiency (DOCP) for each analyst or analytical cell.
   c. A log of names, initials, and signatures for all individuals who are responsible for signing or initialing any laboratory records.
   d. Standard Operating Procedure (SOP) signature sheets.

G) Business files including accounts payable, accounts receivable and payroll data.

Records are stored according to category in standard cardboard file boxes labeled with the category of records, date range, and descriptive information. A unique container number further identifies containers stored off-site.

There is a document control system indicating the time period during which a procedure, manual, or document is in effect. For more information regarding record management, refer to the Records Management SOP (A02) and the SOP Modification Policy (Q23).

11 TEST METHODS UTILIZED BY THE LABORATORY

ESB uses appropriate test methods and procedures for all tests and related activities within its responsibility (including sample collection, sample handling, transport and storage, sample preparation, and sample analysis). The methods and procedures are consistent with the accuracy required, and with any standard specifications relevant to the calibrations or tests concerned.

A) When the use of a specific test method for a sample analysis is mandated or requested, only the specified method is used.
B) When similar tests are combined in an analytical run, the most stringent method requirements are followed.
C) Where test methods are employed in a Performance Based Measurement System approach, the methods are fully documented and validated, and are available to the client and other recipients of the relevant reports.

Test Methods currently used by E.S. Babcock & Sons may be found in *SW-846, Test Methods for Evaluating Solid Wastes Physical/Chemical Methods*, 3rd edition Update III 1996, *Methods for the Determination of Metals in Environmental Samples*; EPA 600-R-93/100; *Methods for the Determination of Metals in Environmental Samples, Supplement I*, EPA-600/R-95/111, EPA 500 and 600 series methods included or referenced in the Federal Register; and *Standard Methods for the Examination of Water and Wastewater*, 18th, 19th, and 20th editions, APHA/AWWA/WEF, or other approved or accepted methods.

12 HOUSEKEEPING AND SAFETY

Each analyst is responsible for keeping his or her work areas as neat and clean as possible. Each employee is warned of potential safety problems and is advised to be familiar with the following:

A) A permanent eye wash fountain is available in each of the prep labs.
B) A drench-type safety shower is available in each of the prep labs and in the inorganic lab.
C) Fire extinguishers are placed at several locations throughout the laboratory. They are easily found by signs that display their location. Analysts should be aware of the fire extinguishers

located in their work areas. All fire extinguishers are serviced annually by contract with an outside company.

D) Chemical spill kits are centrally located and are available for solvents, mercury, and acids.
E) First Aid kits are located in every lab. A fire blanket is located in each of the prep labs.
F) Flammable solvents are stored in an explosion proof cabinet with appropriate venting or below the hoods.
G) Evacuation plans are posted at several locations in the laboratory.
H) There is a Material Safety Data Sheet (MSDS) Library centrally located and readily accessible to all personnel.

Copies of the laboratory *Chemical Hygiene/Injury Illness Prevention Plan* and *Business Emergency/Community Right-to-know Plan* are accessible to all personnel.

13 SAMPLING

Each member of our Field Department has a detailed knowledge of proper sampling techniques, sample handling procedures, and the criteria for sample acceptability. Field Department employees are trained in the proper safety requirements and precautionary measures to be used in field activities and have read and agreed to follow Field Sampling SOP (F02). The Field Department employees are advised to discuss with the on-site supervisor (if applicable) all steps necessary in obtaining the most representative sample possible – especially in unusual sampling situations. The Field Department and Log-in employees have each read and agreed to follow the Sample Acceptability SOP (A08). Samples are collected only in approved containers. Approval is based on the following requirements:

A) **Containers must be compatible with the sample and contain an adequate volume of sample.** The sample must not cause the container to corrode and the container must not contaminate the sample. It must be of sufficient volume to hold enough sample for the required analyses – if not, multiple containers may be used, if needed.

B) **Containers must be made of approved materials.** For most uses, containers may be made of LPE plastic. Soda glass or borosilicate with Teflon is used for organic sampling. Plastic zip-lock bags or Mason jars are acceptable for many types of solid samples. For source gas emissions, tedlar bags, canisters, and absorbent traps are commonly used.

C) **Containers must be sterile for bacterial analysis.** Sterilized containers and lids are utilized for all bacterial analyses. A capacity of at least 100 ml is required. For bacteriological samples, we recommend sealing the containers in a zip-closure bag after collection for transport to the lab.

The next section discusses other criteria used to determine sample acceptability including sample preservation, sample temperature, sample holding time, and condition of sample seal or evidence tape (if present).

The preservation and storage of samples varies according to the analyses to be performed. Proper preservation and storage may be found in *SW-846, Test Methods for Evaluating Solid Wastes Physical/Chemical Methods,* 3rd edition Update III 1996 and in the *Handbook for Sampling and Sample Preservation of Water and Wastewater,* Sept 1982 EPA-600/4-82-029.

For more information regarding sample collection, refer to the Field Sampling SOP (F02).

14 SAMPLE IDENTIFICATION, CUSTODY, AND TRACKING

All written records are in indelible ink. For more information regarding sample acceptability, receiving and log-in, refer to the Sample Acceptability SOP (A08) and the Sample Receiving/Log-in SOP (A03).

Sample Identification

The samples are labeled in the field. The identification on the label includes the following. The information must be presented in such a way that the sample is uniquely identified and include the following:

A) Identification of the sample.
B) The sampler's name.
C) The date the sample was taken.
D) The time (24-hour clock) the sample was taken.
E) The client's name.
F) Any significant item's regarding the analysis is noted (e.g. tests to be performed, temperature upon sampling, chlorine residual, preservation, if the sample is a composite or grab, miscellaneous comments, etc.)

Sample seals may be used to indicate possible tampering with the sample from the time of collection until the sample arrives at the laboratory – this is especially important for samples that may be used for litigation purposes and are delivered to the laboratory by the client or a third party.

Chain of Custody

When necessary, a Chain of Custody form is filled out. A Chain of Custody is required whenever the potential exists that the sample may be used for litigation. An example form is included in Appendix I. For more information on litigation samples, refer to the Legal/Evidentiary Custody for Litigation Samples SOP (A01). This form contains all of the above information included on the label and also "Relinquished by" and "Received by" blocks for the name(s) of the person(s) who submit or release the sample and the name(s) of the person(s) who receive the sample along with the date(s) and time(s) that the custody of the sample changes hands. The Chain of Custody also includes information relating to sample acceptability. The LIMS also contains an internal Chain of Custody.

Sample Receipt Form

Whenever a Chain of Custody is not submitted with a sample, a Sample Receipt Form is filled out to document sample acceptability. This form lists the sample description and E.S. Babcock's laboratory number to unequivocally tie the form to the field sample. An example form is included in Appendix I.

Field Records

Field technicians maintain a logbook to document all of their sampling activities. This logbook contains pertinent information regarding collection of samples, including:

A) Name of contact
B) Location of sampling point
C) Date and time (24-hour clock) of collection
D) Field measurements
E) Comments
F) Any other information that is required by the Project Plan.

G) The field technician retains a copy of each Chain of Custody accompanying that day's samples.

Sample Tracking: Laboratory Information Management System

The laboratory has in place a LIMS for the tracking of all samples from the time they are logged in until the final report leaves the laboratory. At any step in the process, current information regarding the status of the sample can be obtained from the computer. The computer also keeps track of holding times and due dates.

Log-in of Samples

After the sample is collected, custody of the sample is turned over to the laboratory at the front counter. The log-in personnel verify sample acceptability – documenting acceptability on the Chain of Custody or a Sample Receipt Form. The client is contacted if any of the following occur:

A) The container is leaking or damaged.
B) The Chain of Custody seal is broken, if present.
C) The identification of the sample is not the same as that on the Chain of Custody (if the identification is not very different, the information is noted without necessarily contacting the client), if present.
D) The sample is received past holding time (or likely to expire before the lab is able to perform the test).
E) The temperature of the sample exceeds $30^{o}C$.
F) The sterility of the sample container is questionable, if for bacteriological analysis.

The client must verbally authorize the lab to proceed with analysis if any of the above conditions are observed. This authorization is noted on the Sample Receipt Form or the Chain of Custody.

The department supervisor is informed if the samples are not preserved properly, incorrect containers are used, inappropriate sample size is provided, holding times have been exceeded, or any other problems occur so that corrective action, either in the lab or through the client, may be taken. Proper notation and warning is given before any sample is accepted under the conditions above.

Upon acceptance of the sample from the field technicians or directly from a client, the sample is logged-in.

Every laboratory number or SampleID number that is assigned corresponds to a specific sample. The computer generates this number. The information in the computer must unequivocally link the sample to the field identification. Other information recorded in the computer includes the following:

A) The name of the person, company, or agency requesting the analysis.
B) The sample description (corresponding to the field identification).
C) The date and time (24-hour clock) the sample was taken and the identity of the sampler.
D) The date and time (24-hour clock) the sample is submitted to the laboratory and the identity of the person submitting the sample.
E) The identity of the person logging in the sample.
F) The sample matrix.
G) The type of sample container.
H) Sample preservation (see also the Bottle Preservation SOP A09).

I) A note is added if an evidence tape and/or seal are present.

J) Analyses requested - Constituents.

K) Chain of Custody (Y or N).

L) If thermal preservation is required, the temperature of the sample at receipt. (If recently collected, is the sample on ice?)

M) Any other pertinent information (such as any abnormalities or departures from the condition specified in the test method, reporting limit requests, high level QC or QC review requests, contact details, sample preservation exceptions).

After Log-in, two items are generated by the LIMS:

(1) A **Work Order Report** containing information such as Client ID, Laboratory Number, analyses requested, and date/time of receipt is printed. These reports are kept sequentially in three-ring notebooks. The Sample Custodian, the Office Manager, and/or the Project Manager initial the report and verify the log-in information. The Chain of Custody/Sample Receipt Form (including any common carrier documents received) and any other paperwork submitted with the samples are placed in the binder with the Work Order Report. These documents are pulled for inclusion with the final report when the laboratory completes the analysis.

(2) A durable, water resistant, computer-generated **sample label** is printed and affixed to each sample. Every sample container received from the client is uniquely identified on the label with the laboratory reference number and an alpha character (A, B, C) indicating the specific container. Sample preservation is verified and, if necessary, adjusted prior to storage in the proper holding areas. For more information on sample preservation and storage, refer to the Sample Splitting, Preservation, Storage, and Disposal SOP (A06).

For microbiological samples, in addition to the Work Order Report and labels, the lab sheet may be printed from the LIMS.

15 IDENTIFICATION AND STORAGE OF SUBSAMPLES, EXTRACTS, AND DIGESTATES

Unique laboratory numbers generated by the LIMS identify all sample containers. When sub-samples, extracts and/or digestates are made, each additional container is uniquely identifiable. Sub-samples taken for preservation indicate the preservative added in addition to the SampleID number. Vials containing extracts for Organic determinations indicate the SampleID number, the Method Number and the extraction date. Digestate storage containers indicate the laboratory number and type of preparation – each preparation batch on any one date is also color-coded. All sub-samples, extracts, and digestates are stored according to the applicable preservation or the test method requirements.

16 TRANSPORTATION OF SAMPLES

Once samples have been received, they do not leave the premises. Office employees personally place the samples in the refrigerator (temp 2-6 °C) in the proper holding section, in the proper area of the sample storage room, or in the proper analytical section of the lab. Storage of samples must follow preservation protocols. Any relevant instructions regarding storage accompanying the sample must be followed. Samples are stored separate from standards, food, and other sources of potential contamination. Any pertinent information regarding the samples must be discussed with the department supervisor.

All analysts (names and dates) handling the sample are documented electronically in LIMS or on the paperwork associated with the sample and its analysis. Samples that have been completed are held in the storage

area for at least one month – at which time they are disposed of in the proper manner. Occasionally, samples for litigation purposes might be held for a longer period of time at the request of the client or samples may be returned to the client. All doors in the laboratory are locked securely and the entry alarm is armed when no approved personnel are present.

17 EMPLOYEE ORIENTATION

All new employees receive orientation to the company and its mission. Orientation includes familiarization with the E. S. Babcock & Sons, Inc. Employee Manual, the Quality Assurance Manual, the Ethics and Data Integrity Manual, and Laboratory Safety Training. The Employee Manual discusses the standards of conduct, which are expected of all employees, including confidentiality of information. In detailing the contents of the Ethics and Data Integrity Manual, the employee also receives instruction regarding his/her ethical and legal responsibilities and the potential penalties for improper, unethical, or illegal actions. All employees are required to sign a statement acknowledging they have been provided with this information and that they have read and are familiar with the manuals. Statements are on file in the Human Resources or QA Files. As stated in the Ethics and Data Integrity Manual (Appendix F), an ESB Quality Control Follow-up Report may be used to document challenges presented to the Ethics and Data Integrity Program. However, if any possibility of serious potential unethical behavior has been raised, an official Ethics Investigation will be initiated and the committee will report its findings to the President.

18 STANDARD OPERATING PROCEDURES (SOPs)

ESB maintains Standard Operating Procedures (SOPs) that accurately reflect all phases of current laboratory activities such as assessing data integrity, corrective actions, handling customer complaints, and all test methods. Some features of the SOPs include:

A) These documents are internally written documents.
B) For analytical tests, copies of published methods are used initially until the internally written SOP has been developed. Any deviations from the test method are documented *in italics*.
C) Copies of all SOPs are accessible to all personnel. Personnel must read all SOPs that are applicable to their assigned tasks and sign a statement that they have done so.
D) The SOPs are organized.
E) Each SOP clearly indicates the effective date of the document, the revision number and the signature(s) of the approving authority (the technical director or his designee).
F) All SOPs are reviewed at least annually – method SOPs are reviewed when the method is audited; all other SOPs are reviewed as procedure change or at a yearly interval – whichever is more frequent.

19 THE LABORATORY METHOD MANUAL

The laboratory has and maintains an in-house Methods Manual consisting of individual SOPs for each accredited analyte or test method. For more information regarding SOPs, refer to the SOP Modification Policy SOP (Q23). This manual consists of copies of published or referenced test methods or the laboratory SOP. Each test method includes or references, where applicable:

A) Identification of the test method.
B) Applicable matrix or matrices.
C) Detection limit.
D) Scope and application, including components to be analyzed.
E) Summary of the test method.
F) Definitions (see also the Definitions SOP Q15).

G) Interferences.
H) Safety (see also the Safety SOPs S01-S07).
I) Equipment and supplies (see also the Equipment Maintenance SOP Q21).
J) Reagents and standards (see also the Reagent Quality and Documentation SOP Q05 and the Standard Quality and Documentation SOP Q08).
K) Sample collection, preservation, shipment and storage (see also the Bottle Control SOP Q13, the Holding Times/Due Dates SOP Q07, and the Sample Containers, Preservation Techniques, and Holding Times for Aqueous Matrices SOP Q14).
L) Quality control (see also the Quality Control Data SOP Q01).
M) Calibration and standardization.
N) Procedure (see also the General Laboratory Techniques SOP Q04 and the Good Automated Laboratory Practices SOP Q17).
O) Calculations.
P) Method performance.
Q) Pollution prevention (see also Pollution Prevention SOP S07).
R) Data assessment and acceptance criteria for quality control measures (see also the Procedure for the Integration of Chromatographic Peaks SOP Q18).
S) Corrective actions for out-of-control data (see also the Corrective Action for Chemical Analyses SOP Q06).
T) Contingencies for handling out-of-control or unacceptable data.
U) Waste management (see also Pollution Prevention SOP S07).
V) References.
W) Any tables, diagrams, flowcharts and validation data.

It is the policy of Edward S. Babcock & Sons that the Quality Control protocols specified by the Laboratory Methods Manual be followed.

20 DEMONSTRATION OF PROFICIENCY

In order to demonstrate the suitability of a test method for its intended purpose, Edward S. Babcock, Inc demonstrates and documents its ability to meet acceptance criteria either specified by the method, or by the Environmental Protection Agency (EPA), or the State program requirements. Acceptance criteria meet or exceed these requirements and demonstrate that the test method provides correct/expected results with respect to specified detection capabilities, selectivity, and reproducibility.

Microbiological Analyses

The Microbiology laboratory utilizes accepted (official) test methods or commercialized test kits for official test methods. Proficiency with the test method is demonstrated prior to first use. Microbiological test methods are validated in terms of specificity and reproducibility by the use of positive and negative controls covering all aspects of the test. For details, please see the Bacteriology General Procedures and Quality Control SOP (B01). The validation of microbiological test methods is performed under the same conditions as those for routine sample analysis.

Chemical Analyses

Laboratory

The laboratory performs a Demonstration of Capability (IDOC) as required by the method and/or the certifying agency, as detailed in the Quality Control Data SOP (Q01). A follow-up is performed on any analyte that fails the laboratory acceptance criteria and an additional IDOC is performed for that analyte.

Work Cells

Whenever there is a significant change in the method or instrument, where Work Cells are used, the group must perform a Demonstration of Capability (IDOC) as a unit. When a new analyst is added to the cell, the

analyst may work with an experienced analyst until the next four consecutive Laboratory Control Samples (LCSs) meet acceptance criteria are submitted to the QA Department to demonstrate and document analyst proficiency, using a Work Cell Change Form or perform a new IDOC. (See instructions for IDOC under Analyst section C.)

Analyst

New employees or employees assigned new procedures undergo the following training:

A) The analyst reads the applicable SOP and is shown the procedure by the supervisor or other designated trainer.
B) The analyst performs the procedure (or their part of the procedure when working with a Work Cell) under direct supervision until the trainer is confident that the analyst can perform the procedure unsupervised.
C) The analyst performs a Demonstration of Capability (IDOC). The IDOC is performed using either: 1) the method criteria or 2) four aliquots of sample are analyzed at a concentration of 5-50 times the method or laboratory generated detection limit. The aliquots may be either analyzed concurrently or over a period of several days (as long as they are consecutive for the analyst). The standards are from a source separate from the calibration. The average is calculated in the units used for reporting. The average and either the standard deviation or RSD are compared to method or, in the absence of method requirements, in-house acceptance criteria for recovery and reproducibility. If standard is not available for spiking, four aliquots are analyzed at a readable concentration and compared to in-house acceptance criteria for reproducibility. After follow-up, test parameters that fail are reanalyzed with

additional aliquots until they meet the criteria. During this training period, the trainer will co-initial any analyses of client samples by the trainee. The IDOC certificate along with supporting raw data is kept in the QA files.

D) Note: If the analyst is assigned to an existing Work Cell, the new employee trains under an experienced analyst in that area of the Work Cell. This new Work Cell must demonstrate acceptable performance through acceptable continuing performance checks (such as laboratory control samples). Such performance is documented and at the end of the new analyst's training period. Four consecutive preparation batches must meet LCS and Blank acceptance criteria or the IDOC must be repeated for the cell. In addition, if the entire Work Cell is changed/replaced, the Work Cell must perform an IDOC.

E) Notebooks and calculations of the new analyst are reviewed by a peer reviewer.

F) A training log is completed to document the training of the new analyst, including information such as the analyst name, trainer name, method, date SOP read, and date of IDOC or other demonstration.

G) Annually, the analyst must perform a Demonstration of Continuing Proficiency (DOCP), as detailed in the Quality Control Data SOP (Q01). If the analyst has performed an IDOC during that calendar year that will remove this requirement for that calendar year. If the analyst is part of a Work Cell that adds an employee with a Work Cell Change Form or has performed an IDOC that will also remove this requirement for that calendar year. Demonstration of Capability Certification Statements (IDOC), DOCP, and Work Cell Change Form records are kept in the QA files.

21 METHOD DETECTION LIMIT

The method detection limit (MDL) is verified statistically for each analytical method and for aqueous and non-aqueous matrices, as applicable. A minimum of seven replicates of a spiked matrix are processed and analyzed at a concentration of 2.5-5 times the estimated method detection limit or per method specifications. The standard deviation is calculated. The statistical method detection limit is the standard deviation multiplied by the student's T factor for the number of replicates at a 99% confidence level and multiplied by any preparation or dilution factor (the student's T factor for seven replicates at a 99% confidence level is 3.14). The reporting limit must be equal to or above the calculated statistical MDL except for special organic analyses (see Q01 for reporting limit requirements). MDL studies for each analytical procedure are performed per method requirements or whenever major changes in the instrument or procedure occur.

22 PROFICIENCY TESTING (PT) SAMPLES

E.S. Babcock & Sons, Inc. participates in PT studies at least twice each year in each field of accreditation (per matrix-technology/method-analyte/analyte group) in order to maintain accreditation. Certified samples are purchased, where available, from a National Voluntary Laboratory Accreditation Program (NVLAP) approved vendor.

If the laboratory receives a "Not acceptable" result for a PT sample, a Corrective Action: ESB PT Follow-up Form is completed. The data is reviewed and the findings documented. These are reviewed by a QA Manager, signed by the Laboratory Director, and a copy is mailed to the accrediting authority/certifying body (for DMRQA studies, a copy is also sent to any affected DMRQA clients). If the laboratory receives a "Not acceptable" result for two out of three of the last PT samples, the laboratory will order supplemental PT samples from an approved vender

(such as Environmental Resource Associates) every 60 days until a history of passing two out of three PT samples is reestablished.

23 QUALITY CONTROL REQUIREMENTS

For details on laboratory technique, equipment, and instrumentation, see the Equipment Maintenance SOP (Q21) and the General Laboratory Technique SOP (Q04). The following is a general summary however, the current Q04 or Q21 SOP will supercede

Equipment and Instrumentation

Examples of chemical instrumentation include Gas Chromatographs, Gas Chromatograph/Mass Spectrometers, Ion Chromatographs, High Performance Liquid Chromatograph, Inductively Coupled Plasma Emission Spectrophotometer, Inductively Coupled Plasma/Mass Spectrometer, Atomic Absorption Spectrophotometers, Infra-red Spectrophotometer, UV-Visual Spectrophotometers, Total Organic Carbon Analyzer, Total Organic Halogen Analyzer, nephelometers, recorders, and integrators. Bacteriological equipment includes incubators, autoclaves, fecal water baths, agar water baths, dry ovens, and microscopes. A list of current equipment, manufacturer, model, serial numbers, date received, date placed in service, condition when received, and laboratory location is kept on file.

All instruments/equipment are calibrated and maintained in accordance with manufacturer's specifications and well-established quality assurance practices. (See the appendices: NELAC Quality System Information for method specific calibration information.) A copy of the manufacturer's instructions, when available, is kept with the instrument. The analyst using the instrument/equipment maintains the instrument in clean and operating order. Problems are reported immediately so that they can be corrected. When an instrument is taken out of use due to a maintenance problem, a

sign is placed on the instrument indicating the instrument is out of service. All major instruments are kept on maintenance contracts. Maintenance logs are kept for all major analytical equipment. For more information regarding equipment, refer to the Equipment Maintenance SOP (Q21).

The temperatures of refrigerators, ovens, and incubators are monitored daily and recorded in a notebook along with the initials of the person performing the check. The temperatures of water baths are monitored daily (when in use). All thermometer calibrations are checked annually for chemical analyses and semiannually for microbiological analyses against an NIST certified thermometer. If a thermometer is broken, the calibration of the replacement is checked in such a way as to be NIST traceable before use. All calibration checks are recorded and any correction applied to the thermometer is recorded. A label indicating the calibration status is applied to each thermometer.

All glassware is rated as Class A. All glassware is cleaned to meet the sensitivity of the test method (e.g. acid rinsed for metal determination or solvent rinsed for pesticides see the appropriate analytical SOP for the glassware cleaning procedure required by that method).

Balances are calibrated and cleaned annually by an outside vendor. The sensitivity, reproducibility, and internal consistency are checked within the laboratory daily using certified weights. These weights are calibrated at least annually and the weight calibration certificates are in the QA files.

The pH meters are calibrated daily using 7.0 and 10.0 buffers and verified by a 4.0 buffer.

The fume hood velocities are measured and recorded quarterly. Fume hoods are serviced semiannually.

Reagents and Standards

Reagent water meets or exceeds ASTM Type II specifications. It is produced by a triple-stage commercial ion-exchange resin system. If higher quality water is desired, the water is then passed through a "nanopure" system. All chemical reagents are ACS quality or better. Reagents are discarded and prepared freshly as required. The reagent name and date prepared shall serve as the unique identifier. If a second identical reagent is made on a given day, it will be noted so that the name and date remain unique. All standards are prepared from ACS reagents or purchased already standardized by a nationally known chemical manufacturer such as Baker, Eastman Kodak, B & J, Merk, Supelco, Mallinkrodt, Aldrich, Sigma, etc. The date received is recorded in the chemical inventory. The date opened is recorded on the bottle. New standard solutions are compared to a standard of a different manufacturer or lot number. If they fail to agree within method-acceptable criteria, then either the standard is re-made or both standards are compared to another from a third source.

A standard log is maintained either in the logbook or LIMS and a reagent logbook is maintained to document the traceability of standards and reagents and record the manufacturer, lot number, concentration, preparer, and date of preparation.

For further details on the handling and use of reagents and standards, refer to the Reagent Quality and Documentation SOP and the Standard Quality and Documentation SOP (Q05 and Q08, respectively).

24 QUALITY CONTROL OF ANALYTICAL PROCEDURES

See the Quality Control Data SOP (Q01) for details.

Chemical Determinations:

Method QC

Calibration curves and linearity checks are run as prescribed in the applicable method for each procedure and for all parameters. All quality control requirements of each method must be met.

Required Batch QC

A batch is a set of 20 or fewer samples of a similar matrix that are processed together with the same method and personnel, using the same lots of reagents.

A Laboratory Control Sample (LCS), a Method Blank (MB), a Matrix Spike (MS) and Matrix Spike Duplicate (MSD) or sample Duplicate (Dup) are analyzed for each batch. A Dup is analyzed in place of the MS and MSD for gravimetric or titrimetric analyses. Where the method does not require MS/MSD, an LCS duplicate (LCSD) may be used to gather precision data instead. Note: Other documents may refer to these QC samples in different ways. For example, EPA 500 series methods refer to an LCS as a Laboratory Fortified Blank (LFB) and an MS as a Laboratory Fortified Matrix (LFM).

Batch Controls:

The MB is used to assess the preparation batch for possible contamination during the preparation and processing steps. The MB shall be processed along with and under the same conditions as the associated samples to include all steps of the analytical procedure. The MB is used to check and documents the purity of any reagents or waters used. Under NELAC rules, a MB shall consist of a matrix that is similar to the associated samples and is known to be free of the analyte of interest.

The LCS is used to evaluate the performance of the total analytical system, including all preparation and analysis steps. The LCS is analyzed at a minimum of 1 per preparation batch. Exceptions would be for those analytes for which no spiking solutions are available. The LCS is a controlled matrix, known to be free of analytes of interest, spiked with known and verified concentrations of analytes.

Sample Specific Controls

Sample specific controls determine the effect of the sample matrix on method performance. They are designed as data quality indicators for a specific sample using the designated test method. These controls do not judge laboratory performance. Examples include: MS, MSD, Dup and surrogate spikes (Surr).

MS/MSD indicates the effect the sample matrix on the precision and accuracy of the results generated using the selected method. The information is sample/matrix specific and would not normally be used to determine the validity of the entire batch.

Dups are replicate aliquots of the same actual sample taken through the entire analytical procedure to indicate the precision of the results for the specific sample using the selected method. They provide a useable measure of precision only when the target analytes are found in sufficient quantity in the sample chosen for duplication.

Surrogate compounds represent the various chemistries of the target analytes in the method. They are deliberately chosen because they are unlikely to occur as an environmental contaminant.

Other QC

External QC reference samples are obtained from an outside source for inclusion in our procedures for method verification. External QC reference samples from an appropriate source, such as Environmental Resource Associates, are analyzed semi-annually. Internal standards are routinely included with determinations of metals and organics, also methods of addition may be incorporated. An internal standard (IS) is a pure compound that is not a contaminant in the sample and is added to a sample or sample extract in a known amount. The IS is used to measure the relative responses of other target analytes and surrogates that are in the same sample. When an IS in used, it is added to the samples and QC samples or their extracts. Non-routine samples with complex or unfamiliar matrices might need special QC, such as additional procedural spikes or two or more dissimilar methods of analysis. All batch QC is reviewed daily.

Special Procedures for Bacteriological Determinations:

There are general procedures and quality control (QC) requirements that are unique to Bacteriological Determinations. These include sample container sterility checks, glassware cleaning procedures, housekeeping requirements, media maintenance/preparation/QC, dilution water requirements, instrument calibration, monitoring of incubators/water bath/dry oven, autoclave use and QC documentation (including the use of biological indicators of sterilization efficiency), reference culture requirements, and quality control analyses. For details, please refer to the Bacteriology General Procedures and Quality Control SOP (B01).

25 STATISTICAL EVALUATION OF DATA FROM CHEMICAL ANALYSES

All samples are analyzed within analytical batches. An analytical batch includes the QC samples discussed in Section 24 and a calibration check standard.

Calibration curves for most analyses are a minimum of three points. Some methods require additional points in the calibration curve. Calibration requirements that are specified in the applicable test method must be met. See the appendices for Calibration Criteria Charts.

The data from LCSs, MSs, MSDs, Duplicates, and Surrogates are used for statistical evaluation. This is based on the following examinations:

A) From duplicates, both of spikes and samples, precision data is calculated and the Relative Percent Difference (RPD) is determined. The equation is:

$$\text{Relative Percent Difference} = \frac{|A - B|}{\left(\frac{A + B}{2}\right)} \times 100$$

where *A* is the analytical result for the matrix spike (or sample) and *B* is the analytical result for the matrix spike duplicate (or sample duplicate).

B) From results of the MS/MSD (S) accuracy data is calculated and the percent recovery (%Rec) is determined. The equation is:

$$\text{Percent Recovery} = \frac{|\text{M - A}|}{\text{Q}} \times 100$$

where M is the matrix spike analytical result, A is the analytical result of the (unspiked) sample, and Q is the amount of spike added.

C) An LCS the percent recovery (%Rec) is calculated by comparing the LCS analytical result (A) to the "True" value which is the expected value of the spike (Q) (or the historical average of the control).

$$\text{Percent recovery} = \frac{A}{Q} \times 100$$

If the percent recovery is not within the laboratory acceptance criteria, the analysis is considered to be “out of control” and will not continue until the cause is found and corrective measures are taken. Any affected samples associated with the out-of-control LCS are reprocessed for re-analysis or the results are reported with appropriate data qualifying codes.

D) The relative standard deviation (RSD) may be determined from the QC data using the following equation:

$$\text{Relative Standard Deviation} = \frac{S}{\overline{X}} \times 100$$

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

where

where S is the standard deviation, $\overline{X}$ is the mean of the observed value, X is the observed value, and *N* is the number of observations.

Control charts are generated in the LIMS. For details, please refer to the Statistical Evaluation of Data SOP (Q03).

26 DATA REDUCTION AND VALIDATION

To ensure the quality of the data, several review steps are incorporated into the data review process. For detail refer to the Data Review and Validation SOP (Q10). In summary, the first level of review is the analyst who preliminarily assesses whether the batch QC acceptance criteria are meet, adds qualifiers as appropriate and checks calculations, units, significant figures and dilution or concentration factors. The second level of review is peer review. The Supervisor review follows including a check to determine if proper relationships exist among the parameters in the sample. The Standard Methods SM 1030 F procedure may be also used along with the following:

Mineral Balances

Equation (1) for Total Cations (me/L)

$Ca + Mg + Na + K + NH_3\text{-}N$ = total cations

Equation (2) for Total Anions (me/L)

$CO_3 + HCO_3 + OH + SO_4 + Cl + NO_3 + F$ = total anions

Equation (3) for Calculated TDS (mg/L)

Calculated TDS = $Ca + Mg + Na + K + Cl + SO_4 + NO_3 + F + SiO_2 +$ ($0.6 \times$ Total Alkalinity as $CaCO_3$)

The measured TDS may be higher than the calculated TDS because a significant contributor may not be in the calculation.

Equation (4) for Cation/Anion Balance

$$\text{Balance Acceptance Criteria} = 100 \times \frac{(\text{total cations - total anions})}{(\text{total cations + total anions})}$$

The result should be 100 ± 5%.

Equation (5) for Calculated Specific Conductance

EC (Calc) = (total cations + total anions) × 50

(Both the total anion and total cations should be 1/100 of the measured EC value.) The calculated EC is expected to be within 10% of the measured EC. Thus:

Equation (6)

$$0.9 \leq \frac{EC_{calculated}}{EC_{measured}} \leq 1.1$$

If the ratio of TDS to conductivity falls below 0.55, the lower ion sum is suspect and reanalyzed. If the ratio is above 0.7, the higher ion sum is suspect and reanalyzed. If reanalysis causes no change in the lower ion sums, an unmeasured constituent, such as nitrite or organic acids may be present at significant levels. If poorly disassociated calcium and sulfate ions are present, the TDS may be higher than the EC. The acceptance criterion is as follows:

Equation (7)

$$\frac{TDS_{measured}}{EC_{measured}} = 0.55 - 0.70$$

and/or

$$\frac{TDS_{calculated}}{EC_{calculated}} = 0.55 - 0.70$$

Reference: Standard Methods for the Examination of Water and Wastewater, APHA, AWWA, WEF, 18th edition

Demand Ratios

A general rule of thumb is:

BOD = 0.40-0.60 of COD

TOC = 0.40 of COD (approximately)

TOC = 0.60 of BOD (approximately)

Nutrient Relationships

Total Nitrogen = Organic Nitrogen + Inorganic Nitrogen

Inorganic Nitrogen = NO_3-N + NO_2-N + NH_3-N

Kjeldahl Nitrogen = Organic Nitrogen + NH_3-N

Organic Nitrogen = Kjeldahl Nitrogen - NH_3-N

The above nitrogen relationships are checked to ensure proper calculations have been performed.

Trace Organic Contaminants:

TOX = Volatile Organic Halogens + Non-volatile Organic Halogens

Volatile Organic Halogens = Polar + Non-polar Volatile Organic Halogens

Non-volatile Organic Halogens = Polar + Non-polar Non-volatile Organic Halogens

Non-polar Volatile Organic Halogens are measured from EPA Methods 502.2, 601, 8010, 524, 624, or 8260 analysis.

Non-polar Non-volatile Organic Halogens are measured from EPA Method 525, 625, or 8270 analysis.

From the above relationships, the following is performed:

TOX $\geq$ Non-polar (Volatile + Non-volatile) Organic Halides

The supervisor approves the results in the computer when all analyses requested on the sample are completed.

27 FINAL REPORT REVIEW

For some reports the QA Manager or a Project Manager (or other authorized person) will also review the data just prior to generating the final report. These reports are generally given an extra review due to project-specific requirements such as an analyte list or reporting limit that is not typical, such as a request to report of J-flag values, or a request for a higher level QC (see Section 29 for further details on reporting of results). The initials and date of review are recorded on the Work Order report.

After the final report is generated, the President (or other authorized signatory) will be responsible for final review and signing of the final report.

Each reviewer (Analyst, Supervisor, QA Manager/Project Manager, and President) strives to verify that the data has been reported accurately, clearly, unambiguously, and objectively.

28 CORRECTIVE ACTION FOR OUT-OF-CONTROL QC

For details on corrective action, see the Corrective Action SOP (Q06) and the SOP for the method. The following is a general summary however, the current Q06 or method SOP will supercede.

For Chemical Determinations

Corrective action is necessary when the upper or lower control limits for the test parameters have been exceeded for laboratory control samples or when processed blanks show an unacceptable level of contamination.

The first step taken when QC results are "out of control" is to recheck all mathematical calculations including such items as concentration and/or dilution factors and calibration curve readings.

If the first step fails to solve the problem then the reagents are checked for proper chemical reaction, for example, the esterification potency for EPA Method 8151.

Reagents and glassware are checked for contamination. Reagent blanks are checked containing the acids used in metal digestion or the solvents used in organic analysis.

Standards are checked for proper concentration. New standards from a different supplier/lot number are prepared to check against the standards used during the analysis in question.

When a batch of data is transferred or manually entered into the laboratory database and later found to be in error OR to need re-running for verification a follow-up is initiated. For the batches/samples in question, the General Manager/President/Lab Director and the QA Manager are notified that the data is suspect and are provided with a list of the affected laboratory numbers. The answers in the database are flagged as suspect until the problem can be resolved. Samples affected are either reanalyzed or verified. If the problem is not corrected, or the holding time has been exceeded or there is insufficient sample for a follow-up—the client is notified so that it can be determined if the site should be resampled. If suspect results are reported, the report is flagged with a note indicating the problem.

For Bacteriological Determinations

Corrective action is necessary when QC cultures show atypical response or when check sample results exceed the given acceptance criteria. The associated quality control data is reviewed to verify sterility and findings are documented on the associated lab sheet(s) or a follow-up form.

For All Analyses

Quality Control Follow-Up Forms are generated when QC problems cannot be corrected during the run and documented in the analytical data itself. Quality Control Follow-Up Forms are available to document the situation and resolution, refer to the Quality Control Follow-Up Forms SOP (Q24) for further details. As appropriate for the test method in question, further corrective actions, such as troubleshooting instrumentation and re-calibration may be performed.

29 REPORTING OF RESULTS

Analytical Chemistry Reporting Procedure

The final copy of the report must contain all information necessary for the interpretation of the test results and all information required by the method user – including the following information:

A) A report title.
B) The name of the laboratory.
C) The address of the laboratory.
D) The phone number of the laboratory.
E) Laboratory identification number.
F) Unique page identification.
G) Name and address of client and project name, if applicable.
H) Description and unambiguous identification of test sample—including the client identification code.
I) Analytical results including units and reporting limit (RDL).
J) Identification of any quality control failure within the batch that might affect the validity of the result by use of appropriate data qualifiers.
K) The reported units for samples are as received, unless identified as “dry” (corrected for dry weight).

L) Identification of results derived from samples that did not meet acceptance requirements – such as improper container, holding time or temperature noted with appropriate data qualifiers.

M) Date of receipt of sample, name of the submitter, date and time of sample collection, name of the sampler (if known), date(s) and time(s) of analytical test(s), and analyst(s) initials.

N) Identification of the test method used or a description of any non-standard test used.

O) Any other information relevant to the specific test.

P) Definition of data qualifiers.

Q) The approval signature and title of the signatory (or electronic equivalent).

R) Where applicable, reasons that the analysis did not conform to NELAP specifications.

S) Where applicable, clear indication of numerical results with values outside of quantitation limits.

T) Where applicable, a statement to the effect that the results relate only to the items tested or to the sample as received by the laboratory.

U) Where relevant, a statement that the certificate or report shall not be reproduced except in full, without the written approval of the laboratory.

V) Where applicable, clear identification of all data provided by outside sources, such as subcontracted laboratories, clients, etc.

W) Where applicable, amended reports include a case narrative or cover letter indicating that they are amended, the reason for amendment, and the date of the previous report that they supercede.

All paperwork that is submitted by the client and the original Chain of Custody forms are attached to a photocopy of the finalized lab report. This is stored in the client files.

Subcontracted Analyses

The laboratory clearly indicates to the client its intention to subcontract laboratory work in its contract bids and bid quotes.

When a subcontract lab is utilized, clients are sent the original reports from the subcontract lab. Edward S. Babcock & Sons, Inc. does not report subcontracted results on company letterhead (with the exception of transcribed results onto state forms for reporting to the state Office of Drinking Water. This is clearly noted on the report.)

All subcontracted analyses will be performed by a NELAP accredited laboratory or by a laboratory that meets applicable statutory and regulatory requirements for performing the tests (i.e. a CA ELAP certified laboratory).

Mandated Verbal Notification to Water Systems

The laboratory notifies the water system personnel immediately if coliform is found in the presence/absence coliform test, there are any coliform positive tubes, or the sample is declared invalid due to a turbid culture with the absence of gas production using either the multiple tube fermentation technique or the presence/absence coliform test. Following the Total Coliform Rule, follow-up samples are taken until the samples are negative for coliform (see the Microbiology Notification and Reporting Procedures SOP BO8, for further details). Also laboratory notifies the water system personnel if a final drinking water nitrate result exceeds the MCL of 45 mg/L (as NO_3, or 10 mg/L as N).

Quality Control Reports:

QC data are available for all chemical batches and are reported to the client upon request. Each project will be assigned a type of data package (or QC Level) based on the objectives of their project and this will determine the amount of QC data included in the final report.

The **Level I or "short report**" data packages are created from data in the Laboratory Information Management System (LIMS, Element). Level I data packages receive our general data review procedure and include Client Information, Work Order, Sample Information, Analyte(s), Result, Reportable Detection Limit (RDL), Units, Method, Analysis Date, and Analyst information. Data qualifier flags will only appear as needed.

The **Level II or "standard report"** data packages are created from data in the LIMS. Level II data packages receive our general data review procedures and review by a Project Manager or QA Manager (the Work Order Report will indicate that the report "Needs QC"). Standard reports include all elements of the short report. In addition, the Batch Quality Control data for the QC samples are provided. The Batch ID and Method appear as the heading above each set of Batch QC. Each QC sample will have information on the Date Prepared, Date Analyzed, Analyte(s), Result, Reportable Detection Limit (RDL), and Units. As discussed in Section 24, the QC samples will vary by method but LIMS reports may include data on the Blanks, Laboratory Control Samples/Spikes, Laboratory Control Samples/Spikes Duplicates, Matrix Spikes, Matrix Spike Duplicates, and Sample Duplicates. Where applicable, the following data are included with each type of QC sample:

A) Laboratory Control Samples/Spikes:
   a. Spike Level and
   b. Accuracy (Percent Recovery [%Rec] and %Rec Limits)

B) Laboratory Control Samples/Spikes Duplicates:
   a. Spike Level
   b. Accuracy (%Rec and %Rec Limits), and
   c. Precision (Relative Percent Difference [RPD] and RPD Limit)

C) Matrix Spikes:
   a. Source Result,
   b. Spike Level, and
   c. Accuracy (%Rec and %Rec Limits)

D) Matrix Spike Duplicates:
   a. Source Result,
   b. Spike Level,
   c. Accuracy (%Rec and %Rec Limits), and
   d. Precision (RPD and RPD Limit)

E) Sample Duplicates:
   a. Source Result and
   b. Precision (RPD and RPD Limit)

Higher level data packages are created from data in the LIMS and also include special data packages created by a Project Manager. Higher level data packages receive our general data review procedures and review by a Project Manager. **Level III** data packages include all elements of the standard report with the addition of run logs/bench sheets and calibration curves. **Level III+** data packages include all elements of the standard report with the addition of run logs/bench sheets, calibration curves, and raw data (chromatograms etc.). **Level IV** data packages include all elements of the standard report with the addition of run log/bench sheet, calibration curves, raw data (chromatograms etc.), and standard logs. **Custom** QC packages, electronic versions of the data, and other variations are also available to meet the specific needs of each project and will be established on client/project basis.

In addition, reports are available with **J-flag** data. J-flag reports include estimated values for results that fall between the method detection limit (MDL) and Reportable Detection Limit (RDL). The MDL is listed for each Analyte. A J-flag report receives our general data review procedures and a review by a Project Manager or QA Manager (the Work Order Report will indicate that the report needs “J-flag”).

30 AUDITS

Method Audits

Audits of all analytical methods performed by our laboratory (including quality control procedures and documentation) are generally performed on an annual basis by QA Department personnel who are independent of the activities being audited (See Appendix M for an example Audit Form).

Internal Quality System Audits

The QA Manager or other trained and qualified personnel conducts an annual audit of the laboratory with relation to NELAC Chapter 5 requirements to determine that the laboratory operation continues to comply with the laboratories quality system. The current NELAP Quality System Checklist is used to conduct this audit (http://www.epa.gov/ttn/nelac/checklst.html). Also, audits are conducted annually of electronic data generated by laboratory instrumentation. Results of these audits are reported to management for review. If results cast doubt on the correctness or validity of the laboratories calibrations or test results, the laboratory shall take immediate corrective action and shall immediately notify, in writing, any client whose samples were involved. For more information regarding these audits, please refer to the Audit Standard Operating Procedure (Q16).

Managerial Audits

The laboratory management conducts a review, annually, of its quality system and its testing and calibration activities 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 interlaboratory comparisons or proficiency tests, any changes in the volume and type of work undertaken, feedback from clients, corrective actions and other relevant factors. The laboratory has a procedure for review by management and maintains records of review findings and actions. For more information regarding these audits, please refer to the Audit Standard Operating Procedure (Q16).

Audit Reviews

All audit and review findings and any corrective actions that arise from them are documented. The laboratory management ensures that these actions are discharged within the agreed time frame.

31 Quality Assurance Manual – Updates and Reviews:

This QA Manual is designed to be compliant with NELAC requirements (see NELAC Quality System Information Section 5.5.2 in Appendix I for list of requirements). The contents of this manual are reviewed annually (at a minimum) by the QA Manager and the Laboratory Director for compliance to applicable regulations – ensuring that it reflects existing practices within the laboratory.

The QA Manual clearly indicates the revision month and the effective date. The effective date indicates that at midnight at the start of the effective date the new manual goes into effect.

All signatory personnel within the laboratory sign their approval of any new version of this document prior to its release.

The QA Manager maintains an archive of previous versions of this document.

All employees read the effective revision of the QA Manual and are familiar with its contents. Each employee signs a statement that he/she has read the QA Manual and declaring his/her intention of complying with the requirements contained within Edward S. Babcock and Sons, Inc QA Manual.

32 APPENDICES

A. Copies of Certifications

B. Equipment List

C. Organizational Chart

D. Resumes of Key Personnel

E. Job Descriptions of QA Manager and Lab Director

F. Ethics and Data Integrity Manual

G. References for QA Procedures

H. References for Sampling Procedures

I. NELAC Quality System Information - excerpts from Chapter 5

J. Quality Control Criteria Charts

K. Sample Forms: Chain of Custody and Sample Receipt

L. Sample Preservation and Holding Times

M. Documentation Audit Forms