The different positions within the laboratory have job descriptions that are maintained in the Human Resources department. The organization chart of Weck Laboratories, Inc. can be found in Appendix 3.

5 STAFF

5.1 Management Personnel

The managerial and technical personnel have the authority and resources needed to carry out their duties and to identify the occurrence of departures from the quality system or from the procedures for performing environmental tests and/or calibrations, and to initiate actions to prevent or minimize such departures. Technical management has overall responsibility for the technical operations and for the provision of the resources needed to ensure the required quality of laboratory operations.
Deputies are appointed for key managerial personnel, including the technical director(s) and QA Officer, to perform their duties in case of prolonged absences.
The following are the responsibilities and activities within the QAP in which the key and management personnel are engaged:

Laboratory Management

- Defining the minimal level of experience and skills necessary for all positions in the laboratory.
- Ensuring that all technical laboratory personnel have demonstrated capability in the activities for which they are responsible.
- Ensuring that the training of its personnel is kept up-to-date.
- Documenting all analytical and operational activities.
- Supervising all personnel
- Ensuring that all sample acceptance criteria are verified and that samples are logged into the sample tracking system and properly labeled and stored.
- Performing with the other management staff an annual Management System Review.
- Documenting the quality of all data reported by the laboratory
- Ensuring that the laboratory has the appropriate resources and facilities to perform requested work
- Ensuring that corrective actions relating to findings from the internal audit are completed; and
- Nominating deputies when the Technical Directors or QA Officer are absent.
- Developing a proactive program for prevention and detection of improper, unethical or illegal actions.
- Ensuring that only those outside support services and supplies that are of adequate quality to sustain confidence in the laboratory's tests are used.

QA Officer

The QA Officer is responsible for the Quality System of the laboratory and its implementation. He or she has direct access to the highest level of management (President/Laboratory Director) and to the Technical Directors to resolve any dispute involving data quality.

The specific functions and characteristics of the QA Officer are the following:

- Serve as the focal point for QA/QC and be responsible for the oversight and/or review of quality control data.
- Have functions independent from laboratory day-to-day operations for which he or she has quality assurance oversight.
- Be able to evaluate data objectively and perform assessments without any outside influence.
- Have documented training and/or experience in QA/QC procedures and be knowledgeable in the quality system as defined under NELAC.
- Have a general knowledge of the analytical tests methods for which data review is performed.
- Arrange for or conduct internal audits on the entire technical operation annually
- Notify laboratory management of deficiencies and non-compliance items in the quality system and monitor corrective action.
- The QA Officer has sufficient authority to stop work as deemed necessary in the event of serious QA/QC issues.

Technical Directors

The full time individuals who have overall responsibility for the technical operation of the laboratory. There are three technical directors: for Chemistry, Microbiological analysis and Radiochemistry.
The daily activities and responsibilities of the Technical Directors are the following:

- Certifying that personnel with appropriate educational and/or technical background perform all tests for which the laboratory is accredited
- Monitoring standards of performance in quality control and quality assurance.
- Monitoring the validity of the analyses performed and data generated in the laboratory to assure reliable data
- Ensuring that sufficient number of qualified personnel are employed to supervise and perform the work of the laboratory
- Providing educational direction to laboratory staff
- Exercising day-to-day supervision of laboratory operations for the corresponding department.

The Technical Directors of Weck Laboratories meet the requirements specified in Section 4.1.1.1 of the NELAC Standards.

Resumes of management personnel are in Appendix 1

5.2 Personnel Qualifications

The technical staff is responsible for sample analysis and identification of corrective actions. The staff reports directly to the Laboratory Director or Lab Manager. All personnel are responsible for complying with all quality assurance/quality control (QA/QC) requirements that pertain to their organizational/technical function. As documented in the employee records, each employee has the experience and education to adequately demonstrate knowledge for their particular function and the general knowledge of laboratory operations, analytical test methods, QA/QC procedures and records management.

The laboratory management shall ensure the competence of all who operate specific equipment, perform environmental tests, evaluate results, and sign test reports and calibration certificates. When using staff that are undergoing training, appropriate supervision shall be provided. Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.

5.3 Personnel Training

Each employee is required to read, understand, and to use the current versions of the established Standard Operating Procedures and Analytical Method Protocols, which relates to his/her job responsibilities. The Training records show evidence of the revisions of the SOPs the employees have reviewed. Each employee demonstrates initial proficiency by following the procedure described in Appendix 9 of this manual, and demonstrates continued proficiency on a yearly basis by acceptable performance on Laboratory Control Samples (LCS), successful analysis of blind samples or by analyzing in parallel a sample analyzed by a trained or re-trained analyst. The training records of the analysts are organized by analyst and kept with personnel files. They include initial and continuing training, continuing education, participation in technical conferences or seminars and internal training activities.
Initial training for new employees is performed by experienced personnel with management guidance and includes the observation of the QC procedures described in this manual.
The company has a policy that encourages all technical personnel to participate in technical seminars and meetings involving innovative analytical technologies, new instrumentation and software applied to environmental testing. Records of this participation are maintained in the personnel files.

The management of the laboratory shall formulate the goals with respect to the education, training and skills of the laboratory personnel.
The personnel performing analytical and related tasks at the laboratory must be employed by, or under contract to, the laboratory. Where contracted and additional technical and key support personnel are used, the laboratory shall ensure that such personnel are supervised and competent and that they work in accordance with the laboratory's quality system.
The laboratory shall maintain current job descriptions for all personnel who manage, perform, or verify work affecting the quality of the environmental tests.
The management shall authorize specific personnel to perform particular types of sampling, environmental test, to issue test reports and calibration certificates, to give opinions and interpretations and to operate particular types of equipment. The laboratory shall maintain records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel. This information shall be readily available and shall include the date on which authorization and/or competence is confirmed.
Records on the relevant qualifications, training, skills and experience of the technical personnel shall be maintained by the laboratory, including records on demonstrated proficiency for each laboratory test method.

6 LABORATORY CAPABILITIES AND ACCREDITATIONS

Weck Laboratories, Inc. analyzes water, soil, hazardous waste and air samples. The following are the type of analysis performed:

- Drinking Water and Groundwater

- Sampling: production wells and monitoring wells
- Inorganic: trace metals, physical parameters, wet chemistry
- Organic: volatile, semi-volatile, pesticides, herbicides
- Bacteriological: Total and fecal coliforms, Heterotrophic Plate Count

- Waste Water

- Sampling: composite samplers, grabs.
- Inorganic: metals, physical parameters, wet chemistry
- Organic: volatile, semi-volatile, pesticides, herbicides
- Bacteriological: Total and fecal coliforms, Heterotrophic Plate Count

- Hazardous Waste and Soil

- Characteristics: physical properties, leaching tests
- Organic: volatile, semi-volatile, pesticides, herbicides
- Inorganic: metals, wet chemistry

- Industrial Hygiene

- Indoor Air Analysis: air filters (metals)
- Sorbent tubes (organics)

The different analytical techniques and methods performed at the laboratory are described in the laboratory specific SOPs.

The Laboratory is accredited by various regulatory agencies to perform environmental testing. Current accreditations are listed in appendix 11.

The instrumental analytical capabilities of Weck Laboratories, Inc. include the following:

- **Sampling and field equipment**

24 hours composite samplers for water.
Flow measurement instruments
Water quality kits
Encore samplers for soil
Immunoassay determinations

- **Inorganic analysis**:

ICP-AES
ICP-MS
ICP-MS Flow Injection Analysis (hydride generation)
Cold Vapor Atomic Absorption
Cold Vapor Atomic Fluorescence
Cold Vapor Atomic Florescence with Gold Amalgamation
UV-visible spectrometry
Ion Chromatography

IC/MS/MS
Ion Selective Electrodes

- **Organic Analysis**

Purge and Trap equipment for direct purging of soils
Purge and Trap for water
Automated SPME
GC/MS for volatile organics
GC/MS for semi volatile organics
GC/MS/MS (tandem Mass spectrometry)
GC/MS with Chemical Ionization positive ion and negative ion
GC with FID,NPD,ECD,PID,TCD
LC/MS/MS for UCMR 2. EDC/PPCPs & Perchlorate
HPLC with post-column derivatization and UV-Visible and Fluorescence detectors.
TOX
TOC
Infrared analysis

A complete list of laboratory instrumentation is in Appendix 4.

7. QUALITY ASSURANCE OBJECTIVES

The overall QA objective of Weck Laboratories, Inc. is 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. The 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.

7.1 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 relative standard deviations (RSD) for replicate samples. For analyses that have detectable levels of analytes (for example inorganic analyses), laboratory precision is usually assessed through the analysis of a sample/sample duplicate pair and field duplicate pairs. For analyses that frequently show no detectable levels of analytes (e.g., organic analyses), the precision is usually determined through the analysis of matrix spike/matrix spike duplicates (MS/MSD) and field duplicate samples.

7.2 Accuracy

Accuracy (Bias) is the degree of agreement between an observed value and an accepted reference or true value.

Accuracy is 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, external quality control check samples, laboratory control samples (LCS and LCSD) and surrogate compounds spikes.

7.3 Representativeness

Representativeness expresses the degree to which data accurately and precisely represent a characteristic of a population, parameter variations at a sampling point process condition, or an environmental condition within a defined spatial and/or temporal boundary.

Representativeness is ensured by using the proper sampling techniques, proper analytical procedures, appropriate methods; meeting sample holding times and analyzing field duplicate samples.

7.4 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 measurement obtained from all the measurement taken in the project. The laboratory completeness objective is that the generation of valid data for all samples be greater than 95 percent.

7.5 Comparability

Comparability is an expression of the confidence with which one data 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 levels, and consistent rules for reporting data.

7.6 Detection Limits

Method Detection Limits (MDLs) are determined for all analytes as specified in the NELAC standards. From these, Reporting Limits (RLs) are obtained. See section 12.2 for more detailed information.

8. SAMPLING

Most samples processed at the laboratory are collected by clients or their representatives. When required, Weck Laboratories can provide technical assistance for sample collection and handling and can prepare appropriate sample containers with preservatives.
Weck Laboratories field personnel conduct sampling of wastewater and potable water for projects that require this service. Our personnel do not perform industrial hygiene sampling.

In order to assure the quality of the entire analytical process, Weck Laboratories works closely with field personnel employed by the client to meet general QA criteria and if available specific criteria as per the QAPjP.

When performing sampling activities related to environmental testing, the laboratory sampling personnel follows the corresponding SOPs. Copies of the SOPs are kept at the field for reference.

The procedures to obtain subsamples, such as obtaining sample aliquots, are documented in each analytical SOP that requires it.

Where the client requires deviations, additions or exclusions from the documented sampling procedure, these are recorded in detail in the case narrative of the work order and reported with the analytical report. They are also communicated to the appropriate personnel.

In the instances that the laboratory does not perform the sampling and whenever possible all sampling information, such as name of sampler, company that employs the sampler, sampling procedure, etc. is recorded in the sampling section of each work order and reported to the client. All other pertinent sampling information and relevant data for operations relating to sampling that forms part of the environmental testing that is undertaken is also recorded and reported with the analytical report.

9. SAMPLE HANDLING

This section summarizes policies and practices for sample handling. Further details are contained in the corresponding SOPs.

9.1 Sample Tracking

Weck Laboratories, Inc. uniquely identifies each sample to be tested, to ensure that there can be no confusion regarding identity. The sample identification system includes identification for all samples, sub-samples and subsequent extracts and/or digestates. A unique identification (ID) code is placed on each sample container.

9.2 Review of Requests, Tenders and Contracts

When a request, tender or contract is received by the Laboratory, the Management or designated staff member will review and ensure that the requirements, including the methods to be used, are adequately defined, documented and understood and that the laboratory has the capability and resources to meet the requirements. The purpose of this review of capability is to establish that the laboratory possesses the necessary physical, personnel and information resources, and that the laboratory's personnel have the skills and expertise necessary for the performance of the tests in question. The review may encompass results of earlier participation in interlaboratory comparisons or proficiency testing and/or the running of trial environmental test or calibration programs using samples or items of known value in order to determine uncertainties of measurement, detection limits of confidence limits, or other essential quality control requirements. The current accreditation status of the laboratory is also reviewed. The laboratory then informs the client of the results of this review if it indicates any potential conflict, deficiency, lack of appropriate accreditation status, or inability on the laboratory's part to complete the client's work.
Another item to review is whether or not the appropriate test method is selected and capable of meeting the clients' requirements.
The management or designated staff will discuss and resolve any differences between the request or tender and the contract before any work commences in order to assure that each contract is acceptable both to the laboratory and the client.
A contract may be any written or oral agreement to provide a client with environmental testing or other laboratory services.

Records of reviews, including any significant changes, shall be maintained. Records shall also be maintained of pertinent discussions with a client relating to the client's requirements or the results of the work during the period of execution of the contract.
For review of routine and other simple tasks, the date and the identification (e. g. the initials) of the person in the laboratory responsible for carrying out the contracted work are considered adequate.
For repetitive routine tasks, the review need be made only at the initial enquiry stage or on granting of the contract for on-going routine work performed under a general agreement with the client, provided that the client's requirements remain unchanged. For new, complex or advanced environmental testing, a more comprehensive record should be maintained.
The review shall also cover any work that is subcontracted by the laboratory.
The client shall be informed of any deviation from the contract.
If a contract needs to be amended after work has commenced, the same contract review process shall be repeated and any amendments shall be communicated to all affected personnel.
If there is any suspension of accreditation, revocation of accreditation, or voluntary withdrawal of accreditation during the time the contract is in effect, this must be reported to the client.

9.3 Sample Acceptance Policy

The following are the requirements for sample acceptance. Data from any samples, which do not meet the policy here specified, are noted in the laboratory report defining the nature and substance of the variation:

- 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. This information must be fully documented in the chain of custody record. Appendix 5
- Unique identification of samples using durable labels completed in indelible ink on all sample containers.
- Use of appropriate sample containers and preservatives as per table in Appendix 6.
- All samples have adequate holding time to be analyzed (Appendix 6).
- If no previous special arrangements were made, parameters that are "field" analysis (i.e. pH, residual chlorine, etc.) will be analyzed within 24 hours from arrival at the laboratory. Samples that arrive at the laboratory after 4 PM on Friday or on the weekend will be analyzed no later than the next business day after receipt (Monday unless a holiday).
- Adequate sample size for all analysis requested.
- Special instructions and additional information required to perform the analysis properly (i.e., time, flow rate, etc.).
- Procedures that are used when samples show signs of damage or contamination.
- Samples received at the required temperature (usually $4^{o}C \pm 2\ ^{o}C$) or with evidence of chilling process started (received "on ice") if they were collected the same day as received at the lab.

If any of the above requirements are not met, the client is notified immediately, and the irregularity is documented:

- If the client acknowledges the irregularity and instructs the laboratory to continue with analysis this is documented and samples accepted.
- If the client does not acknowledge the irregularity the samples are rejected.
- If the irregularity is noted in samples submitted for bacteriological analysis for compliance purposes, the samples are rejected without exception.

When a request for a new project is received involving multiple samples or tests that have a short holding time the Management is notified. The Management staff with the assistance of the appropriate technical personnel evaluates the project and calculates the resources needed to complete it within the turn around time required and the holding times, taking into consideration the volume of work in house and/or expected. If it is determined that the new project will not affect the proper completion of jobs already in house and that the laboratory has the resources (personnel, equipment and facilities) necessary to accommodate the new project, this is accepted.
If the Management or any of the technical staff involved thinks that the new job will create problems in terms of reduced quality of work, completion out of specified or required time, or any other detrimental situation, the new project is not accepted and the client notified.
If there are alternatives, such as postponement, modification of sampling schedules or partial subcontracting to another lab in order to accommodate the project, this is proposed to the client.

9.4 Sample Receipt Protocol

Upon receipt, the condition of the sample, including any abnormalities or departures from standard condition is recorded. All samples, which require thermal preservation, are considered acceptable if the arrival temperature is either within +/- 2 ^{o}C of the required temperature or the method specific range. Samples that are hand delivered to the laboratory immediately after collection may not meet these criteria. In these cases, the samples will be considered acceptable if there is evidence that the chilling process has begun, such as arrival on ice. The temperature at which the samples are received is measured and recorded in the documents and in the LIMS.

Where applicable, Weck Laboratories, Inc. verifies chemical preservation using readily available techniques, such as pH or free chlorine, prior to or during sample preparation or analysis. The results of all checks are recorded.
When there is any doubt as to the sample's suitability for testing or if the sample does not meet any of the above criteria or if irregularities are noted, the client is notified immediately, and the irregularity is documented. If the client acknowledges the irregularity and instructs the laboratory to continue with analysis this is also documented. If the client does not acknowledge the irregularity the samples are rejected. If the irregularity is noted in samples submitted for bacteriological analysis for compliance purposes, the samples are rejected without exception.

The sample identification number is affixed to all sample containers and worksheets are prepared for the different types of analyses requested. When there are different containers or sub-samples belonging to one sample for multiple tests, the fraction name is indicated on the sample bottle by a suffix letter or other means. Alternatively, pre-labeled bottles containing the required tests are also provided.

9.5 Storage conditions

Samples that require thermal preservation are stored under refrigeration, which is +/- 2 ^{o}C of the specified preservation temperature. When this temperature is 4 ^{o}C, a storage temperature of just above the freezing temperature to 6 ^{o}C is considered acceptable. Samples are stored in a manner that prevents cross contamination, normally they are separated based on matrix, analysis and level of known contamination. Other samples are kept in specific areas while they are being tested. Evidence samples are stored in secured and controlled access areas.

9.6 Custody of Samples and Documentation

The Chain-of-Custody procedures begin when the sample is collected. At that time, a COC form is prepared, containing all the information about the sample (project name, sample identification, date and time of collection, name of person performing the sampling, matrix type, tests requested, number of containers, field measurements, and all other pertinent information).

The person who does the sampling must sign the COC record. The relinquishing and receiving parties must also sign the COC, indicating the date and time this operation was performed.
If the client submits the sample to the laboratory, a copy of the COC form is given to the client as evidence of receipt, while the other two copies are kept at the laboratory.

For samples received in sealed ice chests by commercial freight companies (UPS, FedEx), copies of shipping papers are attached to the COC form for future reference. The person receiving the sample also makes a notation of the type of shipment on the COC.

Access to all samples and sub-samples is controlled. The laboratory area is maintained secured and is restricted to authorized personnel only.

When full Legal/Evidentiary Chain of Custody protocols are required, COC records are used to establish an intact, continuous record of the physical possession, storage and disposal of sample containers, collected samples, sample aliquots, and sample extracts or digestates, The COC records account for all time periods associated with the samples. The COC records identify all individuals who physically handled individual samples. The COC forms remain with the samples during transport or shipment. If shipping containers and/or individual sample containers are submitted with sample custody seals, and any seals are not intact, the lab shall note this on the chain of custody. Other documents pertaining to the transport of the samples, such as receipts from common carriers are kept as part of the documentation.
When evidentiary samples, subsamples, digestates or extracts are transferred to another party they are subject to the requirements of legal chain of custody. These samples are kept in a locked area or refrigerator with the key in possession of the designated sample custodian.

9.7 Sample disposal

Samples are retained for thirty days from report date unless otherwise instructed by the client or if the samples are part of litigation or have been received under legal/evidentiary requirements, in which case the disposal of the physical sample is accomplished with the concurrence of the affected legal authority.
After the retention period samples are either returned to the client or properly disposed of according to federal and state laws and regulations.

10 CALIBRATION PROCEDURES AND FREQUENCY

10.1 Measurement Traceability

10.1.1 General

Whenever applicable, calibration of analytical support equipment and instruments and the overall program of calibration and/or verification is designed and operated so as to ensure that measurements are traceable to national standards of measurement.

All equipment used for environmental tests and/or calibrations, including equipment for subsidiary measurements (e. g. for environmental conditions) having a significant effect on the accuracy or validity of the result of the environmental test or sampling shall be calibrated before being put into service and on a continuing basis. The calibration of such equipment is performed according to the established program and procedure. This includes balances, thermometers, and control standards. The program also includes a system for selecting, using, calibrating, checking, controlling and maintaining measurement standards, reference materials used as measurement standards, and measuring and test equipment used to perform environmental tests.

10.1.2 Specific Requirements

The calibration of equipment shall be designed and operated so as to ensure that calibrations and measurements made by the laboratory are traceable to the International System of Units (SI).
The traceability is established for measuring instruments to the SI by means of an unbroken chain of calibrations or comparisons linking them to relevant primary standards of the SI units of measurement. The link to SI units may be achieved by reference to national measurement standards. National measurement standards may be primary standards, which are primary realizations of the SI units or agreed representations of SI units based on fundamental physical constants, or they may be secondary standards which are standards calibrated by another national metrology institute. When using external calibration services, traceability of measurement shall be assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability.
There are certain calibrations that currently cannot be strictly made in SI units. In these cases calibration shall provide confidence in measurements by establishing traceability to appropriate measurement standards such as the use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material and the use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned.
Participation in a suitable program of interlaboratory comparisons is required where possible.

The requirements above specified do not apply when it has been established that the associated contribution from the calibration contributes little to the total uncertainty of the test result. When this situation arises, the laboratory shall ensure that the equipment used can provide the uncertainty of measurement needed.

Where traceability of measurements to SI units is not possible and/or not relevant, the same requirements for traceability to, for example, certified reference materials, agreed methods and/or consensus standards, are required.

- The overall program of calibration and/or verification and validation of equipment shall be designed and operated so as to ensure that measurements made by the laboratory are traceable to national standards of measurement.
- Calibration certificates shall indicate the traceability to national standards of measurement and shall provide the measurement results and associated uncertainty of measurement and/or a statement of compliance with an identified metrological specification. The laboratory shall maintain records of all such certifications.
- Where traceability to national standards of measurement is not applicable, the laboratory shall provide satisfactory evidence of correlation of results, for example by participation in a suitable program of interlaboratory comparisons, proficiency testing, or independent analysis.

Calibration certificates obtained by the laboratory shall indicate the traceability to national standards of measurement and shall provide the measurement results and associated uncertainty of measurement and/or

a statement of compliance with an identified metrological specification. The laboratory shall maintain records of all such certifications.

Where traceability to national standards of measurement is not applicable, the laboratory shall provide satisfactory evidence of correlation of results, for example by participation in a suitable program of interlaboratory comparisons, proficiency testing, or independent analysis, if any is available.

10.2 Reference Standards and Reference Materials

Reference standards of measurement (such as Class S or equivalent weights or traceable thermometers) are used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated. Reference standards are subjected to in-service checks between calibrations and verifications. Reference standards shall be calibrated before and after any adjustment.

Where traceability of measurements to SI units is not possible or not relevant, the same requirements for traceability to, for example, certified reference materials, agreed methods and/or consensus standards, are required. The laboratory shall provide satisfactory evidence of correlation of results, for example by participation in a suitable program of interlaboratory comparisons, proficiency testing, or independent analysis.

Reference materials that require re-certification are submitted promptly to a qualified certification body can provide traceability to national standards of measurement.

Reference materials shall, where commercially available, be traceable to SI units of measurement, or to certified reference materials. Where possible, traceability shall be to national or international standards of measurement, or to national or international standard reference materials. Internal reference materials shall be checked as far as is technically and economically practicable.

Checks needed to maintain confidence in the status of reference, primary, transfer or working standards and reference materials are carried out according to defined procedures and schedules recommended by the manufacturer or maintenance organization.

The procedures employed for safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity, are the ones recommended by the manufacturer or other organization involved in the maintenance of such materials/standards.

10.3 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.

10.4 Analytical Support Equipment

Analytical support equipment includes but it is not limited to: balances, ovens, refrigerators, freezers, incubators, water baths, temperature measuring devices (including thermometers and thermistors), thermal/pressure sample preparation devices and volumetric dispensing devices (such as Eppendorf®, or automatic dilutor/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.
- Calibrated or verified annually using NIST traceable references when available, over the entire range of use. The results of such calibration must be within the specifications required in the application for which the equipment is used, if not, the equipment is either removed from service until repaired or a correction factor is applied to it, if applicable.

Raw data records shall be retained to document equipment performance.

Prior to use on each working day, balances, ovens, refrigerators, freezers, incubators and water baths are verified for the expected use range using NIST traceable references (where possible). The acceptability for use or continued use is according to the needs of the analysis or application for which the equipment is being used.
Mechanical volumetric dispensing devices (except Class A glassware and microsyringes) are checked for accuracy quarterly.

For chemical tests the temperature, cycle time, and pressure of each run of autoclaves is documented by the use of appropriate chemical indicators or temperature recorders and pressure gauges.
For biological tests that employ autoclave sterilization see SOP MIS031.

10.4.1 Balances and reference weights

Laboratory balances and Class S reference weights are serviced and calibrated once a year by a third party specialist, Watson Bros. Weck Laboratories has a contract with Watson Bros., by which they automatically come for balance and weights inspection and calibration every year. The calibration or service is performed more frequently if a problem is suspected or observed by visual inspection.

10.4.2 Thermometers

All thermometers are checked annually against a NIST traceable reference thermometer, which is submitted for certification on annual basis.

10.4.3 Monitoring of Temperature

All refrigerators and freezers used for storage of samples and standards or reagents are monitored for temperature daily. The incubators used for bacteriological analysis are monitored twice a day for temperatures and the incubator for BOD is monitored daily. The temperatures are entered in charts posted on each unit that also include the initials of the person performing the checks and the acceptance ranges. When a temperature is out of compliance in any refrigerator, freezer or incubator, immediate action is taken to correct the problem.
Some support instruments such as ovens and water bath for fecal coliforms are not in use every day, so temperature is checked only for the days they are actually in operation.

10.5 Initial Instrument Calibration and Continuing Calibration Verification

All instruments are calibrated in accordance with the respective SOPs and/or method of analysis. The typical calibration procedure consists of an initial calibration, performed by running a series of standards and calculating the response by using either the response factors or by linear or polynomial regression analysis. This is followed by a calibration verification when an initial instrument calibration is not performed on the day of analysis. All calibration procedures are thoroughly documented. The frequency, acceptance criteria and the conditions that will require recalibration are described in the corresponding SOPs. In all cases, the initial calibration is verified using an independently prepared calibration verification solution. For all chemical determinations in which standards are involved for calibration, it is the policy of the company to use a secondary reference material obtained from a different source, such as another supplier (preferred) or a different lot number, or prepared in house. This secondary reference can be an LCS or other standard run to verify the integrity of the primary standard.

Specific analyses' calibrations are checked more frequently. Some instruments, such as TOX analyzers have built-in calibration features. The internal calibration of these instruments is monitored daily for accuracy.

Some calibration curves for spectrophotometric methods are very stable over a long period of time, however it is the policy of the Laboratory to perform a new initial calibration curve even if the continuing calibration check meets specified criterion, in any of the following events:

- At least every three years
- When the instrument is moved to a different location
- If any maintenance that can affect the calibration has been performed
- If the analysts judges it necessary for special projects or different range of calibration

Spectrophotometers are also subject to wavelength calibration which it shall be performed at least annually, according to the procedure described by the manufacturer in the instrument manual or other documentation.

All results are calculated based on the response curve from the initial calibration and generally not quantitated from any continuing instrument calibration verification unless otherwise required by regulation, method, or program. The results are bracketed by calibration standards being the lowest calibration standard the lowest concentration for which quantitative data are to be reported. Any data reported below the lower limit of quantitation is considered to have an increased quantitative uncertainty and consequently it is reported using defined qualifiers or flags or explained in the case narrative; and the highest calibration standard is the highest concentration for which quantitative data are to be reported. Any data reported above this highest standard is considered to have an increased quantitative uncertainty and it is reported as an estimated value using the defined data qualifiers or explained in the case narrative, unless the sample can be diluted and re-run within the limits of the initial calibration curve.

The following is the criteria used for the acceptance of an initial calibration, unless specified differently in the analytical methods:

- Use the average response factor (RF) if the percent relative standard deviation (%RSD) of the points is less than 20%. In this case, linearity through the origin is assumed.
- If the %RSD is greater than 20%, linearity through the origin cannot be assumed and a linear regression, a weighed linear regression or a non-linear regression can be used. The acceptance criteria for linear regression are a coefficient of correlation (r) equal or greater than 0.99 and for non-linear regression the coefficient of determination (COD) must be equal or greater than

0.98. In both cases, the curve is not to be forced through the origin nor the origin is used as another point. The sample results must be within the first and last standards.

- The number of data points to construct the initial calibration curve shall be obtained from the analytical method employed. If no criteria are specified, the laboratory shall construct initial calibration curves using a minimum of two data points without counting the blank and zero standard.
- The lowest standard shall be at or near the reporting limit for the method and at or below the regulatory limit/decision level if known by the laboratory.
- The lowest calibration standard must be above the detection limit. Noted exception: The following shall occur for instrument technology (such as ICP or ICP/MS) with validated techniques from manufacturers or methods employing standardization with a zero point and a single point calibration standard:
    - Prior to the analysis of samples the zero point and single point calibration must be analyzed and the linear range of the instrument must be established by analyzing a series of standards, one of which must be at the lowest quantitation level.
    - Zero point and single point calibration standard must be analyzed with each analytical batch.
    - A standard corresponding to the lowest quantitation level must be analyzed with each analytical batch and must meet established acceptance criteria.
    - The linearity is verified at a frequency established by the method and/or the manufacturer.
    - If a sample within an analytical batch produces results above its associated single point standard then one of the following should occur:
        - analyze reference material at or above the sample value that meets established acceptance criteria for validating the linearity;
        - dilute the sample such that the result falls below the single point calibration concentration;
        - Report the data with an appropriate data qualifier and/or explain in the case narrative.

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 acceptable before analyzing samples. If samples can not be reanalyzed, data associated with an unacceptable initial instrument calibration must be reported with appropriate data qualifiers.

When an initial calibration is not performed on the day of the analysis, a calibration verification check standard is analyzed at the beginning and at the end of each batch. An exception to this policy is for internal standard methods (e.g. most organic methods). For these analyses, the calibration check is only analyzed at the beginning of the analytical sequence or analytical batch. The concentration of this calibration check is specified in each method SOP and whenever possible is varied within the established calibration range.

Sufficient raw data records are retained electronically as printouts to permit reconstruction of the continuing instrument calibration verification, e.g., test method, instrument, analysis date, each analyte name, concentration and response, calibration curve or response factor, or unique equations or coefficients used to convert instrument responses into concentrations. Continuing calibration verification records explicitly connect the continuing verification data to the initial instrument calibration by listing in the quantification report the initial calibration file that was used for the calculation.

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 constructed. 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 as qualified data, otherwise the samples affected by the unacceptable check are reanalyzed after a new calibration has been established, evaluated and accepted. If the continuing calibration acceptance criteria are below the low limit, results may be reported as qualified data if sample results indicate a concentration above an action level and accurate values are not required by the customer. Otherwise, additional sample analysis does not occur until a new calibration curve is established and verified.

When intermediate checks are needed to maintain confidence in the calibration status of the equipment, these checks shall be carried out according to each Standard Operating Procedure for the analytical method.

Where calibrations give rise to a set of correction factors, the laboratory shall have procedures to ensure that copies (e. g. in computer software) are correctly updated.

If the continuing instrument calibration verification results obtained are outside established acceptance criteria, corrective actions are performed. If routine corrective action procedures fail to produce a second consecutive (immediate) calibration verification within acceptance criteria, the following options are available:

- Demonstrate performance after corrective action with two consecutive successful calibration verifications
- Perform a new initial instrument calibration.

If acceptable performance has not been demonstrated, sample analyses shall not occur until a new initial calibration curve is established and verified. However, sample data associated with an unacceptable calibration verification may be reported as qualified data under the following special conditions:

- When the acceptance criteria for the continuing calibration verification are exceeded high, i.e., high bias, and there are associated samples that are non-detects, then those non-detects may be reported.
- When the acceptance criteria for the continuing calibration verification are exceeded low, i.e., low bias, those sample results may be reported if they exceed a maximum regulatory limit/decision level or if the samples are not for regulatory compliance and accurate values are not required by the customer.

11 TEST METHODS AND STANDARD OPERATING PROCEDURES

The methods and procedures used at the laboratory are the appropriate ones for all environmental tests within its scope. These include sampling, handling, transport, storage and preparation of samples, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of environmental test and/or calibration data.

The methods used at the laboratory, including methods for sampling, must meet the needs of the client and are appropriate for the environmental tests it undertakes. These analytical procedures currently in use are based on the methodology approved by the EPA, the California Department of Health Services, the AIHA, and other regulatory agencies.

In some cases, Weck Laboratories can perform analyses that are not specifically described in the guidelines cited above. In these cases, the following approach is taken:

- Review other sources of test methods such as AOAC, ASTM, Pesticide Manual, etc., to find a suitable method for the matrix and analyte in question.
- Produce a modification of a standard test procedure for similar parameter or matrix
- Develop a special method in house suitable for the particular problem

For these special situations the analytical procedure is discussed with the client and performed upon the client's approval. Whenever possible, the same QA/QC guidelines as for standard methods are used, but the laboratory may deviate from these guidelines if necessary.

The Laboratory in some instances must deviate from prescribed environmental test methods; if this occurs the deviation is documented, technically justified, authorized, and accepted by the client.

The Laboratory 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.
The SOPs provide all information needed to perform the different analytical tasks in accordance with regulatory requirements and in a consistent and controlled manner following the guidelines described in this QAP manual. They are subject to continuous review and update. Copies of all SOPs are accessible to all personnel. Each SOP has an alphanumeric code that indicates the section it belongs, the number that identifies it, the revision number, the effective date and the signature of the QA Officer, Technical Director or Laboratory Director.

If other documents besides laboratory generated SOPs (i.e. equipment manuals, copies of published methods, etc.) are used as Standard Operating Procedures, they must be written in a way that they can be used as written and any changes, including the use of a selected option must be documented and included in the laboratory's SOP manual.

A current list of the Standard Operating Procedures in use is in Appendix 7.

11.1 Test Methods

11.1.1 Source of Methods

The sources of Methods used at the laboratory are the following:

- Methods published in international, regional or national standards are preferably used, ensuring that the latest valid edition of a standard is used unless it is not appropriate or possible to do so. When necessary, the standard shall be supplemented with additional details to ensure consistent application.
- When the use of specific methods for a sample analysis are mandated or requested, only those methods shall be used.
- When the client does not specify the method to be used or where methods are employed that are not required, as in the Performance Based Measurement System approach, the methods shall be fully documented and validated, and be available to the client and other recipients of the relevant reports. The laboratory shall select appropriate methods that have been published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific

texts or journals, or as specified by the manufacturer of the equipment. In some cases Laboratory-developed methods or methods adopted by the laboratory might be used if they are appropriate for the intended use and if they are validated. The client shall be informed as to the method chosen.
- The client is informed when the method proposed by the client is considered to be inappropriate or out of date.

The Laboratory in some instances will develop methods for its own use; in this case this is considered a planned activity and will be assigned to qualified personnel equipped with adequate resources. Plans shall be updated as development proceeds and effective communication amongst all personnel involved shall be ensured.

When it is necessary to use methods not covered by standard methods, these shall be subject to agreement with the client and shall include a clear specification of the client's requirements and the purpose of the environmental test and/or calibration. The method developed shall have been validated appropriately before use.

Most methods in use at the laboratory are described in the following publications:

- Tests Methods for Evaluating Solid Waste, Physical/Chemical Methods, SW-846, current edition,
- Methods for Chemical Analysis of Water and Wastewater, EPA-600/4-79-020.
- Standard Methods for the Examination of Water and Wastewater, current approved edition, APHA, AWWA, WPCF.
- Criteria for Identification of Hazardous and Extremely Hazardous Wastes, California Code of Regulations Title 22.
- Methods for Organic Chemical Analysis of Municipal and Industrial Wastewater EPA-600/4-82-057.
- Recommended Methods of Analysis for the Organic components required for AB1803, 5th Edition Revised April 1986.
- Draft Method for Total Petroleum Hydrocarbons and Total Organic Lead, LUFT Methods, California Department of Health Services.
- Methods for the Determination of Organic Compounds in Finished Drinking Water and Raw Source Water - EPA 500 series.
- NIOSH Manual of Analytical Methods, US Department of Health and Human Services.
- Laboratory Methods of Analysis for Enforcement samples, SCAQMD, 1986.
- Stationary Source Test Methods, Air Resources Board, 1990.
- OSHA Analytical Methods Manual, 2nd Ed., U.S. Dept. of Labor, 1990.

Reference methods for all analytical procedures are kept in the Laboratory Office. Copies of specific methods are also in the corresponding sectors where the analyses are performed.

11.1.2 Validation of Methods

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

The laboratory shall validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application. The laboratory shall record the results

obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.
The range and accuracy of the values obtainable from validated methods (e. g. the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object), as assessed for the intended use, shall be relevant to the clients' needs.

The minimum requirements for method validation are the ones specified in Appendix C.3 of NELAC chapter 5.

11.2 SOPs for Sample Management

These SOPs describe the receipt, handling, scheduling, and storage of samples

Sample receipt and handling – These procedures describe the precautions to be used in opening sample shipment containers and how to verify that chain of custody has been maintained, examine samples for damage, check for proper preservatives and temperatures, and log samples into the laboratory sample streams.

Sample scheduling – These procedures describe the sample scheduling in the laboratory and includes procedures used to ensure that holding time requirements are met.

Sample storage – These procedures describe the storage conditions for all samples, verification and documentation of daily storage condition, and how to ensure that custody of the samples is maintained while in the laboratory.

11.3 SOPs for Reagent/Standard Preparation

These SOPs describe how to prepare standards and reagents. Information concerning specific grades of materials used in reagent and standard preparation, appropriate glassware and containers for preparation and storage, and labeling and record keeping for stocks and dilutions is included.

11.4 SOPs for General Laboratory Techniques

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

Procedures for test methods describing how the analyses are actually performed in the laboratory are specified in method SOPs. These SOPs for sample preparation, cleanup and analysis are based on publications listed in Section 11.1 above or on internally developed methods validated according to EPA's Performance-Based Measurement System.

The elements included or referenced in the SOPs, when applicable are the following:

11.4.1 Identification of the test method
11.4.2 Applicable matrix or matrices
11.4.3 Method detection limit
11.4.4 Scope and application, including components to be analyzed

11.4.5 Summary of the method
11.4.6 Definitions
11.4.7 Interferences
11.4.8 Safety
11.4.9 Equipment and supplies
11.4.10 Reagents and standards
11.4.11 Sample collection, preservation and handling
11.4.12 Quality control
11.4.13 Calibration and Standardization
11.4.14 Procedure
11.4.15 Calculations
11.4.16 Method Performance
11.4.17 Pollution prevention
11.4.18 Data assessment and acceptance criteria for quality control measures
11.4.19 Corrective actions for out-of-control data
11.4.20 Contingencies for handling out-of-control or unacceptable data
11.4.21 Waste management
11.4.22 References
11.4.23 Tables, Diagrams, flowcharts and data verification checklists.

11.5 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, services agreements 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.

12 QUALITY CONTROL DETERMINATIONS

12.1 General

The quality control procedures are used for monitoring the validity of environmental tests undertaken. The resulting data is recorded in a computerized database contained within the LIMS system which permits the monitoring of trends and the application of statistical techniques for the reviewing of the results. This monitoring includes among other parameters the use of certified reference materials and/or internal quality control using secondary reference material, participation in interlaboratory comparisons and proficiency-testing programs, replicate tests using the same or different methods, retesting of retained samples and correlation of results for different characteristics of a sample (for example, total phosphate should be greater than or equal to orthophosphate).

12.2 Essential QC determinations

The data acquired from QC determinations are used to estimate the quality of analytical data, to determine the need for corrective action in response to deficiencies, and to interpret results after corrective action procedures are implemented. Each method SOP includes a QC section, which addresses the minimum QC requirements for the procedure. The internal QC checks may differ slightly for each individual procedure

but in general are described below. The acceptance limits and corrective actions for these QC checks are described in Section 15 and 16 of this manual.

The quality control protocols specified in each analytical method and method SOP are followed, as well as the essential standards outlined in Appendix D of NELAC Chapter 5 or mandated methods or regulations (whichever are more stringent). When it is not apparent which is more stringent the QC in the mandated method or regulations is to be followed.

All quality control measures are assessed and evaluated on an on-going basis, and quality control acceptance criteria is used to determine the usability of the data. The procedures for the development of acceptance/rejection criteria where no method or regulatory criteria exist have been established (See Section 9.3, Sample Acceptance Policy)

12.2.1 Blanks – Negative Controls

Method Blanks or LRBs are performed at a frequency of one per preparation batch of samples per matrix type. The result of this analysis is one of the QC measures to be used to assess batch acceptance.

The method blank is used to assess the preparation batch for possible contamination during the preparation and processing steps. The method blank is processed along with and under the same conditions as the associated samples to include all steps of the analytical procedure.

The method blank is analyzed at a minimum of 1 per preparation batch or one every 20 environmental samples, whichever is more frequent. The method blank shall consist of a matrix that is similar to the associated samples and is known to be free of the analytes of interest.

Blanks and negative controls are used in microbiological analysis on regular basis. They consist of blanks, sterility checks and known negative cultures. The detailed description is contained in the corresponding SOP.

Blanks are prepared and analyzed in the following situations, or whenever there is a need to obtain further information:

- A blank is extracted for every batch and type of matrix for analysis of semi-volatile organics by GC, GC/MS or HPLC.
- A blank is carried through all the digestion procedures for analysis of metals by AA, ICP or ICP-MS for every batch of samples and type of matrix for each instrument used.
- A blank is carried through the leaching procedures (TCLP, EP TOX, and WET) using the same extraction fluid, bottles and agitators as the samples.
- System/Reagent blanks are analyzed at the beginning of the day prior to calibration, after a high level standard, after changing matrix and after samples that are known or suspected to be very concentrated.
- Reagent blanks are analyzed for all wet chemistry determinations involving titrations or colorimetry and their value are subtracted from the reading of the samples, if appropriate.
- Blanks for mobility procedures (TCLP, ZHE, EP TOX, and WET) are analyzed by the appropriate method.
- Additional field and trip blanks are prepared and analyzed where required or whenever requested by the client

Sometimes the blanks may show detectable amounts of target analytes. In these cases the source of the contamination must be investigated and measures taken to correct, minimize or eliminate the problem if:

- The blank contamination is at or above the reporting limit and exceeds a concentration greater than 1/10 of the measured concentration of any sample in the associated sample batch or
- The blank contamination exceeds the concentration present in the samples and is greater than 1/10 of the specified regulatory limit.
- The blank contamination otherwise affects the sample results as per the test method requirements or the individual project data quality objectives.

Any sample associated with the contaminated blank shall be reprocessed for analysis or the results reported with appropriate data qualifying codes.

12.2.2 Reproducibility and Recovery Determinations – Positive Controls

For the determination of accuracy and precision of the analytical methods, the techniques of fortified blanks, matrix spike/ matrix spike duplicate, sample duplicates and surrogate spiking are used on a regular basis. The frequency is dictated by each analytical method or Standard Operating Procedure (minimum 1 per batch of 20 samples). The results obtained are compared with current acceptance limits (Appendix 8) and recorded in the LIMS. For methods that do not specify the acceptance criterion, this is statistically obtained from data generated at the lab.
For microbiological determination of total and fecal coliforms positive checks are included with each batch analyzed. A more detailed description is included in the corresponding SOP.

12.2.2.1 Duplicates

Matrix duplicates are defined as replicate aliquots of the same sample taken through the entire analytical procedure. The results from this analysis indicate the precision of the results for the specific sample using the selected method. The matrix duplicate provides a usable measure of precision only when target analytes are found in the sample chosen for duplication and it is performed on replicate aliquots of actual samples, usually of unknown composition.
The frequency of the analysis of matrix duplicates may be determined as part of a systematic planning process (e.g. Data Quality Objectives) or as specified by the mandated test method. Duplicate analysis is also performed when unusual or suspicious results are obtained or when a higher degree of confidence in the analytical result is desired.
The routine analysis of field duplicates is often impractical (many analytes are frequently not detected) or not possible (not enough sample provided), so the evaluation of precision for most methods is accomplished by comparing the results obtained for matrix spike and matrix spike duplicate determinations (Section 12.1.2.3), rather than analysis of field duplicate samples. This is preferred since in many cases samples with frequent “not detected” results yield no useful information for statistical determinations of precision.

The results from matrix duplicates are primarily designed to assess the precision of analytical results in a given matrix and are expressed as relative percent difference (RPD) or another statistical treatment (e.g., absolute differences). The calculation of the RPD is detailed in Section 12.1.2.5.
Results are compared to the acceptance criteria as published in the mandated test method. Where there are no established criteria, internal criteria developed at the laboratory is used, which consists on using a minimum of 20 data points and calculating the maximum acceptable RPD based on 3 standard deviations

of the historical values. For matrix duplicates results outside of established criteria corrective action shall be documented or the data reported with appropriate data qualifying codes.

12.2.2.2 Laboratory Control Sample (LCS)

Laboratory Control Samples are also known as LFBs or Blank Spikes and are defined as a quality system matrix, free from the analytes of interest, spiked with verified known amounts of analytes from a source independent of the calibration standards or a material containing known and verified amounts of analytes. The LCS is used to evaluate the performance of the total analytical system, including all preparation and analysis steps. Results of the LCS are compared to established criteria and, if found to be outside of these criteria, indicates that the analytical system is "out of control". Any affected samples associated with an out of control LCS shall be reprocessed for re-analysis or the results reported with appropriate data qualifying codes.

At least one LCS is analyzed per preparation batch. Exceptions would be for those analytes for which no spiking solutions are available such as total suspended solids, total dissolved solids, total volatile solids, total solids, pH, color, odor, temperature, dissolved oxygen or turbidity. In those instances for which no separate preparation method is used (example: volatiles in water) the batch shall be defined as environmental samples that are analyzed together with the same method and personnel, using the same lots of reagents, not to exceed the analysis of 20 environmental samples.

The LCS is a quality system matrix, known to be free of analytes of interest, spiked with known and verified concentrations of analytes. The matrix spike (Sect. 12.1.2.3) may be used in place of this control as long as the acceptance criteria are as stringent as for the LCS. Alternatively the LCS may consist of a media containing known and verified concentrations of analytes or as Certified Reference Material (CRM). All analyte concentrations shall be within the calibration range of the methods.

The components to be spiked shall be as specified by the mandated test method or other regulatory requirement or as requested by the client. In the absence of specified spiking components the laboratory shall spike per the following:

- For those components that interfere with an accurate assessment such as spiking simultaneously with technical chlordane, toxaphene and PCBs, the spike should be chosen that represents the chemistries and elution patterns of the components to be reported.
- For those test methods that have extremely long lists of analytes, a representative number may be chosen. The analytes selected should be representative of all analytes reported. The following criteria shall be used for determining the minimum number of analytes to be spiked. However, the laboratory shall insure that all targeted components are included in the spike mixture over a 2-year period.
    a) For methods that include 1-10 targets, spike all components.
    b) For methods that include 11-20 targets, spike at least 10 compounds or 80% of the total, whichever is greater.
    c) For methods with more than 20 targets, spike at least 16 components.

The results of the individual batch LCS are calculated in percent recovery as specified in Sect.12.1.2.5. The individual LCS is compared to the acceptance criteria as published in the mandated test method. Where there are no established criteria, internal criteria are generated based on recoveries of past LCSs. To determine these criteria, at least 20 data points are used and the upper and lower acceptance limits are calculated as the "Mean + 3 SD" and "Mean – 3 SD" respectively, where SD is the standard deviation. A LCS that is determined to be within the criteria effectively establishes that the analytical system is in control and validates system performance for the samples in the associated batch. Samples analyzed along with a LCS determined to be "out of control" should be considered suspect and the samples reprocessed and re-analyzed or the data reported with appropriate data qualifying codes.

If a large number of analytes are in the LCS, it becomes statistically likely that a few will be outside control limits. This may not indicate that the system is out of control, therefore corrective action may not be necessary. Upper and lower marginal exceedance (ME) limits can be established to determine when corrective action is necessary. A ME is defined as being beyond the LCS control limit (3 standard deviations), but within the ME limits. ME limits are between 3 and 4 standard deviations around the mean. The number of allowable marginal exceedances is based on the number of analytes in the LCS. If more analytes exceed the LCS control limits than is allowed, or if any one analyte exceeds the ME limits, the LCS fails and corrective action is necessary. This marginal exceedance approach is relevant for methods with long lists of analytes. It will not apply to target analyte lists with fewer than 11 analytes.

The number of allowable marginal exceedances is as follows:

1) >90 analytes in LCS, 5 analytes allowed in ME of the LCS control limit;
2) 71-90 analytes in LCS, 4 analytes allowed in ME of the LCS control limit;
3) 51-70 analytes in LCS, 3 analytes allowed in ME of the LCS control limit;
4) 31-50 analytes in LCS, 2 analytes allowed in ME of the LCS control limit;
5) 11-30 analytes in LCS, 1 analytes allowed in ME of the LCS control limit;
6) <11 analytes in LCS, no analytes allowed in ME of the LCS control limit;

Marginal exceedances must be random. If the same analyte exceeds the LCS control limit repeatedly, it is an indication of a systemic problem. The source of the error must be located and corrective action taken.

The procedure to monitor the application of marginal exceedance allowance to the LCS to ensure random behavior consist of establishing a data base with all exceedances and compare the analytes affected on quarterly basis to verify is not the same analyte having the problem.

12.2.2.3 Matrix Spikes and Matrix Spike Duplicates

The procedure to determine the effect of the sample matrix on method performance is by analyzing with each preparation batch matrix spikes, matrix spikes duplicates sample duplicates and surrogates, which are designed as data quality indicators for a specific sample using the designated test method. These controls alone are not used to judge laboratory performance.

Matrix specific QC samples indicate the effect of the sample matrix on the precision and accuracy of the results generated using the selected method. The information from these controls is sample/matrix specific and would not normally be used to determine the validity of the entire batch.
The frequency of the analysis of matrix specific samples is determined as part of a systematic planning process (e.g. Data Quality Objectives) or as specified by the required mandated test method or SOP and it is at a minimum, one per batch of 20 samples or less, per matrix type.
The components to be spiked are the ones specified by the mandated test method or laboratory SOP. Matrix spikes are not performed for analytes for which spiking solutions are not available such as, solids determinations (total suspended, total dissolved, total volatile), pH, color, odor, temperature, dissolved oxygen, BOD, COD or turbidity.
The selected sample(s) for spiking are to be rotated among client samples, as much as possible, so that various matrix problems may be noted and/or addressed. The spiked samples are then analyzed as the other samples in the batch and the recoveries calculated and compared with acceptance limits. Results are recorded in the LIMS, where the analysts or QA Officer can track and manage the results for QC samples. For industrial hygiene samples, unused sample collection media is used for spiking. Samples that are labeled equipment blanks, field blanks or trip blanks must not be used for matrix spiking. All efforts shall be made to obtain additional sample aliquots for matrix spiking; when bottles are prepared in house,

additional containers are provided for matrix spikes. If the sample containers are prepared by the client or provided by a third party, good communication should be established with all parties involved in order to obtain enough sample aliquots to perform matrix spiking for all test methods required. If, in spite of all efforts made, there are no extra samples received for matrix spiking, a pair of LCS/ LCS duplicate is analyzed for assessing accuracy and precision.

Any permit specified analytes, as specified by regulation or client requested analytes shall also be included. If there are no specified components, the laboratory shall spike per the following:

- For those components that interfere with an accurate assessment such as spiking simultaneously with technical chlordane, toxaphene and PCBs, the spike should be chosen that represents the chemistries and elution patterns of the components to be reported.
- For those test methods that have extremely long lists of analytes, a representative number may be chosen using the following criteria for choosing the number of analytes to be spiked, but alternating them in order to ensure that all targeted components are included in the spike mixture over a 2 year period.
- For methods that include 1-10 targets, spike all components;
- For methods that include 11-20 targets, spike at least 10 components or 80% of the total, whichever is greater;
- For methods with more than 20 targets, spike at least 16 components.

The results from matrix spike/matrix spike duplicate are primarily designed to assess the precision and accuracy of analytical results in a given matrix and are expressed as percent recovery (%R) and relative percent difference (RPD). The calculations are performed as specified in Sect.12.1.2.5.
Results are compared to the acceptance criteria as published in the mandated test method. Where there are no established criteria, the laboratory established internal criteria determined as described in Sect. 12.1.2.2 for LCSs. Poor performance in a matrix spike generally indicates a problem with the sample composition, and not the laboratory analysis and is reported to the client whose sample was used for the spike with the appropriate data qualifiers or in the case narrative to assist in data assessment.

12.2.2.4 Surrogates

For GC and GC/MS analysis, surrogate standards are added to all samples, blanks and QC samples, prior to sample preparation/extraction, for all organic chromatography test methods except when the matrix precludes its use or when a surrogate is not available. Surrogates are compounds that are very similar in their chemical and chromatographic characteristics as the target compounds but are not present in environmental samples, or at least they are not part of the target compounds list.
Results from recoveries of surrogate standards are compared with acceptance values, mandated by the method if available or lab generated and recorded in the LIMS. Acceptance limits generated at the laboratory are established based on a minimum of 20 valid data points by calculating the mean and standard deviation, the upper limit is set at “mean + 3SD” and the lower limit at “Mean – 3SD”.
Surrogates outside the acceptance criteria are evaluated for the effect indicated for the individual sample results. A corrective action is initiated which is guided by the data quality objectives or other site specific requirements. Results reported from analyses with surrogate recoveries outside the acceptance criteria include appropriate data qualifiers.

12.2.2.5 Equations used for calculations

The following equations are used in the calculation of recovery and RPD:

From duplicate sample:

$$RPD = \frac{S_a - S_b}{((S_a + S_b) \div 2)} x100\%$$

Where: S_a = First sub-sample analyzed
S_b = Second sub-sample analyzed

From MS/MSD analysis:

$$RPD = \frac{R_a - R_b}{((R_a + R_b) \div 2)} x100\%$$

Where: R_a = Amount of analyte found in Matrix Spike.
R_b = Amount of analyte found in Matrix Spike Duplicate

Recovery of matrix spikes:

$$\text{Recovery} = \frac{SSR - SR}{CA} x100\%$$

Where: SSR= Results of spiked sample
SR = Results of sample (unspiked)
CA = Concentration of spike added

Surrogate recoveries:

$$\%\ \text{Recovery} = \frac{ConcentrationFound}{ConcentrationAdded} x100\%$$

Where: Concentration found = Result obtained after analysis
Concentration added = Amount of surrogate spiked

12.2.2.6 Quality Control Charts

Quality Control charts can be generated at any time from data stored in the LIMS for recoveries of matrix spikes, LCSs, surrogates and RPD and they are a valuable tool to monitor in real time the performance of the analytical method, providing a graph with the mean and upper and lower warning and acceptance limits (2 and 3 standard deviation respectively).

12.2.3 External References and Control Samples

External Reference Samples or QCS are obtained from various sources are analyzed on a regular basis, minimum quarterly. Reference samples simulating matrix and analytes of interest are purchased from Environmental Resource Associates, Inc. or other NIST approved vendors, and analyzed for drinking water, wastewater, hazardous waste and priority pollutants.

Interlaboratory comparisons are run whenever possible, as well as intralaboratory comparisons by analyzing an analyte by different analytical methods.

12.3 Method Detection Limit and Reporting Limits

In general the laboratory utilizes a test method that provides a Limit of Detection (LOD) that is appropriate and relevant for the intended use of the data. LODs are determined by the protocol in the mandated test method or applicable regulation, e.g., Method Detection Limit (MDL) and all sample-processing steps of the analytical method are included. If the protocol for determining detection limits is not specified, the selection of the procedure must reflect instrument limitations and the intended application of the test method.

The MDL is defined as the minimum concentration of an analyte that can be measured and reported with 99% confidence that the analyte concentration is greater than zero.

For analytes for which spiking is a viable option, detection limits are determined by a Method Detection Limit (MDL) study for each common matrix (water and soil/solid) by the procedure described in 40CFR Part 136, Appendix B. This procedure consists of spiking seven or more aliquots of the matrix with each compound of interest, at a concentration between 3 and 5 times the estimated MDL. These spiked samples are subject to the entire analytical process and analyzed. The MDL is calculated as follows:

$$MDL = S \times t$$

Where

S	=	Standard deviation of the seven replicates.
t	=	Student's "t" value for 99% confidence for the corresponding number of degrees of freedom. For 7 replicates this number is 3.14.

The method detection limit is initially determined for the compounds of interest in each method and in each matrix (aqueous or soil/solid). Laboratory pure reagent water and Ottawa sand are used as matrices for aqueous and soil/solid matrix respectively.

The detection limit is initially determined for the compounds of interest in each test method in a matrix in which there are neither target analytes nor interferences at a concentration that would impact the results. Detection limits are repeated each time there is a change in the test method that affects how the test is performed, or when a change in instrumentation occurs that affects the sensitivity of the analysis.

The MDL studies are documented in spreadsheets created for that purpose. The documentation includes the matrix type, date of analysis, analyst name or initials, instrument used, values obtained and calculations. The raw data and supporting documents are retained, either attached to the spreadsheet used for calculation or filed by date with the general raw data.

The validity of the LOD shall be confirmed by qualitative identification of the analyte(s) in a QC sample in each quality system matrix containing the analyte at no more than 2-3X the LOD for single analyte tests and 1-4X the LOD for multiple analyte tests. This verification must be performed on every instrument that is to be used for analysis of samples and reporting of data.

A LOD study is not required for any component for which spiking solutions or quality control samples are not available such as temperature, or, when test results are not to be reported to the LOD (versus the limit

of quantitation or working range of instrument calibration), according to Appendices D.1.2, D.4.5, D.5.4, and D.6.6 of NELAC chapter 5, 2003. Where an LOD study is not performed, the laboratory may not report a value below the Limit of Quantitation.

The Limit of Quantitation (LOQ) is normally set at 10 times the standard deviation. This is equivalent to multiply the MDL (obtained for 7 replicates) by 3.18 and rounding to the nearest 1, 2 or 5. In other cases, for certain methods the reporting limit is obtained by multiplying the MDL by another factor (between 2 and 10). The reporting limit for each analyte in each method is referenced in the corresponding SOP.

The LOQ is often referenced as Reporting Level or Practical Quantitation Limit (PQL). Certain projects require reporting all detected analytes, even below the reporting limit; in this case, when an analyte is detected but it is below the PQL, it is reported with a "J" flag indicating that the concentration is only estimated.

Unless the analytical method specifies otherwise, the LOQ is confirmed for each analyte of concern by analyzing a standard at the LOQ level or near and obtaining a recovery between 50 and 150% of the true value. This confirmation is not performed for any component or property for which spiking solutions or quality control samples are not commercially available or otherwise inappropriate (e.g., pH).
In certain cases the recovery of each analyte must be within the established test method acceptance criteria or client data quality objectives for accuracy.

In some cases project-specific reporting limits are used, when the DQOs mandate a different reporting limit than the RLs used routinely by Weck Laboratories.

For potable water analysis, the Detection Limit for Reporting purposes (DLRs) is used instead of the actual MDLs or RLs. For this matrix the calculated MDL must not be greater than the DLR. DLRs are verified on regular basis by including the lowest calibration point at or below the DLR.

12.4 Selectivity

Absolute retention time and relative retention time aid in the identification of components in chromatographic analyses and to evaluate the effectiveness of a column to separate constituents.
Acceptance criteria for retention time windows are documented in the corresponding method SOP or in the SOP ORG074.
A confirmation shall be performed to verify the compound identification when positive results are detected on a sample from a location that has not been previously tested by the laboratory. Such confirmations shall be performed on organic tests such as pesticides, herbicides, or acid extractable or when recommended by the analytical test method except when the analysis involves the use of a mass spectrometer. Confirmation is required unless stipulated in writing by the client. The confirmation is documented in the bench sheets and/or the LIMS.
Other procedures for evaluating selectivity are described in the analytical methods, which may include mass spectral tuning, ICP inter-element interference checks, sample blanks, spectrochemical absorption or fluorescence profiles, co-precipitation evaluations, and electrode response factors.
Acceptance criteria for mass spectral tuning are contained in the corresponding SOPs.

12.5 Demonstration of Method Capability

Prior to acceptance and use of any method, satisfactory initial demonstration of method performance is required. The initial demonstration of method performance is performed each time there is a significant

change in instrument type, personnel or test method. The process is described in Appendix 9. A Certification Statement is completed for each analyst documenting that this activity has been performed (Appendix 9). The associated records supporting the activity are also retained at the laboratory and they are available to reproduce the analytical results summarized in the Certification Statement.
The demonstration of method capability consists of performing the analysis on a clean quality system matrix, which has been spiked with the compounds of interest or purchased from a certified vendor.
For analysis that require the use of a specialized "work cell" (a group consisting of analysts with specifically defined tasks that together perform the test method), the group as a unit performs the IDC. The supporting documentation is also kept at the laboratory.
When a work cell is employed, and the members of the cell change, the new employee works with experienced analysts in the specialty area and this new work cell demonstrates acceptable performance through acceptable continuing performance checks, such as laboratory control samples. This continued performance check is documented and the four preparation batches following the change in personnel is monitored to ensure that none of the batches result in the failure of any batch acceptance criteria (method blank and laboratory control sample). If there is a failure, the demonstration of capability is repeated. When the entire work cell is changed or replaced, the new work cell repeats the demonstration of capability (Appendix 9).
When a work cell(s) is employed the performance of the group (work cell) is linked to the training records of the individual members of the work cell.

For test methods that have been in use by the laboratory before July 1999, and there have been no significant changes in instrument type, personnel or test method, the continuing demonstration of method performance and the analyst's documentation of continued proficiency is considered acceptable. Records are kept on file to demonstrate that a demonstration of capability is not required.

12.6 Performance and Proficiency Testing Programs

The following are the proficiency testing programs in which the laboratory currently participates on regular basis:

- Drinking water analysis: WS Studies
- Wastewater analysis: WP studies
- Hazardous waste and soil
- Bacteriological Performance Evaluation Study.

The Proficiency Testing samples are purchased from NIST approved vendors.

The PT samples are analyzed and the results returned electronically to the PT Provider by the closing date of the study, which is no later than 45 calendar days from study opening. All PT samples are handled (i.e., managed, analyzed, and reported) by the laboratory management and individual analysts in the same manner as real environmental samples utilizing the same staff, methods as used for routine analysis of that analyte, procedures, equipment, facilities, and frequency of analysis. When analyzing a PT sample, the same calibration, laboratory quality control and acceptance criteria, sequence of analytical steps, number of replicates and other procedures are employed as used when analyzing routine samples.

In addition to the required PT studies, the laboratory participates in other special PT programs managed by government agencies or private entities.

12.7 Additional Quality Control Checks

The laboratory shall assure that the test instruments consistently operate within the specifications required of the application for which the equipment is used.

Glassware shall be cleaned to meet the sensitivity of the test method. The cleaning and storage procedures that are not specified by the test method are documented in the method SOPs or in SOP MIS028 for cleaning protocols.

Whenever possible, additional QC checks are performed such as running a sample using different techniques and different standards (EPA Method 602 & EPA Method 624), correlations between COD, BOD and TOC; TDS & Specific Conductivity, balance between cations and anions on water analysis, etc.

12.8 Estimation of Uncertainty of Measurement

A procedure to estimate the uncertainty of measurement for all analytical methods used at the laboratory has been established.
In certain cases the nature of the test method may preclude rigorous, metrologically and statistically valid, calculation of uncertainty of measurement. In these cases the laboratory shall attempt to identify all the components of uncertainty and make a reasonable estimation, and shall ensure that the form of reporting of the result does not give a wrong impression of the uncertainty. Reasonable estimation shall be based on knowledge of the performance of the method and on the measurement scope and shall make use of, for example, previous experience and validation data.
The need of estimating uncertainty will be considered satisfied where a well-recognized test method specifies limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results and the test method and reporting instructions are followed appropriately.
When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation shall be taken into account using appropriate methods of analysis.

13 DATA REDUCTION, VERIFICATION AND REPORTING

13.1 Laboratory worksheets - Raw data documentation

Upon acceptable receipt of samples by the laboratory, sample worksheets are generated for the required testing. These worksheets are distributed to the respective laboratory departments.

The data that is being obtained, such as weights, extraction volumes, calculations, etc. are recorded in the worksheets or in the LIMS. “Bench sheets” are generated either from the data entered in the LIMS or manually for all raw data being produced.

After raw data is entered in the corresponding worksheets and run logs, it is initialed by the analyst and saved chronologically for future review. All electronic raw data is stored in magnetic tapes or CDs.

13.2 Data Reduction and Review

Some instruments have a computerized data reduction and calculation, such as GC/MS, HPLC, GC and ICP. The protocols to perform these tasks are described in the corresponding SOPs and the computer programs used for data reduction are validated before use and checked periodically by manual calculations. The results obtained from computer data reduction are double checked by the analyst and transferred directly to the LIMS, whenever possible, or manually entered. Most methods have a Data Review Checklist that is completed by the analyst and addresses all the required QC determinations.
A supervisor or second analyst performs a secondary review of the raw data (e.g. chromatograms and reports summary) for proper integration of peaks, identification of compounds, QC, etc. If a discrepancy is noted, the package is returned to the primary analyst for corrective action. For analyses that do not have automatic data reduction, the analyst performs the necessary calculations to obtain the final result, and then the results are reviewed by the supervisor or second analyst.

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) as well as sample preparation information (e.g. weight or volume of sample used, percent dry weight for solids, extract volume, dilution factor used) are recorded in order to enable reconstruction of the final result.

As described in Section 16, the results of the quality control sample analysis are reviewed, and evaluated before data are reported.

After the results are entered into the LIMS they are verified for completeness and correctness and if no discrepancies are encountered they are released for reporting.

13.3 Report Format and Contents

After the data is entered in the LIMS and approved, a report or “Certificate of Analysis” is generated from the information contained in the LIMS database. The certificate of analysis, containing the results of each test, or series of tests, is then submitted with all supporting documentation to the Project Manager for signature. Other authorized signatory personnel include the Lab Technical Director, QA Officer or Lab Manager. The signature could be either in the form of “wet signature” or “electronic signature” which is stored in the LIMS database.

The analytical report, of which the Chain of Custody Document is part, contains the following information, at a minimum:

- Header with complete laboratory information.
- Unique identification of each page and an indication of the total number of pages included in the report
- Client’s information (Company name, address, contact person, etc.)
- Project name or number
- Lab ID number assigned to the sample (unique identification number).
- Description and unambiguous identification of the sample(s) including the client identification code.
- Sample login information (date, time and initials of person that received the sample)
- Sampling information (date, time, name of sampler)
- If the laboratory collected the sample, reference to sampling procedure.
- Analysis performed.
- Results obtained with reporting units

- Date of preparation and analysis
- Time of preparation and/or analysis for tests with holding times of equal or less than 72 hours when required to demonstrate that the test was performed within holding times (the time of preparation/analysis can be entered in the case narrative section of the report).
- Name of method used for preparation and analysis
- Minimum Reporting Level or PQL
- Identification of results for any sample that did not meet sample acceptance requirements.
- Signature of authorized person (Lab Manager, Lab Director, etc.)
- Any additional information that is important to be reported.
- Any deviations from, additions to, or exclusion from SOPs; any conditions that may have affected the quality of results and any failures (such as failed quality control), including the use and definitions of data qualifiers (appendix 12).
- Measurements, examinations and derived results, supported by tables, graphs, sketches and photographs as appropriate, and any failures identified; identification of whether data are calculated on dry weight basis; identification of the reporting units such as ug/l or mg/kg
- Clear identification of all test data provided by outside sources, such as subcontracted laboratories, clients, etc.
- Clear identification of numerical results with values below the RL (J qualifier).

Exceptions to this standard approach for reporting are allowed with the approval of the Technical Director and are documented.

Any result not obtained in accordance with the approved method and the lab QA Plan by use of proper lab technique, must be documented as such in the case narrative section of the Certificate of Analysis.

Material amendments to a test report after issue are made only in the form of a further document, or data transfer including the statement “Supplement to Certificate of Analysis, identification number”.

Clients are notified promptly, in writing, of any event such as the identification of defective measuring or test equipment that cast doubt on the validity of results given in any test report or amendment to a report.

Test results are certified to meet all requirements of the NELAC standards, or reasons are provided if they do not.
After signed, the Certificates of Analysis are sent to the client by US mail. In some cases the report is submitted by facsimile, electronically or electromagnetically. In this last case, all reasonable steps are taken to preserve confidentiality and the data is only sent to fax numbers or email addresses properly authorized by the client. Hard copies are submitted by US Mail.

13.4 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 must be legible, identifiable, and retrievable, and protected against damage, deterioration or loss. All records referenced in this section are retained for a minimum of ten years.

The laboratory has established and maintain procedures to control all documents that form part of its quality system (internally generated or from external sources), such as regulations, standards, other

normative documents, environmental test and/or calibration methods, as well as drawings, software, specifications, instructions and manuals. Documents include policy statements, procedures, specifications, calibration tables, charts, textbooks, posters, notices, memoranda, software, drawings, plans, etc. These may be on various media, whether hard copy or electronic, and they may be digital, analog, photographic or written.
A procedure has been established to review and approve for use by authorized personnel prior to issue, all documents issued to personnel in the laboratory as part of the quality system. The procedure also establishes a document control system and the policy to be followed with invalid and/or obsolete documents.

Laboratory records generally consist of bound notebooks with pre-numbered pages, official laboratory worksheets, personnel qualifications and training forms, facilities, Corrective Action reports, PT records, equipment maintenance and calibration forms, chain-of-custody forms, sample analysis request forms, and analytical change request forms. All records are recorded in indelible ink and retained for ten years. Records that are stored or generated by computers have hard copy or write protected backup copies. Electronic records are supported by the hardware and software necessary for their retrieval.

Any documentation changes are corrected by drawing a single line through the change so that it remains legible and is initialed by the responsible individual, along with the date of change and reason. The correction is written adjacent to the error. Strip-chart recorder or computer printouts are signed by the person who performed the instrumental analysis. If corrections need to be made in computerized data, a system parallel to the corrections for handwritten data is used.
In the event the Laboratory is sold, all past records shall be transferred to the custody of the new legal owner or operator of the Laboratory.
This management however shall maintain responsibility and accountability for laboratory work performed prior to the transfer. A written statement to this effect shall be provided.
The new owner/operator shall be accountable and liable for all work performed after the transfer date and he/she shall provide a written statement to that effect.
In the case the laboratory goes out of business, the present management shall maintain custody of all records and make them available to clients for a period of ten years.

Laboratory records include the following:

13.4.1 Standard Operating Procedures

SOPs are controlled documents. They are reviewed on regular basis and if there are any revisions, these are distributed to all affected individuals to ensure implementation of changes. All revisions of SOPs are archived.

13.4.2 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.

13.4.3 Calibration Records and Traceability of Standards/Reagents

The frequency, conditions, standards, reagents and records reflecting the calibration history of a measurement system are recorded. These include but are not limited to the source of standards and reagents, receipt, preparation and use.

The overall program of calibration and/or verification and validation of equipment is designed and operated so as to ensure that measurements made by the laboratory are traceable to national standards of measurement.
Calibration certificates indicate the traceability to national standards of measurement and provide the measurement results and associated uncertainty of measurement and/or a statement of compliance with an identified metrological specification. The laboratory maintains records of all such certifications.
Where traceability to national standards of measurement is not applicable, the laboratory will provide evidence of correlation of results by participation in a suitable program of interlaboratory comparisons, proficiency testing, independent analysis or other suitable means.

13.4.4 Sample Management

A record of all procedures to which a sample is subjected while in the possession of the laboratory is maintained, including the personnel involved in each activity. These include records pertaining to:

- Sample preservation including appropriateness of sample container and compliance with holding time requirements.
- Sample identification, receipt, acceptance or rejection and log-in
- Sample storage and tracking including shipping receipts, transmittal forms, and internal routing and assignment records.
- Disposal of hazardous samples including the date of sample or sub-sample disposal and name of responsible person.
- Automated sample handling systems

13.4.5 Original Data

The raw data and calculated results for all samples is maintained in laboratory notebooks, logs, bench sheets, files or other sample tracking or data entry forms. Instrumental output is stored in a computer file and/or a hard copy report. These records include:

- Laboratory sample ID code
- Date of analysis
- Instrumentation identification and instrument operating conditions/parameters
- Analysis type and sample preparation information, including sample aliquots processed, cleanup, and separation protocols.
- All manual, automated, or statistical calculations
- Confirmatory analysis data, when required to be performed
- Review history of sample data
- Analyst’s or operator’s initials/signature
- All data generated, except those that are generated by an automated data collection system, are recorded directly, promptly and legibly in permanent ink.
- Date of analysis and extraction as well as time if the Hold Time is 72 hours or less.

13.4.6 QC Data

The raw data and calculated results for all QC samples and standards are maintained in the manner described in 13.4.5. 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, control samples, method blanks, matrix spikes and matrix spike duplicates.

13.4.7 Correspondence

Correspondence pertinent to a project is kept and placed in the project files.

13.4.8 Deviations

When a deviation from a documented policy occurs, including SOPs, analytical methods, QA/QC criteria, etc., the laboratory notifies the client of this in the Certificate of Analysis under the case narrative section or in a supplemental report indicating the deviation and the reasons for it.
All deviations from SOPs are reviewed and approved by the QA Officer or Technical Director.
When mistakes occur in records, each mistake is crossed out, leaving it legible, and the correct value and initials of person making the correction are entered alongside.
When corrections are due to reasons other than transcription errors, the reason for the correction is documented.

13.4.9 Final Reports

Copies of final reports are kept in each client's file, along with supporting documentation

13.4.10 Administrative Records

The following are maintained:

- Personnel qualifications, experience and training records
- Initial and continuing demonstration of proficiency for each analyst
- A log of names, initials and signatures for all individuals who are responsible for signing or initialing any laboratory record.

13.5 Document Control System

The laboratory has established and maintains procedures to control all documents that form part of its quality system (internally generated or from external sources).

A document control system is used to ensure that all personnel have access to current policies and procedures at all times. Documents, which are managed by this system, include this Quality Manual, all SOPs, policy statements, procedures, specifications, calibration tables, charts, textbooks, posters, notices, memoranda, software, drawings, plans, etc. The system consists of a document review, revision and approval system, and document control and distribution. The documents may be on various media, whether hard copy or electronic, and they may be digital, analog, photographic or written.

All quality documents (this manual, SOPs, policies, etc.) are reviewed and approved by the QA Officer, the Technical Director and the Laboratory Director. Such documents are revised whenever the activity described changes significantly. All documents are reviewed at least every 5 years, with the exception of the QA Manual, which is reviewed annually.

All QA/QC documents are controlled by the QA Officer. Controlled copies are provided to individuals in the laboratory who need copies. The QA Officer maintains a distribution list for controlled copies and ensures that any revisions are distributed appropriately.

More detailed procedures related to Document Control are specified in the corresponding SOP (MIS045).

13.6 Confidentiality

All analytical reports, results, electronic records and transmission of results are kept in confidence to the customer who requested the analyses and only released to third parties with written permission from a properly authorized representative of the client. This information includes, but is not limited to COCs, Certificates of Analysis, raw data, bench sheets, electronic information and sample results.
In addition no information pertaining to clients is posted in public areas where the access is not restricted. Access to laboratory records and LIMS data is limited to authorized laboratory personnel except with the permission of the QA Officer or Laboratory Director. NELAP-related records are made available to authorized accrediting authority personnel.

13.7 Service to the Client

The laboratory shall afford clients or their representatives' cooperation to clarify the client's request and to monitor the laboratory's performance in relation to the work performed, provided that the laboratory ensures confidentiality to other clients.

14 PERFORMANCE AND SYSTEM AUDITS AND FREQUENCY

14.1 Internal Laboratory Audits

Annual internal audits are performed to verify that laboratory operations continue to comply with the requirements of the quality system and the corresponding NELAC Standard. The internal audit program shall address all elements of the quality system, including all of the environmental testing activities.
The quality assurance officer plans and organizes internal audits as required by a predetermined schedule and requested by management. Such audits are performed by the Quality Assurance Officer or personnel designated by the QA officer, who are by trained and qualified and wherever resources permit, independent of the activity to be audited. Technical personnel are not allowed to audit their own activities unless it can be thoroughly demonstrated that an effective audit will be carried out.
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 must be notified in writing within 30 days of the finding if investigations show that the laboratory results may have been affected.
The laboratory shall notify clients promptly, in writing, of any event such as the identification of defective measuring or test equipment that casts doubt on the validity of results given in test report or test certificate or amendment to a report or certificate.
The internal system audits include 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.

14.2 Management Review

At least once per year, laboratory executive management conducts a review of the quality system and environmental testing 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 the following:

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

The managerial review is performed according to specified procedures detailed in the corresponding SOP and the records of review findings and actions are kept at the laboratory.
The area of activity audited, the audit findings and corrective actions that arise from them shall be recorded. The laboratory management shall ensure that these actions are discharged within the agreed time frame as indicated in this QA manual and/or in the corresponding SOPs.
Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken.
The management shall ensure that those actions are carried out within an appropriate and agreed timescale.
The laboratory, as part of their overall internal auditing program, shall insure that a review is conducted with respect to any evidence of inappropriate actions or vulnerabilities related to data integrity. Discovery of potential issues shall be handled in a confidential manner until such time as a follow up evaluation, full investigation, or other appropriate actions have been completed and the issues clarified. All investigations that result in finding of inappropriate activity shall be documented and shall include any disciplinary actions involved, corrective actions taken, and all appropriate notifications of clients. All documentation of these investigation and actions taken shall be maintained for 10 years.

14.3 Other Audits

The Laboratory is also subject to external audits performed by regulatory agencies and clients. The State regulatory agency under which the laboratory is accredited under NELAC performs a bi-annual quality systems audit. The QA Manager and other relevant management personnel ensure that all the items identified in NELAC Chapter 5 Quality Systems are available for on-site inspection at the time they are requested in order to facilitate the audit process.
Audits performed by clients are non-routine and could be part of the evaluation process in selecting a laboratory for a particular project. For these audits, the management personnel can make available all items requested that are relevant to the evaluation of the Quality System and specific QA/QC practices without releasing information that could be considered confidential or pertaining to other clients data.

15 FACILITIES, EQUIPMENT AND REAGENTS

15.1 Facilities

The Laboratory is segregated into different areas for operations that are not compatible with each other. This separation prevents contamination of low levels of common laboratory solvents in the volatile organics analyses and maintains culture handling or incubation areas segregated from other areas.
The access to the volatile organics laboratory and microbiology laboratory is restricted to appropriate personnel only; signs to that effect are posted on the entry doors of these areas.
It is the policy of the company to assure that the facilities housing the laboratory and the workspaces are adequate to perform the analyses for which it is accredited. These include physical space, energy sources, lighting and environmental conditions, sufficient storage space, workbenches, ventilation, utilities, access and entryways to the laboratory, sample receipt area(s), sample storage area(s), chemical and waste storage area(s); and data handling and storage area(s). For microbiology, floors and work surfaces shall be non-absorbent and easy to clean and disinfect. Work surfaces shall be adequately sealed and shall be clean and free from dust accumulation. Plants, food, and drink shall be prohibited from the laboratory work area. The company will procure to improve the condition of the facilities whenever possible and make plans for future expansions or improvements.

The laboratory, as per Standard Operating Procedures, monitors, control and records environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of the results, for example monitoring biological sterility and other environmental effects, as appropriate to the technical activities concerned. Environmental tests shall be stopped when the environmental conditions jeopardize the results of the environmental tests and/or calibrations.

Adequate measures are taken to ensure good housekeeping in the laboratory and to ensure that any contamination does not adversely affect data quality.

15.2 Equipment and Equipment Maintenance

The Laboratory is furnished with all items of sampling, measurement and test equipment required for the correct performance of the environmental tests (including sampling, preparation of samples, processing and analysis of environmental data). If the laboratory needs to use equipment outside its permanent control, this equipment must meet the requirements of other lab equipment according to this QA Manual.

The Laboratory acquires only equipment and its software required for testing and sampling that is capable of achieving the accuracy required and that complies with specifications relevant to the environmental tests concerned.

Before being placed into service, equipment (including that used for sampling) is calibrated and/or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications.

Records are maintained for all major equipment, including documentation of all routine and non-routine maintenance activities.

The records include:

- The name of the equipment
- The manufacturer’s name, type identification, and serial number or other unique identification of the equipment and its software.
- Date received and date placed in service (if available)
- Current location, where appropriate.
- If available, condition when received (e.g. new, used, reconditioned)

- Dates and results of calibrations, if appropriate
- Details of routine and non-routine maintenance carried out to date and planned for the future
- History of any damage, malfunction, modification or repair

When purchasing new laboratory equipment and accessories, only reputable brands will be considered and always the instruments that have the best quality shall be considered, regardless of the difference in price with a similar instrument, considered of an inferior quality.

Instruments and equipment are maintained in optimum condition. Frequent inspections, routine preventative maintenance, prompt service, etc. ensure optimal performance.

It is the policy of the company to provide analytical instruments and software adequate to meet the method requirements and the quality control operations specified in both NELAC and the individual methods. Older instruments shall be replaced with newer ones as technology improves and efforts shall be made to provide a greater degree of automation and security in analytical instruments. A list of major instruments and reference materials is in Appendix 4.

Equipment shall be operated by authorized personnel. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) shall be readily available for use by the appropriate laboratory personnel.

Service contracts or agreements with the manufacturer or instrument Maintenance Company are maintained for the following instruments:

- ICP and/or ICP-MS instruments for metal analysis
- GC/MS units for volatile organics
- Purge and Trap systems and autosamplers
- GC/MS units for semi-volatile organics

The analyst in charge of each particular instrument performs preventive maintenance for all other analytical instruments.

All maintenance and repairs are thoroughly documented in logbooks, with information pertaining to the description of the problem or routine maintenance, date of occurrence and name of person that performed the maintenance operation.

A routine preventive maintenance program is used to minimize the occurrence of instrument failure and other system malfunctions. Designated employees regularly perform routine scheduled maintenance and repair of instruments. They also check that equipment complies with the specifications, design a plan for maintenance, where appropriate, and verify that the maintenance is carried out to date. All laboratory instruments are maintained according with manufacturer’s specifications.

Any item of the equipment which has been subjected to overloading or mishandling, or which gives suspect results, or has been shown by verification or otherwise to be defective, is taken out of service, isolated to prevent its use or clearly labeled as being out of service until it has been repaired and shown by calibration, verification or test to perform satisfactorily. The laboratory will examine the effect of this defect or departure from specified limits on previous tests and shall institute the "Control of nonconforming work" or Corrective Action procedures.

The equipment and its software used for testing, calibration and sampling used at the laboratory is capable of achieving the accuracy required and comply with specifications relevant to the environmental tests concerned. Calibration programs are established for key quantities or values of the instruments where these properties have a significant effect on the results. All new analytical and sampling equipment is calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications before being placed into service. All pieces of equipment are calibrated or checked before use.

Whenever practicable, all equipment under the control of the laboratory and requiring calibration shall be labeled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due.

When, for whatever reason, equipment goes outside the direct control of the laboratory, the laboratory shall ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service.

Test and calibration equipment, including both hardware and software, shall be safeguarded from adjustments which would invalidate the test and/or calibration results.

Glassware is cleaned to meet the sensitivity of the method. Any cleaning and storage procedures that are not specified by the method are documented in laboratory records or SOPs.

15.3 Reagents and Chemicals

The reagents and chemicals used in the laboratory are obtained from reputable suppliers that have proven consistency over the years. Purity specifications are chosen based on the analysis and this is always verified by the analysis of solvent blanks and check standards. In methods where the purity of reagents is not specified, analytical reagent grade are used. Reagents of lesser purity than those specified by the test method are not used. Upon receipt of reagents, the labels on the container are checked to verify that the purity of the reagents meets the requirements of the particular test method. Such information is documented in the corresponding logbook for reagents and chemicals.

The following are some of the reagents used:

- Solvents used for Gas Chromatography and GC/MS are “organic residue analysis” grade.
- Methanol used for volatile organics by GC or GC/MS is “Purge and Trap” grade.
- All inorganic chemicals are “reagent grade” or better, depending of the requirement.
- Nitric acid used for preparation of standards for ICP/MS analysis is “trace metals”.

The quality of reagent water sources is monitored for trace metals, TKN, TOC and bacteria content. The results are documented in the corresponding logbook kept at the Microbiological Lab. On daily basis, the quality of reagent water is monitored by performing method blanks and system blanks for all tests that require water and the results documented with the analytical batch. If the reagent water does not meet method specific requirements a corrective action procedure is initiated.

The concentration of titrants is verified in accordance with written laboratory procedures (SOPs) and documented in the Standardization log book kept in the Wet Chemistry section of the Laboratory.

15.4 Analytical Standards and Reference Materials

In general the Laboratory uses reference materials that are traceable, when possible to SI units of measurement, or to certified reference materials. Where possible, traceability shall be to national or international standards of measurement, or to national or international standard reference materials. Internal reference materials are checked as far as is technically and economically practicable.

Most of the standards used are purchased as certified solutions from qualified vendors. These stock standards are traceable to NIST, the corresponding documentation, including certificate of analysis or purity, date of receipt, recommended storage conditions, expiration date, etc., is maintained in laboratory files.

The original containers provided by the vendor are labeled with an expiration date.

All analytical standards received at the laboratory are inspected for appearance and expiration date, if any. They are recorded in the LIMS, which assigns a unique identification number. All chemicals received are also inspected and recorded into a book to assure traceability. The identification number is referenced when a dilution of the stock is made or when a reagent solution is prepared.

All reference materials after they have been properly inspected and logged in, are handled, transported, stored and used, according to the manufacturer's instructions in order to prevent contamination or deterioration and to protect their integrity.

Analytical standards prepared in the laboratory are prepared from certified stock solutions or pure product. Quality Control Standards (QCS) are prepared or obtained from a separate source other than the working standards.

The management does not reject any request from technical personnel to obtain a reference material or any type of instrument or chemical that he or she considers essential for the normal operation of the laboratory.

15.5 Computers and Electronic Data Related Requirements

Where computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test data the following are taken into consideration:

- Computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use;
- Procedures are established and implemented for protecting the data; including, but not limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing;
- Computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of environmental test data.
- Establishment and implementation of appropriate procedures for the maintenance of security of data including the prevention of unauthorized access to, and the unauthorized amendment of, computer records.
- Commercial off-the-shelf software (e. g. word processing, database and statistical programs) in general use within their designed application range is considered to be sufficiently validated, however, laboratory software configuration or modifications must be validated.

16 SPECIFIC ROUTINE PROCEDURES USED TO EVALUATE DATA QUALITY

Quality control acceptance criteria are used to determine the validity of the data based on the analysis of internal quality control check (QC) samples (see section 11). 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 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.

Many published EPA methods do not contain recommended acceptance criteria for QC sample results. In these situations, Weck Laboratories, Inc. uses 70 – 130 % as interim acceptance criteria for recoveries of spiked analytes, until in-house limits are developed. In-house limits are based on a 95% confidence interval and should include all historical data points (minimum of 20 data points).

16.1 Laboratory Control Samples

A Laboratory Control Sample 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 LCS 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 or reported with qualifiers.
LCS samples are prepared in each corresponding matrix (reagent water for aqueous and Ottawa sand for soil/solid), which must be free of the target analytes to be analyzed.

16.2 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, Weck Laboratories, Inc. 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.

16.3 Surrogates Recoveries

Surrogates are exclusively used in organic analysis. Surrogate recovery data from individual samples are compared to surrogate recovery acceptance criteria in the methods. As for MS/MSD results, surrogate recoveries are used primarily to evaluate data quality and not laboratory performance.

16.4 Method Blanks

Method blank analyses are used to assess acceptance of sample results. The source of contamination is investigated and measures taken to correct, minimize or eliminate the problem in the situations detailed in Section 12.1.1.

Any sample associated with the contaminated blank is reprocessed for analysis or the results reported with appropriate qualifying codes.

17 NON-COMFORMING WORK, CORRECTIVE ACTION AND PREVENTIVE ACTION

17.1 Control of Nonconforming Environmental Testing Work

A policy has been established to handle situations when any aspect of the Laboratory's environmental testing work, or the results of this work, do not conform to its own procedures or the agreed requirements of the client.

The procedures to be implemented when this situation occurs are detailed in the corresponding SOP (MIS044),

17.2 Corrective Action

Corrective action is the process of identifying, recommending, approving and implementing measures to counter unacceptable procedures or out of control QC performance that can affect data quality. To the extent possible, samples are reported only if all quality control measures are acceptable. If a quality control measure is found to be out of control, and the data is to be reported, all samples associated with the failed quality control measure are reported with the appropriate data qualifier(s). Sample results may also be qualified when holding times are not met, improper sample containers and/or preservatives are used or when other deviations from laboratory standard practices and procedures occur.

Corrective action in the laboratory may occur prior to, during and after initial analyses. A number of conditions such as broken sample containers, multiple phases, low or high pH readings, and potentially high concentration samples may be identified during sample login or just prior to analysis. The SOPs specify conditions during and after analysis that may automatically trigger corrective action or optional procedures. These conditions may include dilution of samples, additional sample extract cleanup, and automatic reinjection/reanalysis when certain QC criteria are not met.

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.

The analyst will identify the need for corrective action. The Technical Director will approve the required corrective action to be implemented by the laboratory staff. The QA Officer will ensure implementation and documentation of the corrective action.

Corrective actions are performed prior to release of the data from the laboratory. The corrective action will be documented in both a corrective action log (Appendix 10), signed by the personnel involved, and the narrative in the data report.

Where a complaint, or any other circumstance, raises doubt concerning the laboratory's compliance with the laboratory's policies or procedures, or with the quality of the laboratory's tests, the laboratory shall ensure that those areas of activity and responsibility involved are promptly audited in accordance with internal audit procedures established under this QA Manual. All complaints received at the laboratory from clients or other parties shall be treated according to the corresponding standard operating procedure for its resolution. Records of the compliant and subsequent actions are maintained for future review.

There are some cases in which the QC checks do not fail but the analyst or supervisor discovers that an unexpected or contradictory result has been obtained. These situations are considered also as "Out-Of-Control" and an investigation is carried out.

The investigations/corrective action procedures include but are not limited to:

- Identification of the individuals responsible for assessing each QC data type
- Identification of the individuals responsible for initiating and/or recommending corrective actions
- Definition of how the analyst should treat the data set if the associated QC measurements are unacceptable
- Investigate the probable cause of irregularity and determine the root cause(s) of the problem.
- Review the sample's documented history.
- Review the documentation for errors.
- Scrutinize the sample preparation (digestion, extraction, dilutions, cleanup, etc.)
- Verify standards with reference materials.
- Re-analyze the sample if possible.
- Investigate alternate methodologies.
- If the event is determined to be matrix dependent the data is reported with a qualifier.
- Definition of how out-of-control situations and subsequent corrective actions are to be documented
- Definitions of how management, including the QA Officer, review corrective action reports

Where corrective action is needed, the laboratory shall identify potential corrective actions. It shall select and implement the action(s) most likely to eliminate the problem and to prevent recurrence.

Corrective actions shall be to a degree appropriate to the magnitude and the risk of the problem. The laboratory shall document and implement any required changes resulting from corrective action investigations.

The laboratory shall monitor the results to ensure that the corrective actions taken have been effective.

Where the identification of nonconformances or departures casts doubts on the laboratory's compliance with its own policies and procedures, or on its compliance with the NELAC Standard, the laboratory shall ensure that the appropriate areas of activity are audited in accordance with Section 14.1 of this Manual, Internal Laboratory Audits as soon as possible.

17.3 Preventive Action

Preventive action is a pro-active process to identify opportunities for improvement rather than a reaction to the identification of problems or complaints.

Needed improvements and potential sources of nonconformances, either technical or concerning the quality system, shall be identified. If preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformances and to take advantage of the opportunities for improvement.

Procedures for preventive actions shall include the initiation of such actions and application of controls to ensure that they are effective.

18 SUBCONTRACTING AND SUPPORT SERVICES AND SUPPLIES

18.1 Subcontracted Laboratory Services

A subcontracted laboratory will be used only if Weck Laboratories does not have the capability of performing the requested test, because of unforeseen reasons (e. g. workload, need for further expertise or temporary incapacity) or if the client specifically requests a particular analysis to be subcontracted.
Weck Laboratories advises the client in writing or by other means of its intention to subcontract any portion of the testing to another party, and when appropriate, gain the approval of the client, preferably in writing.
When subcontracting any part of the testing, this work will be placed with a laboratory accredited under NELAP for the tests to be performed or with a laboratory that meets applicable statutory and regulatory requirements for performing the tests and submitting the results of tests performed.
The corresponding records demonstrating that the above requirements are met are retained (e.g. copies of the subcontracted lab certifications, communications with the client, etc.)
When subcontracted laboratories are used, this is indicated in the Certificate of Analysis and a copy of the subcontractor's report is kept in file in case the client requests it at a later time. Subcontracted work performed by non-NELAP accredited laboratories is also clearly identified in the final report.
Weck Laboratories is responsible to the client for the subcontractor's work, except in the case where the client or a regulatory authority specifies which subcontractor is to be used.
A register of all subcontractors that are routinely used by the laboratory is kept on file, along with evidence of certifications.

18.2 Outside Support Services and Supplies

Weck Laboratories, Inc. only uses those outside support services and supplies 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.
Specific procedures to evaluate, select and monitor suppliers of materials and services as well as required documentation is detailed in the corresponding SOP (MIS042)

19 REFERENCES

19.1 NELAC 2003 Standard
19.2 Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans,
19.3 QAMS-005/80, December 29, 1980, Office of Monitoring Systems and Quality Assurance, ORD, USEPA, Washington, DC 20460
19.4 RCRA QAPP Instructions, USEPA Region 5, Revision: April 1998

19.5 ASTM D-5283-92. Generation of Environmental Data Related to Waste Management Activities: Quality Assurance and Quality Control Planning and Implementation.
19.6 American National Standards Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs (ANSI/ASQC E-4), 1994.
19.7 EPA 2185 – Good Automated Laboratory Practices, 1995
19.8 ISO/IEC Guide 25: 1990. General Requirements for the Competence of Calibration and Testing Laboratories.
19.9 QA/R-2: EPA Requirements for Quality Management Plans, August 1994.
19.10 QA/G-4: Guidance for the Data Quality Objectives Process EPA/600/R-96/055, September 1994.
19.11 A/R-5: EPA Requirements for Quality Assurance Project Plans Draft – November 1997
19.12 QA/G-5: Guidance on Quality Assurance Project Plans EPA/600/R-98/018, February 1998.
19.13 A/G-6: Guidance for the Preparation of Standard Operating Procedures for Quality Related Operations EPA/600/R-96/027, November 1995.
19.14 A/G-9: Guidance for the Data Quality Assessment: Practical Methods for Data Analysis EPA/600/R-96/084, January 1998.
19.15 Manual for the Certification of Laboratories Analyzing Drinking Water EPA/570/9-90/008.

Appendix Detail

Appendix 1	**Resumes of Key Personnel**
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APPENDIX 1
RESUMES OF KEY PERSONNEL

Name	**Position**
Alfredo Pierri	President/CEO – Laboratory Director
David Cerna	QA Officer
Joe Chau	Technical Director Inorganics
Alan Ching	Technical Director Organics
Hai-Van Nguyen	Technical Director Microbiology - Senior Project manager

ALFREDO E. PIERRI

Title

President, Laboratory Director

Education

M.S. (equiv.) - University of Buenos Aires, Argentina, 1978. Organic Chemistry

- University of California, Los Angeles
Certificate in Hazardous Materials Control and Management,
1991 - 1993

Affiliations

American Chemical Society, member
American Water Works Association, member
Water Environment Federation, member
American Council of Independent Laboratories (ACIL), member
The NELAC Institute, member

Professional Experience

Jan/1987 to Present	Weck Laboratories, Inc., City of Industry, CA Full Service Environmental Testing laboratory
Sep/1984 to Dec/1986	SCS Engineers, Long Beach, CA Environmental Testing laboratory owned by Large Environmental Engineering Firm
Jul/1979 to Aug/1984	Argentina Atomic Energy Commission, Buenos Aires, Argentina Government Agency – Research and Development

Mr. Pierri has extensive experience in analytical chemistry. Most of his work in this field has been in the application and development of instrumental methods of analysis for organic analytes using GC, GC/MS, HPLC, IR and UV-Visible spectrometry. He has also worked in Spectrometric techniques for metals analysis such as Atomic Absorption with flame and graphite furnace and Inductively Coupled Plasma with Optical Emission and Mass Spectrometry.

Since 1984 he has been working exclusively in the environmental field obtaining in 1993 the certification as Registered Environmental Assessor (REA-04975) from the California Environmental Protection Agency.

As Laboratory Director, Mr. Pierri is responsible for all laboratory operations including the supervision of the overall performance of the laboratory, revision of analytical reports and Quality Assurance Program, provision of technical assistance and direction to laboratory personnel and consulting with clients about technical and regulatory issues.

Mr. Pierri is well acquainted in all aspects of environmental regulations at Federal and State level, providing consulting services and guidance to clients in regulatory compliance and chemical treatment issues as well as understanding and interpreting analytical data.

Other relevant experience and projects in which Mr. Pierri has participated are as follows:

- For over 22 years provided Project Management for large environmental monitoring projects for wastewater treatment plants, desalination plants, groundwater studies, potable water compliance monitoring and unregulated contaminants studies managed by the EPA such as ICR, UCMR 1 and UCMR 2. These projects required dealing with significant technical issues, regulatory compliance and innovative analytical methods.

- Characterization of wastes to be classified as hazardous as per State of California and Federal Regulations.

- Developing of analytical methods for emerging contaminants in water using GC/MS, LC/MS and other analytical techniques and writing the operating procedures.

- Identification and selection of new laboratory equipment for the laboratory

- Determination of contamination in soil and groundwater due to leaking underground storage tanks.

- Design and implementation of a Quality Assurance Program based on NELAC requirements for the laboratory, writing of the QA manual and training of laboratory personnel.

- Developing and implementation of an Ethics Training Program for the Laboratory, writing the documentation and training course for laboratory employees.

- Interpretation of analytical data and compliance with regulations for drinking water for different potable water purveyors in Southern California.

- Compliance for wastewater discharges with local regulatory agencies and NPDES permits.

- Consulting services to industrial clients on pre-treatment of effluents in order to minimize organic matter and solids and reduce costs in taxes imposed by POTWs.

- Identification of unknown materials by chemical and physical methods.

- Implementation of a LIMS and use of personal computers for data acquisition, handling, and reporting.

- Teaching of Analytical Organic Chemistry at University Level for MS program.

Participation in Seminars and Conferences

Over the years, Mr. Pierri has participated in innumerable conferences and technical meeting involving environmental testing, environmental policy and remediation.

He has been speaker in several conferences and technical meetings related to environmental monitoring in general and emergent contaminants in particular.