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 mmms 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.
- Ensu, .

- 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 annuallyl operllyl ntntl

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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 recornnesn-0.10176 Tc (z) Tj-.12 Tc ( ) Tj-0.18912 Tc (i) Tj-0.24 Tc (n) (t) Tj
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- 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 atTfboc (t) Tj0 Tc (u(hn) Tj-0. (824 Tc (a) Tj0 ff) Tj-0.34176 Tc (e)(f) Tj-0.24 Tc ff) Tj-0.34176 Tc (e) Tj0.16

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 ah wiyn(e) Tj-0.24 Tc (d) Tj0.12 Tc ( ) Tj0.05088 Tc (t) Tj-0.24 Tc (o) Tj( ) Tj0 -13Tj( ) Tj0 -13Tj( ) T

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 currefrfrfir ofrdeTj-0.24 Tc (on) Tj0.050c ( ) Tj-0.24 Tc 3fqngdeh-0.24 Tc (j0.02544c6 Tc (e) Tj0.0v Tc

Weck Laboratories, Inc.

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 (pro

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, ce rused Tc (a) Tj-0.42912 Tc (m) Tj-0.3417c (e) TjTc ( ) T3D.24ace WeT0.12 Tc ( ) Tj (no) Tj(s) Tj-0.34176 Tc (e) Tj-0.24 T( ) Tj-v8 Tc (r) Tj-0.34176 unoseeeeplf menosœ pse /or notrued

Analytical support equipment includes but it is not limited to: balances, ovens, refrigerators, freezers, incubators, water baths, temperature measuring devices (includ

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 thorou canea0.12 Tc ( ) Tj0.4.29088 Tc (A) Tj-0.189c (s)

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 OPERATd a m no e l a m a Tj-0.24 Tc (y) Tj ( ) TjC (a) Tjj0 Tc (u) Tj-
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1 Tc (r).1017p Tc (u) Tj-0.24 Tc (no) Tj0.0508Tj0.0uno cusrOeo cm t. nog. O. crmD 0 Tc (11) Tjy rmOs. e

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 SO

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 test or calibration. The method developed shall have been validated adequately before use.

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)tooaofo oaseor -13.2 TD -0.24 Tc ()) Tj0.12 Tc (.Tj0.02544 Tc4 Tc ()) Tj 0.163

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 forTc (i) Tj-0.24 Tc (on) Tj0.12 Tc ( ) Tj-0.2

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 concentedi

If a large number of analytes are in the LCS, it becomes statistically likely that a few will be outside
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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.

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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 samplesee76 Tc11.04166co

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 reihehperson tigned tonamret

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, pers

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 ilc rftrcthocy a thory br aerred da8 Tc (r) Tj0.13824 Tc () icceplycrryad, e

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 occvj-0.24 Tc (n) Tj0.12 Tc24 Tc (a)2912 Tc (m) Tj-0.188 Tc (r) Tj0.05088 TcDj-0.104176 Tcc (s) Tj-0.2

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 pe
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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

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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 establisheicate the ecriteria indicate the laboratory was as aria indicatindicatend heorw establisheicatetabindic2145hei ein d sbl lte tbhatcechae e t a -0.18912 Tc (l) Tj0.1636 (t) Tj (b) Tj-00.1891 (h) Tj-0.34176 Tc (0c (c) Tj0.13

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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

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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**

Appendix 2 **Code of Ethics**

Appendix 3 **Organization Chart**

Appendix 4 **List of Major Equipment**

Appendix 5 **Chain of Custody Form**

Appendix 6 **Sample Collection and Holding Times**

Appendix 7 **List of SOPs**

Appendix 8 **Acceptance Limits for QC Determinations**

Appendix 9 **Initial Demonstration of Capability Procedure**

Appendix 10 **Corrective Action trt t**

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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.