Orange County Public Health Laboratory

QUALITY MANUAL

FOR THE

WATER QUALITY LABORATORY

600 Shellmaker Road Bldg. A
Newport Beach, CA 92660

2018

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1.0 Introduction

1.1 The Water Quality Laboratory (WQL) is one of five technical areas of the Orange County Public Health Laboratory (OCPHL). This section is responsible for recreational and drinking water testing. The main OCPHL in Santa Ana contains the departments that perform HIV, Tuberculosis, bioterrorism, molecular epidemiology and other infectious disease testing.

1.2 The activities of the WQL:

1.2.1 Perform all beach water quality testing as administrated by the HCA Ocean Water Protection Program

1.2.2 Perform the majority of water bacteriological testing for OC Public Works Watersheds program.

1.2.3 Collaborates with other agencies and organizations to perform water quality research projects to locate and reduce pollution.

1.2.4 Performs applied research on new techniques to make testing more rapid and accurate.

1.2.5 The WQL utilizes testing resources at the main laboratory to apply advanced techniques to water quality issues.

1.2.6 Provides testing of drinking water for HCA Environmental Health and in cases of emergency.

1.3 The goals of the WQL:

1.3.1 Act as a resource for accurate and unbiased testing to improve water quality in Orange County.

1.3.2 Perform all testing with the fastest and most accurate methods available.

1.3.3 Enhance research capabilities to develop rapid testing, determine the source of contamination and methods to reduce pollution.

1.3.4 Provide educational activities to increase the knowledge of water quality among professionals and the general public.

2.0 References

2.1 The National Environmental Laboratory Accreditation Conference Institute (TNI). (2016). *Volume 1, Module 2 Quality systems general requirements* (EL-V1M2-2016-ISO-Rev2.1). Weatherford, TX.

2.2 ISO/IEC 17025. (2005). General Requirements for the Competence of Testing and Calibration Laboratories. Switzerland

2.3 Standard Methods. 23rd Edition (2017). Washington, DC: American Public Health Association, American Water Works Association, Water Environment Federation.

2.4 Forster, L. (2003). Measurement of Uncertainty in Microbiology. *Journal of AOAC International.* Vol. 86. (5), pg. 1089-1094.

2.5 Hogan, R. (2016). *4 Ways to Calculate Uncertainty in Microbiology*. Retrieve from http://www.isobudgets.com/4-ways-to-calculate-uncertainty-in-microbiology-labs/

3.0 Definitions and Acronyms

3.1 Definitions

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

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

3.1.3 **Accuracy** - Estimate of how close a measured value is to the true value; includes expression of bias and precision

3.1.4 **Analyst** - The designated individual who performs the "hands-on" analytical methods and associated techniques, and who is the one responsible for applying required laboratory practices and other pertinent quality controls to meet the required level of quality.

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

3.1.6 **Analytical Uncertainty** - A subset of measurement uncertainty that includes all laboratory activities performed as part of the analysis.

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

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

3.1.9 **Chain of Custody (COC) form** – Record that documents the possession of the samples from the time of collection to receipt in the laboratory. This record generally includes the client, sample type, sample collector, sample collection time, preservation and requested analyses.

3.1.10 **Complaints** – Negative reactions usually in written form made to the organization related to a specific product or service produced or provided by the organization after the product has been released or service completed.

3.1.11 **Confirmation** - Verification of the identity of a component through the use of an approach with a different scientific principle from the original method.

3.1.12 **Corrective Action** – The action taken to eliminate the causes of a detected non- conformance, defect, or other undesirable situation in order to prevent reoccurrence.

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

3.1.14 **Data Reduction** - The process of transforming the number of data by arithmetic or statistical calculations, standard curves, and concentration factors, and collating them into a more useable form.

3.1.15 **Demonstration of Capability -** A procedure to establish the ability of the analyst to perform analyses with acceptable accuracy and precision.

3.1.16 **Field of Accreditation (FOA)** – Method for which the accreditation body offers accreditation.

3.1.17 **iPassport** - A quality management software for document control and compliance management.

3.1.18 **Limit of Detection (LOD)** – A minimum concentration of an analyte that can be measured by the method.

3.1.19 **Lot -** A definite amount of material produced during a single manufacturing cycle, and intended to have uniform character and quality.

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

3.1.21 **Method Blank** - A sample of a matrix similar to the batch of associated samples (when available) that is free from the analytes of interest and is processed simultaneously with and under the same conditions as samples through all steps of the analytical procedures, and in which no target analytes or interferences are present at concentrations that impact the analytical results for sample analyses.

3.1.22 **Nonconformance** – Non-fulfillment of a specified, or implied, requirement of the Quality Management System or of a quality work product. Fitness-for-use criteria and evaluations determine the significance of a nonconformance.

3.1.23 **Precision** – A measure of the degree of agreement among replicate analyses of a sample.

3.1.24 **Preventive Action** - A pro-active process to identify opportunities for improvement rather than a reaction to the identification of problems or complaints.

3.1.25 **Procedure -** A specified way to carry out an activity or process. Procedures can be documented or not.

3.1.26 **Proficiency Testing (PT)** – A means to evaluate a laboratory's performance under controlled conditions relative to a given set of criteria, through analysis of unknown samples provided by an external source.

3.1.27 **Proficiency Testing Provider (PT Provider)** – An organization accredited by a TNI approved proficiency testing provider accreditor to operate a TNI-compliant PT program.

3.1.28 **Proficiency Testing Provider Accreditor (PTPA)** – An organization that is approved by TNI to accredit and monitor the performance of proficiency testing providers.

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

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

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

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

3.1.33 **Reference Method** - A reference method is a published method issued by an organization generally recognized as competent to do so

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

3.1.35 **Standard Operating Procedures (SOPs) -** A written document that details the method for an operation, analysis, or action, with thoroughly prescribed techniques and steps. SOPs are officially approved as the methods for performing certain routine or repetitive tasks.

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

3.1.37 **Verification -** Confirmation by examination and objective evidence that specified requirements have been met.

3.2 Acronyms

3.2.1 ATCC - American Type Culture Collection
3.2.2 CA - California
3.2.3 CF - Correction Factor
3.2.4 COC – Chain of Custody
3.2.5 DOC – Demonstration of Capability
3.2.6 ELAP – Environmental Laboratory Accreditation Program
3.2.7 FOA – Fields of Accreditation (formerly fields of testing)
3.2.8 LCS – Laboratory Control Sample
3.2.9 LIS – Laboratory Information System
3.2.10 LOD - Limit of Detection
3.2.11 NCE – Nonconforming Event
3.2.12 NELAC – National Environmental Laboratory Accreditation Conference
3.2.13 NIST – National Institute of Standards and Technology
3.2.14 OCHCA – Orange County Health Care Agency
3.2.15 OCPHL – Orange County Public Health Laboratory
3.2.16 P&P - Policies and Procedures
3.2.17 P/A - Presence or Absence
3.2.18 PHIRE – Public Health Initiative for Results and Excellence
3.2.19 PHM I – Public Health Microbiologist I
3.2.20 PHM II – Public Health Microbiologist II
3.2.21 PT - Proficiency Testing
3.2.22 PTCR – Personnel Training and Competency Record
3.2.23 PTPA - Proficiency Testing Provider Accreditor
3.2.24 QA – Quality Assurance
3.2.25 QC – Quality Control
3.2.26 QI – Quality Improvement
3.2.27 SM – Standard Method
3.2.28 SOP – Standard Operating Procedure
3.2.29 SPHM – Supervising Public Health Microbiologist
3.2.30 TNI - The NELAC Institute
3.2.31 WQL – Water Quality Laboratory

4.0 Management Requirements

4.1 Organization

4.1.1 The WQL in Newport Beach works in conjunction with the OCPHL in Santa Ana. Both laboratories are part of the Orange County Health Care Agency's Public Health Services division which can be held legally responsible for providing accurate laboratory testing and results. See Section 7.0 *Appendices*.

4.1.2 The WQL performs testing and calibration activities that meet the accreditation requirements of CA ELAP, as well as, the requirements of its clients and regulatory authorities.

4.1.3 All routine work is carried out at the WQL in Newport Beach. More advanced or research techniques could potentially be performed at the OCPHL in Santa Ana.

4.1.4 The WQL works in collaboration with intra-agency and inter-agency partners. The roles of key personnel involved in these partnerships are clearly defined to avoid conflicts of interest.

4.1.5 The WQL:

4.1.5.1 has managerial and technical personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including the implementation, maintenance and improvement of the management system, and to identify the occurrence of departures from the management system or from the procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimize such departures.

4.1.5.2 has policies in place to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work. (Refer to Compliance and Code of Conduct P&Ps)

4.1.5.3 has policies and procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results. (Refer to Confidentiality P&P)

4.1.5.4 has policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity. (Refer to Compliance and Code of Conduct P&Ps)

4.1.5.5 defines the organization and management structure of the laboratory, its place in any parent organization, and the relationships between quality management, technical operations and support services. (HCA Org Chart)

4.1.5.6 specifies the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the tests and/or calibrations. (OCPHL Org Chart)

4.1.5.7 provides adequate supervision of testing and calibration staff, by persons familiar with methods and procedures, purpose of each test and/or calibration, and with the assessment of the test or calibration results.

4.1.5.8 appoints the SPHM as the technical manager which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operation.

4.1.5.9 appoints the PHM II's as quality managers who, among other duties and responsibilities, shall have defined responsibility and authority for ensuring that the management system related to quality is implemented and followed at all times; the quality managers shall have direct access to the highest level of management at which decisions are made on laboratory policy or resources.

4.1.5.10 appoints PHM II's as deputies to the technical manager. They will assume the role of the technical manager when out of office.

4.1.5.11 ensures that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system.

4.1.6 Management ensures that appropriate communication processes are established within the laboratory and that communication takes place regarding their effectiveness.

4.1.7 The designated Quality Managers (PHM II's) will:

4.1.7.1 serve as the focal point for QA/QC and be responsible for oversight and review of QC data.

4.1.7.2 be able to evaluate data objectively and perform assessments without outside influence.

4.1.7.3 have training in QA/QC procedures and the laboratory's quality system.

4.1.7.4 have knowledge of the analytical methods that they are reviewing.

4.1.7.5 arrange for or conduct annual internal audits

4.1.7.6 notify technical manager or lab management of laboratory deficiencies.

4.1.7.7 initiate and oversee NCE forms and follow-up with any corrective actions.

4.1.8 The designated Technical Manager (SPHM) will:

4.1.8.1 supervise the day-to-day laboratory operations for the appropriate FOA's and reporting of results.

4.1.8.2 be experienced in the FOA's for which the laboratory seeks accreditation.

4.1.8.3 monitor standards of performance in QA/QC.

4.1.8.4 monitor the validity of the analyses performed and the data generated to assure reliable data.

4.1.8.5 notify clients and accrediting body in writing of interim replacement if Technical Manager will be out of office for more than 35 days.

4.2 Management

4.2.1 The Orange County Water Quality Laboratory (WQL) is a part of the Orange County Public Health Laboratory (see Section 7.0 *Appendices*). The primary supervision of the WQL is performed by the Supervising PHM.

4.2.2 **Quality statement:** The Orange County WQL is committed to providing high quality testing and service to its clients. The quality of work performed by the WQL shall meet or exceed all standards set forth by its governing regulatory bodies, including CA ELAP. All services provided by the laboratory shall be performed according to these standards, while maintaining the highest sample through-put and the lowest possible sample turn-around time. These quality objectives shall be communicated to, understood by, available to, and implemented by the appropriate laboratory personnel.

4.2.3 The WQL management personnel are committed to the development, implementation and continuous improvement of the quality management system.

4.2.4 The Data Integrity System serves to combine the elements currently in place and document further procedures to ensure our compliance with requirements in the Safe Drinking Water Act, California Environmental Laboratory Accreditation Act, and the California Code of Regulations Title 22, Division 4, Chapter 19 and from other regulatory agencies. See Section 4.16.4 regarding mandatory annual compliance training for all staff.

4.2.5 All employees are to follow the requirements spelled out in the analytical procedures for which the WQL is accredited by CA ELAP and not deviate from them in any way that significantly alters the results in a way that imperils public health or misrepresents the results.

4.2.6 It is the policy of the WQL to assure confidentiality and a receptive environment in which all employees may privately discuss ethical issues or report items of ethical concern. Link to HCA Compliance Program policy and reporting: http://intranet/docs/compliance/Policies/I-5.06.pdf

4.2.7 The WQL follows County of Orange policies regarding Code of Conduct, Confidentiality, and Compliance to investigate ethical or data integrity problems which are consistent with Volume 1, Module 2, and Section 4.16 Data integrity training and documentation in section 5.2.9.

4.2.8 All environmental testing activities are carried out in such a way as to meet the requirements of the Safe Drinking Water Act, California Environmental Laboratory Accreditation Act, and the California Code of Regulations Title 22, Division 4, Chapter 19 and to satisfy the needs of the client, the regulatory authorities or organizations providing recognition.

4.2.9 It is the goal of the WQL to provide our clients with the best possible services, in terms of quality of laboratory work, integrity in our procedures and reporting, efficiency in our turnaround time and reasonable prices for our services and at the same time satisfy the needs of our clients and CA ELAP.

4.2.10 Management Reviews

4.2.10.1 The Technical and Quality Managers will annually review the laboratory's management system and testing activities based on the requirements set forth in the 2016 TNI Standard Section 4.15.2.

The results of the review will be done in conjunction with the laboratory planning system. The findings from the review will be documented and an appropriate corrective action plan will be determined for each finding.

4.3 Document Control

4.3.1 WQL has a procedure to control all documents that form the quality and management system whether externally or internally generated. The Quality Assurance manual (*WQL-101*), SOPs, and related documents are maintained on the iPassport software. The software tracks all actions performed on the documents.

4.3.2 Document control procedures for developing, authorizing, revising, reviewing, issuing, and archiving SOPs are detailed in *WQL-107*: *Creating Standard Operating Procedures* and *Laboratory Operation-6*: *OCPHL iPassport Guide*. SOP format and content are standardized with *WQL-105*: *WQL SOP template* and *WQL-106*: *WQL SOP Instructions*. iPassport tracks all revisions, authorization, review, and inactivation procedures related to the document. The software notifies staff of new or revised documents and requires staff review and acknowledgement.

4.4 Review of Requests, Tenders, and Contracts

4.4.1 All requests for laboratory services are reviewed by the Technical Manager. Larger projects or contracts may require the approval of the Lab Director or upper management.

4.4.2 Any agreements for lab services will include:

4.4.2.1 Client contact information

4.4.2.2 Acceptance of lab fees if applicable

4.4.2.3 Length of study

4.4.2.4 Numbers and types of samples that will be tested

4.4.2.5 Sample collection and COC forms

4.4.2.6 Analysis methods that will be used

4.4.2.7 Turnaround time for results

4.4.2.8 Result reporting methods

4.4.3 Any deviations from agreements will require notification to the client.

4.4.4 Any amendments to established agreements will need to go through the review process.

4.5 Subcontracting

4.5.1 The WQL does not subcontract work out.

4.5.2 In situations where workload cannot be completed and samples cannot be stored for later processing, the client will be notified of the situation and follow-up action plans will be discussed and documented on an NCE form.

4.6 Purchasing Services and Supplies

4.6.1 The WQL is aware of and adheres to all OCHCA Purchasing Policies and Procedures.

4.7 Service to Client

4.7.1 Any feedback from clients regarding the laboratory's performance is welcomed.

4.7.2 As part of the WQL's improvement plan, client needs assessments will be performed at least every 3 years using a customer satisfaction survey. Results from these assessments will be reviewed and used to enhance client services.

4.8 Complaints

4.8.1 OCPHL has a policy and procedure to resolve complaints received from clients. Complaints are documented on Non-Conforming Event (NCE) forms. The NCE forms are reviewed and maintained by the technical manager. The form contains client information, the nature of the complaint, investigation, corrective action, and follow-up. Details on NCE procedure are addressed in section 4.9 *Control of Nonconforming Events.*

4.9 Control of Non-Conforming Events

4.9.1 Non-conforming events are documented on the NCE form when any aspect of testing or procedure do not conform to policies set in the Quality manual. Situations requiring NCE report may include:

4.9.1.1 Client complaint

4.9.1.2 Equipment, calibration, or media quality control out of acceptable range

4.9.1.3 Data entry error

4.9.1.4 Aspects affecting the work or data quality

4.9.1.5 Deviations from polices and SOPs

4.9.1.6 Proficiency testing outside of expected range

4.9.1.7 Management reviews and internal audits

4.9.2 When a nonconforming event is identified, a detailed description is documented on the NCE form. The Quality manager is consulted to investigate the cause and impact of the event. A corrective action is defined to resolve the issue and prevent future occurrence. Refer to 4.11 *Corrective Action* for procedure. Clients are notified when NCE impact client samples, data, and turnaround time. Where necessary, resumption of work is authorized by the Technical manager after review of the corrective action.

4.9.3 The Technical manager reviews and follow-up on the NCEs. An annual review of all NCE is conducted by management to provide improvement.

4.10 Improvement

4.10.1 The WQL participates in the County's QI and PHIRE programs, which are HCA programs dedicated to continuous quality improvements.

4.10.2 The WQL will develop annual QI and PHIRE projects based on client needs assessments, or through employee suggestions, that will enhance laboratory efficiency and overall performance.

4.11 Corrective Action

4.11.1 The laboratory will implement corrective action procedures when there is nonconforming work or departures from standardized operating procedures or method modifications. All nonconformities will be documented on a NCE form. Refer to 4.9 *Control of Nonconforming Event* for the detailed procedure.

4.11.2 Cause analysis

Once a nonconforming event is identified, an investigation is initiated to determine the root cause with Quality manager consultation. An investigation includes all potential causes leading up to the nonconforming event.

4.11.3 Selection and Implementation of Corrective Actions

The Technical and Quality managers will implement the corrective action most likely to eliminate the problem and prevent recurrence. Corrective action is implemented immediately after review by technical manager. The extent of the corrective action required is evaluated against the seriousness of the nonconformity. Where necessary, re-training of staff and/or changes to SOPs are implemented.

4.11.4 Monitoring

The Technical manager is responsible for corrective action follow-up. All NCEs are reviewed monthly to determine corrective action effectiveness or if further action is required.

4.11.5 Additional audits

An internal audit will be conducted when nonconformities which cast doubts on the laboratory's policies and procedures or compliance with regulations are encountered. Refer to 4.14 *Internal Audits.*

4.12 Preventative Action

4.12.1 Management performs annual review of NCEs to identify problematic areas or trends and initiate preventive action. OCPHL has a QI committee to identify opportunities for improvement, develop action plans, implement, and monitor the improvements. Refer to 4.10 *Improvement.*

4.13 Control of Records

4.13.1 WQL has a traceable record keeping system which allows the history of the sample and any associated data to be available to the accreditation body. Records include sample records, testing records, results records, QA and QC records, equipment records and procurement records.

4.13.1.1 Sample records include sample receiving log and COC. COC includes sample locations, date and time sample collected, accession numbers, client information, and test requested, which are entered into CERNER. COC also includes times, dates, initials of personnel relinquishing samples, receiving samples, analyzing samples, reviewing results, and reporting results.

4.13.1.2 Testing Records includes worksheets to record sample readings, results worksheets, equipment records and any other generated raw data handwritten or from equipment.

4.13.1.3 Result spreadsheets are sent out to clients electronically and are saved in the PhWaterLab share folder.

4.13.1.4 Quality assurance records includes all NCE, internal audits and QA reports requested by clients.

4.13.1.5 Quality control records includes all laboratory supplies receivables log and quality control worksheets. This includes reagents, supplies, equipment, incubators, refrigerators, freezers and water baths.

4.13.1.6 Records of calibration services for the incubators, thermometers, refrigerators, freezers, pipettes, balances and hoods are will be labeled and stored in the filing cabinets.

4.13.1.7 Procurement records includes requisitions, vendor quotes, packing slips, and vendor certificate of analysis.

4.13.2 On any lab records, corrections of errors are recorded legibly by personnel finding the error. Line through any errors and write in the correct value alongside, then initial and date the correction.

4.13.3 Lab records are collected in binders or are kept electronically.

4.13.4 Records kept in binders are easily accessible. As binders get filled, the records are moved to file folders and stored in file cabinets. Electronic records are stored in CERNER or on the PhWaterLab share folder. All WQL staff are given access to CERNER and the share folder at the Supervisors discretion.

4.13.5 All lab records are maintained by the Quality Managers and Technical Manager, who regularly review for accuracy and completeness. Electronic records are maintained on the HCA network which is backed-up daily.

4.13.6 Lab records are kept on-site for five years and are then discarded in the trash bin. Clients are notified prior to disposal of hard copy records.

4.14 Internal Audits

4.14.1 The Quality Mangers will conduct the annual internal audit. The lab will use the most current TNI Microbiology check list as its guide for the audit.

4.14.2 All findings of internal audits are recorded along with the topic of audits and its corrective actions.

4.14.3 After completion of the internal audit management review report shall be prepared and annual management summary will be recorded for current and future improvements for the WQL.

4.15 Management Review

4.15.1 Annual review by management following list provided in TNI and will be documented.

4.16 Data Integrity Investigations

4.16.1 The WQL takes data integrity very seriously. Any internal or external allegations of fraud or misconduct will initiate a thorough investigation.

4.16.2 All employees are encouraged to report any data integrity issues directly to the Supervisor or Lab Director. If the employee is not comfortable going to the Supervisor or Lab Director, they can report anonymously to the County's Office of Compliance through the 24-hour Compliance Hotline (866) 260-5636.

4.16.3 All WQL clients are encouraged to report data integrity issues directly to the WQL or through the County's Office of Compliance.

4.16.4 All employees are required to complete a mandatory compliance training annually through the County's Office of Compliance. Annual compliance training is documented and certificates of completion are kept in the employee's file.

4.16.5 Data integrity investigations will be conducted confidentially. Investigation results will be documented and any corrective actions will be implemented. Any clients adversely affected will be notified.

4.16.6 The severity and nature of the data integrity investigation may warrant initiation of an internal audit.

5.0 Technical Requirements

5.1 General

5.1.1 The laboratory recognizes that many factors affect the correctness and reliability of the tests that the laboratory performs, including:

- human factors
- accommodation and environmental conditions
- test methods and validation
- equipment
- measurement traceability
- sampling
- handling of test item

5.1.2 The laboratory takes into account these factors in developing test procedures, personnel training and equipment selections.

5.2 Personnel

5.2.1 Lab management ensures that staff are competent to perform their assigned duties. The duties are assigned based on staff qualifications and proper supervision is provided at all times.

5.2.2 As new staff come into the department, they are properly trained and must demonstrate competence prior to performing their assigned tasks on their own. Staff competency is documented and reviewed regularly.

5.2.3 The lab employs certified Public Health Microbiologists and Laboratory Assistants that are hired through the County's Human Resources department following County hiring policies.

5.2.4 Official job descriptions are kept on file at the County's Human Resources department.

5.2.5 All WQL staff fill out a Personnel Qualifications form that lists pertinent education and training and is kept on file. Public Health Microbiologists prominently display their Public Health Microbiologist Certificates issued by the California Department of Public Health Laboratory Field Services.

5.2.6 Technical Manager

5.2.6.1 The Supervising Public Health Microbiologist (SPHM) will be designated the Technical Manager of the Water Quality Laboratory.

5.2.6.2 The SPHM meets the qualifications for Technical Manager that are set forth by the TNI standard.

5.2.6.2.1 They have the appropriate education and training

5.2.6.2.2 They are an employee of the lab

5.2.6.2.3 They are present onsite at least 30-40 hours per week to address technical issues for staff and clients and provide adequate supervision.

5.2.7 Quality Manager

5.2.7.1 The Public Health Microbiologist II (PHM II) will be designated the Quality Manager of the Water Quality Laboratory.

5.2.7.2 The PHM II meets the qualifications for Quality Manager that are set forth by the TNI Standard.

5.2.7.2.1 They have the appropriate education and training

5.2.7.2.2 They are an employee of the lab

5.2.7.2.3 They are present onsite at least 30-40 hours per week to address all quality control/quality assurance issues

5.2.7.2.4 They can cover the laboratory when the Technical Manager is out of office

5.2.8 Analyst

5.2.8.1 The PHM I and Laboratory Assistants are the main analysts performing the routine methods. The PHM II and SPHM can perform analyst duties as needed.

5.2.8.2 All analysts receive training for each method they will be performing. Competency is assessed and documented for each method before analysts can perform the methods on their own. PTCR will be maintained for each analyst and reviewed regularly.

5.2.9 Data Integrity Training

5.2.9.1 As part of the hiring process, all new employees and volunteers are required to go through compliance training. Upon successful completion of the compliance training a Certificate of Completion is printed and signed by the employee and copies of the certificate are kept on file.

5.2.9.2 All employees are required to complete annual compliance training.

5.2.9.3 Along with compliance training, all staff are made aware of and agree to follow the Laboratory Ethics policy.

5.2.9.4 Annual training on lab ethics will be provided to all staff and participation will be documented.

5.2.9.5 Refer to section 4.16 for data integrity reporting, investigation, and documentation practices.

5.3 Accommodation and Environmental Conditions

5.3.1 Environmental controls in the laboratory are appropriate for the tests being performed. Environmental conditions that can affect test results are listed in the relevant SOPs. For each area that requires a controlled environment, the conditions are documented. Environmental factors such as light, temperature, ventilation, and space are considered to allow tests to be performed safely and effectively.

5.3.2 The physical location of activities will be such that potential contamination will be minimized.

5.3.3 Access to all laboratories is restricted to authorized personnel and approved visitors. Visitors are supervised at all times.

5.3.4 All laboratory areas are maintained in a clean and orderly manner.

5.4 Environmental Methods and Validation

5.4.1 The laboratory follows EPA or Standard Methods 23rd Ed. guidelines for routine testing. The reference method for each test is documented in the SOPs. All SOPs are reviewed annually and revised as needed. Changes to the SOPs are tracked by iPassport. Refer to section 4.3 *Document Control*. A list of all test methods performed by the WQL can be generated and made available to staff through iPassport.

5.4.2 Sampling, handling, transport, storage and preparation for testing is specified in *WQL-104: Sample: Collection, Acceptance, and Disposal.* Specific requirements and equipment operations are specified in the test method SOP. Equipment manuals are located in the equipment folders and are retained for the lifespan of the equipment with the lab. Preventive maintenance follow SM 9020B and are performed by a contracted county approved company.

The WQL strictly adheres to the reference method procedures. Deviations from the test is prohibited without prior approval from the Technical manager. Deviations must be authorized, documented, justified, and accepted by the client.

5.4.3 Selection of Methods

Selection of method is based on state, regional regulations and client permit requirements or requests. The methods are the latest valid edition of Standard Methods or EPA. The laboratory will inform the client when the method proposed is inappropriate and make recommendations for a more appropriate method. If no method is specified by the client, the laboratory will select the most appropriate, regulation approved method.

5.4.4 Validation of Methods

New, laboratory developed, non-standard, or standard methods require method verification and validation prior to implementation. Approval of the Verification and Validation Plan for New Laboratory Procedure by the technical manager and laboratory director is required.

The plan includes:

- Objective
- Principle investigators
- Type of verification
- Parameters determined (accuracy, precision, sensitivity, specificity, detection limit, uncertainty, etc.)
- Study design (media, reagents, equipment, standards, environmental conditions)
- Acceptance criteria
- QC plan
- Safety
- Results
- Summary of study
- Recommendation

- SOP
- LIS
- Proficiency plan
- Staff training

Regular review of the validation is conducted and changes to the process require approval by the technical director. All methods used by the laboratory will be validated before use to ensure that the laboratory has the capability to perform and use the method for its intended purpose. The laboratory will follow Standard Methods or EPA validation requirements when the reference method is used outside of its intended scope.

5.4.5 Estimation of Analytical Uncertainty

5.4.5.1 The laboratory attempts to lower the measurement of uncertainty by:

- Purchasing class "A" glassware and NIST thermometers.
- Monitoring equipment temperatures and humidity.
- Purchasing equipment meeting method specific requirements.
- Performing preventive maintenance on all equipment.
- Calibrating pipettes, weights, and balances annually.
- Performing QC and sterility checks on all media and reagents prior to use.
- Following reference method QC requirements and Standard Method 9020B, *Intralaboratory Quality Control Guidelines.*

5.4.5.2 The measurement of uncertainty does not apply to two test categories:

- Test methods that are qualitative, categorical, or nominal scale where visual observation or interpretation is used to determine, detect, or identify the target. Such test method include "presence" or "absence", completed, and identification methods.
- Well recognized test methods that specifies limits to the values of the major sources of uncertainty and specifies the form of presentation of calculated results. In such cases, the laboratory is considered to have satisfied the uncertainty requirements by following the

method and reporting instructions such as most probable number (MPN) tests.

5.4.5.3 Estimating Uncertainty Procedures

The estimation of uncertainty does not include sampling uncertainty or bias, it is a post-sampling evaluation. Calculations are based on 95% confidence level. Review the test method, the method validation, the published information, the calibration certificates and the manufacture's specifications to determine the sources contributing to the uncertainty.

5.4.5.3.1 Procedure for calculating duplicate uncertainty are as follows:

1. Convert raw data to a log base 10 value
2. Average the Log base 10 values
3. Calculate the difference between the duplicates
4. Calculate the pooled Standard Deviation by
    a. Determine the sum of squares for the values calculated in step 3.
        i. Square each value in the sample set.
        ii. Add all the values
    b. Divide the result by 2*t*, *t* = number of samples
    c. Calculate the Square root of the result.

$$S^2 = \frac{\sum (\mathrm{LogR}_1 - \mathrm{LogR}_2)^2}{2t}$$

5. Calculate the Relative Standard Deviation (RSD). Express as a percentage.
6. Use the Student's T Table to find the appropriate coverage factor (k) based on sample size and degree of freedom. A coverage factor of 2 is used for 95% confidence with 20 or more samples.
7. Calculate the expanded relative measurement of uncertainty at 95% confidence level as follows:

$$U = (k)\ (RSD)$$

U = uncertainty
K = coverage factor
RSD = relative standard deviation

5.4.5.3.2 The estimation of uncertainty based on recovery of a Laboratory Control Sample (LCS) procedure is as follows:

1. Convert raw data to log base 10 value.
2. Calculate the percent recovery.
   $$\%\ \text{Recovery} = \frac{\text{Recovered value}}{\text{Expected value}}$$
3. Calculate the mean of the percent recovery.
4. Calculate the standard deviation of the percent recovery.
5. Use the Student's T Table to find the appropriate coverage factor (k) based on sample size and degree of freedom. A coverage factor of 2 is used for 95% confidence with 20 or more samples.
6. Calculate the expanded measurement of uncertainty at 95% confidence level as follows:
   $$U = (k)\ (SD)$$

   U = uncertainty
   K = coverage factor
   SD = standard deviation

5.4.6 Control of Data

A series of calculation and data checks are in place to ensure quality and confidential data is provided to the client. Data are reviewed for trends and client demographics are reviewed for accuracy. Manual calculations are checked by another staff member knowledgeable in the procedure prior to reporting.

The laboratory uses an LIS to receive, track, record and report samples. Refer to *WQL-129: LIS User Guide*. The software developed is documented and validated as adequate for use. Test scripts are performed after each software upgrade on all WQL orderables to ensure the software is functioning properly. The LIS system is maintained on a secure network by the IT department. Network security and back-up procedures are handled by the IT department. Refer to section 4.13 *Control of Records*.

5.5 Calibration

5.5.1 The laboratory is furnished with all items of sampling, measurement and test equipment required for the accurate performance of tests and calibration. All equipment and instruments used for determining the testing parameters and its calibration test parameters are described in the respective SOPs.

5.5.2 All laboratory equipment are calibrated and checked to establish that it meets all the specification as required in the field of testing methods.

5.5.3 Management ensures that all personnel who operate laboratory equipment are adequately trained and have access to the manufacturer's instruction manual.

5.5.4 Wherever applicable, the laboratory maintains unique identifier for certain equipment and instruments.

5.5.5 Records for all equipment are maintained in respective equipment folders. The equipment folder includes:

- The identity of the equipment
- The manufacturer's name, serial number, model number, and any other unique identifier
- The manufacturer's instructions and manuals
- Dates, results and copies of reports and certificates of all calibrations, adjustments, and acceptance criteria
- Maintenance record logs - including any damage, malfunction, modification or repair to the equipment

5.5.6 All repairs and routine maintenance services are performed in the laboratory by laboratory personnel or hired contracted services. In event of catastrophic failure, back up equipment will be used to continue testing effectively.

5.5.7 Equipment that are not performing within the testing parameters are not used until repaired. If the equipment cannot be repaired, it is surplused and replacement equipment is purchased. All issues are documented in the Equipment Folder.

5.5.8 Laboratory equipment is labeled with most recent calibration date and next calibration due date.

5.5.9 The Laboratory keeps most equipment under direct control. Any equipment sent out for service will be checked upon return to ensure that it is functioning adequately to meet the calibration method criteria.

5.5.10 Method SOPs include the frequency of intermediate calibration checks if needed.

5.5.11 Correction factors are applicable to adjustment and will be clearly labeled and posted. Correction factors for thermometers shall be posted on the daily temperature charts and are updated after each calibration.

5.5.12 Only trained staff or contracted service providers are permitted to make adjustments to test and/or calibration equipment.

5.5.13 All support equipment such as balance, manifolds, refrigerators, freezers, thermometers, water baths, incubators, pipets, and pH meter follows 9020B QC guidelines. Equipment acceptable ranges are found on the QC or temperature charts to detect any performance issues.

5.6 Measurement Traceability

5.6.1 All equipment and instruments used in the laboratory that has a significant effect on the accuracy and validity of the results are calibrated before use. See section 5.5

5.6.2 WQL is not a calibration laboratory and therefore contribution to total uncertainty from calibration is very minimal.

5.6.3 All reference standards are checked internally to make sure they are meeting specifications before use. Reference materials such as QC organisms are confirmed prior to use.

5.6.4 Reference standards and materials are purchased commercially and its traceability shall be based on the national standards of measurements as established by CDC, NIST or EPA.

5.6.4.1 All methods SOPs details the use of all specific method required reference standards and materials' acquired sources, preparation frequency, storage and traceability if any.

5.6.4.2 Consumables such as media, broths, saline, waters, dilution buffers, pH buffers reagents, and solvents are logged and labelled upon arrival with date and time received, lot numbers and expiration dates. They are subjected to QC criteria before use. QC worksheets are maintained in the QC binders and is also referenced in the QC SOPs.

5.7 Sample Collection

5.7.1 General

Sample collection is primarily performed by the client but the laboratory is capable of collecting samples as needed. Collection procedures adhere to the latest edition of Standard Methods or EPA. Refer to *WQL-104: Sample: Collection, Acceptance and Disposal.*

5.7.2 The laboratory strictly adheres to the sampling procedure. Deviation from this procedure requires authorization and documentation prior to sampling. The documentation will include the deviation and explanation.

5.7.3 The laboratory requires a chain of custody (COC) form for all samples submitted. The COC contains the following fields:

- Client Name
- Study Name
- Collection Date
- Sampler Name
- Program Manager
- Sample Collection Time
- Sample Location
- Matrix
- Test Requests
- Sampler Relinquish

Required fields on the COC for sample acceptance is stated in *WQL-104*: *Sample: Collection, Acceptance and Disposal*.

5.8 Sample Handling

5.8.1 The laboratory has a procedure for transportation conditions, receipt, handling, protection, storage, retention and/or disposal of samples to ensure the integrity of the samples as well as the interests of the laboratory and our clients. These procedures are discussed in detail in *WQL-104: Sample: Collection, Acceptance and Disposal SOP*.

5.8.2 Samples are assigned a unique accession number for identification purposes. The format is WL-YY-#####, where YY is the year the sample is collected followed by sample number. Each year, the accession numbers are assigned sequentially starting from 1. All procedures and documents related to the sample are traced by the accession number throughout its duration in the laboratory. Accession numbers are printed on durable, water-resistant labels.

5.8.3 Upon receipt of the samples, any departures from Standard Method or EPA requirements are recorded on the COC and the Technical or QA manager is consulted to address the departure. The information on the client's COC must coincide with the information on the sample containers. Clients are notified of any discrepancies.

5.8.4 The laboratory has procedures and appropriate facilities to avoid sample deterioration or damage during storage, handling and preparation. The equipment which holds the test samples and plates are monitored daily and preventive maintenance are performed routinely.

5.8.5 Upon receipt of the sample, a unique accession number is assigned to the sample. The number is printed on a durable, adhesive label which contains an alpha numeric code and a barcode representing the alpha numeric code. The accession number is affixed to the sample bottle and to the corresponding COC. The number serves as the link between the sample and all laboratory activities and data associated with the sample.

5.8.6 Laboratory staff adhere to the *WQL-104: Sample: Collection, Acceptance and Disposal* when accepting samples for testing. If the samples do not meet the following requirements, the client will be notified and the sample will be qualified or rejected. All activities will be documented on the COC.

- Accurate sample documentation (i.e. COC)
- Adherence to holding times
- Proper sample labeling with a unique identifier
- Appropriate type of collection container
- Sufficient volume for analysis

5.8.7 A permanent record of all samples are logged into and retained in the LIS. Refer to *WQL-129*: *LIS User Guide*. Upon receipt of the samples, laboratory staff will record the following information on the *Sample Received Log:*

- Date and time sample received
- Client
- Study name
- Starting accession number
- Number of samples received
- Initials

5.8.8 All documentation submitted with the samples or transmitted to the laboratory by the submitter are retained. Refer to 4.13 *Control of Records*.

5.8.9 Samples are stored according to Standard Method or method specific criteria. Samples are disposed once the client receives all requested test procedures for the sample. Refer to *WQL-104*: *Sample: Collection, Acceptance, and Disposal SOP.*

5.9 Quality Assurance

Quality control procedures are used for all test methods performed in the laboratory to ensure quality, accurate test results. The type of QC, the frequency at which they are performed, and the limit of detection (LOD) are listed in the method SOP. LOD varies because of differences in test methods, calculation procedures, and sample volume but have the same principle. QC is performed according to the reference test method requirements in accordance to EPA or Standard Methods. The results are tracked at least annually or as needed per client's request in a QA report. In instances where the QC falls outside of acceptable limits, NCE documentation and procedures are implemented to determine data validity. QC consists of both internal and external checks to monitor quality and validity of the test results.

5.9.1 Internal Quality Control

Internal QC determines if the quality of reagent and media used is appropriate for the test method. It includes sample set, day to day, or monthly monitoring. Dependent on the test method, internal QC may include the following:

- Supply, reagent and media suitability – QC procedures and interpretations are detailed in individual QC charts to determine acceptability.

- ATCC QC organisms – are used to determine reagent or media suitability.
- Sterility – is part of the supply, reagent, and media suitability determination. Sterility checks also applies to test methods to measure possible contamination or interferences during testing.
- Duplicate – are analyzed randomly to assess precision on an ongoing basis. One sample is tested twice by the same test method. Frequency of duplicate processing is dependent on reference method and is stated in the method SOP.
- Precision criteria – is a measure of the degree of agreement among replicate analyses of a sample. Each analyst will establish a criteria on 15 sets of duplicates annually. Procedures for establishing the criteria is explained in *WQL – 120: Measurement of Method Precision SOP*.
- Daily precision – are daily checks on precision to ensure the analyst performs within their precision criteria for the test method. Duplicates are performed after every 8 – 10 samples.
- Accuracy – an estimate of how close a measured value is to the true value. Accuracy is a data quality indicator includes a combination of random error (precision) and systematic error (bias) components which are due to sampling and analytical operations. Accuracy is assessed in terms of percent recovery for quality control check samples and matrix spikes.

$$\text{Recovery \%} = \text{(Measured value / True value)} \times 100$$

- Correlation – evaluates the interrelated characteristic of the sample. Certain characteristics have an analogous relationship to one another. For example, total and fecal coliform recovery.
- Verification – is a process used to determine whether the method and the analyst are performing as expected to provide reliable data. Typical or positive and atypical or negative reactions by one test method are confirmed by another test method. Refer to *WQL – 119: Membrane Filtration Media Verification SOP*.
- Completed test – typical or positive reactions are further tested to confirm or identify the organism.
- Analyst comparison – replicate counts on one positive set is conducted between analysts monthly. Replicate counts between

analysts should agree within 10% and within 5% by the same analyst. Refer to *WQL – 124: Analyst Comparison for Plate Count SOP*.

- Daily QC – Positive and negative controls are set-up concurrently with the samples for required reference methods

5.9.2 External Quality Control

External QC include proficiencies from a CA ELAP compliant provider and QC samples submitted by the client such as:

Trip or Equipment Blanks – used to check contamination during collection of the sample.

Synthetics (spiked samples) – determines the accuracy of the procedure.

Replicates – determines the precision of the procedure.

Proficiencies are performed biannually on fields of testing provided by the laboratory. PT results are reviewed by the Quality and Technical managers before the electronic report is submitted to the PT provider. PT reports are reviewed by Quality and Technical managers upon receipt. Unacceptable results are investigated and documented as an NCE. The cause will be determined and a corrective action will be implemented

5.9.3 Essential Quality Control Procedures

Essential QC includes internal and external QC discussed with specific requirements detailed in the method SOPs. Quality control charts for precision and accuracy will be implemented to observe for trends and monitor the performance of the test method to produce quality data.

Environmental testing conditions are monitored to assure consistent testing condition.

- Equipment - temperature checks, humidity checks, preventive maintenance
- Calibration - thermometers and balances
- Air density - must be less than 15 colonies

QC measures are assessed on an on-going basis. Any data out of the acceptable range is documented as a NCE and is brought to the Quality or Technical manager's attention.

5.10 Reporting

5.10.1 Test results are reported accurately and clearly through results spreadsheets. The results are generated from the LIS and electronically reported to the clients after careful review for accuracy and completeness.

5.10.2 Results spreadsheets are identified as Laboratory Reports, they contain the address and phone number for the Water Lab, and are uniquely identified. The name of the client is on the report and the test methods used are identified.

5.10.3 Any deviations in the test methods, or deviations in regulatory requirements are conveyed to the client and if test results will be delayed the clients are notified.

6.0 Microbiological Testing

6.1 Introduction

The Orange County Public Health Water Quality Laboratory performs microbiological analysis on a variety of environmental sample types, including various water matrices, sediments, or biofilms. Testing includes the detection, isolation, enumeration, or identification of microorganisms, or the determination of presence or absence of growth in materials and media. It is the lab's intent to generate microbiological data of the highest quality by following the TNI quality system requirements as well as the quality control practices specified in section 6.7.3.

6.2 Scope

The lab follows all QC practices specified in section 6.7.3, along with any additional procedures indicated by the method or in Standard Methods section 9020. Each method SOP will list the QC practices that will be followed and documented.

6.3 Terms and Definitions

Refer to Section 3.0 *Definitions and Acronyms*

6.4 Method Selection

Refer to section 5.4.2 *Method Selection* for details.

6.5 Method Validation

Test method verification and validation is required prior to method implementation. The validation procedure is outlined in section 5.4.3 *Validation of Methods.* Accuracy, precision, specificity and sensitivity are included in the validation process. Validation documentation is maintained for as long as the method is used, and five years past the date of last use.
The WQL participates in proficiency testing (PT) for each field of accreditation (FOA) to maintain accreditation for the specified method. PTs are ordered biannually from an approved proficiency testing provider (PT Provider) accredited by an approved proficiency testing provider accreditor (PTPA).

6.6 Demonstration of Capability (DOC)

6.6.1 General DOC

6.6.1.1 Staff that performs any activity involving analysis of samples will have constant, close supervision until a satisfactory initial DOC is completed (see Section 6.6.2).

6.6.1.2 Thereafter, ongoing DOC (Section 6.6.3), is performed and documented at least every twelve (12) months.

6.6.1.3 In cases where staff has been analyzing samples using a method that has been in use by the laboratory for at least one (1) year prior to applying for accreditation and where there have been no significant changes in instrument type or method, the ongoing DOC shall be acceptable as an initial DOC.

6.6.1.4 All demonstrations shall be documented using the DOC form for Microbiology. All data applicable to the demonstration shall be retained and readily available at the laboratory.

6.6.2 Initial Demonstration of Capability (DOC)

6.6.2.1 Prior to using any method, or with any change in instrument type, personnel or method, or any time that a method has not been performed by the laboratory or analyst in a twelve (12) month period an initial DOC is performed.

6.6.2.1.1 The laboratory shall document each initial, and thereafter, any DOC in a manner such that the following information is available for each staff:

a) analyst(s) involved in preparation and/or analysis;
b) matrix;

c) organism(s);
d) identification of method(s) performed;
e) identification of lab-specific SOP used for analysis;
f) date(s) of analysis; and
g) summary of analysis

6.6.2.2 Lead staff will provide training to new staff on each method they will be responsible to perform. After adequate training, staff will be able to demonstrate capability by meeting precision and accuracy criteria.

6.6.3 Ongoing DOC

6.6.3.1 The lab has procedures in place to check ongoing DOC through daily, weekly, monthly, bi-annual, and annual checks. After initial DOC is completed and formally documented, on-going DOC will be formally documented 6 months after initial DOC, then annually thereafter. Formal documentation is through the individual staff's PTCR and the DOC form for Microbiology.

6.7 Technical Requirements

6.7.1 Calibration

WQL's microbiology field of testing is supported by few equipment and instruments. Equipment and instruments used in WQL are subjected to in-house laboratory internal calibration and or external calibration by County contracted service vendor. This includes all such equipment and instruments that have direct impact on the client results.

All tests performed at the WQL has referenced SM testing methods that could be quantitative and or qualitative in nature. Calibrations are performed as described by their respective methods' SOPs. SOPs are prepared, reviewed and numbered in the laboratory software "iPassport". For qualitative calibration presence or absence (P/A) test protocols are followed. Manufacturer's calibration procedures are taken into consideration in all the methods' SOP. Refer to section 5.5 for basic calibration criteria.

6.7.2 Continuing Calibration (CC)

Continuing calibration values of equipment such as incubators, water and bead baths, refrigerators and freezers are pre-determined for their respective applications. These are monitored by internal thermometers or by external display for freezers. These equipment are serviced and calibrated bi-annually by contracted services and or whenever instrument is returned to service after any corrective action.

Thermometers used to verify daily secondary continuing calibration of these equipment are also calibrated bi-annually by contracted services. Daily physical and manual monitoring of temperatures are performed and recorded within desired temperature of acceptable ranges whenever tests are in progress or performed.

Laboratory balances are also calibrated bi-annually by outside contracted vendor and calibrated during each use.

Daily media QC SOP includes calibration of miscellaneous equipment such as densitometer for measuring McFarland values with its manufacturer's acceptable calibration values.

For continuing calibration verification (CCV) reference materials with certified values are use daily to QC procedures whenever test is performed. Refer to Section 5.5 *Calibration*.

6.7.3 Quality Control

6.7.3.1 Quality and Sterility of Standards, Reagents, Materials, and Media

Internal quality control and sterility procedures are performed on materials, reagents and media to determine suitability prior to use for testing. QC procedures includes sterility, pH, volume check and positive/negative controls. The procedures follow Standard Methods, EPA or TNI recommendations. When recommendations conflict, the stricter method is incorporated. Refer to section 5.6.4.2 *Measurement Traceability* and 5.9.1 *Internal QC*.

Media are purchased from a contracted vendor but can be made by the laboratory during emergencies. Media validation and performance will be determined prior to initial use. The laboratory uses media within the expiration date or shelf-life recommended by the manufacturer and accredited method. QC procedures and interpretations are detailed in individual QC charts. The charts may include:

- Name of the product

- QC procedure (set-up, incubation requirements, interpretation)
- Set-up date
- Date read
- Manufacture
- Lot number
- Expiration date
- pH
- Volume check
- Results
- Preparer's initial

The quality of reagent water is monitored for total organic carbon (TOC) and heterotrophic plate count by SIM plate monthly. Trace metals, inhibitory residue and water suitability is performed annually or when using a new detergent, a new water treatment system, or after a period of non-use of a month. TOC, trace metals and water suitability testing are performed by a certified, contracted laboratory. The laboratory uses Type I water therefore are not required to perform bacteriological water quality testing to determine the presence of toxic agents or growth promoting substance. Water quality analysis results are maintained for 5 years.

6.7.3.2 Method Blanks

For membrane filtration, method blanks are conducted at the beginning and end of the filtration process. A middle blank is performed after every 10 samples processed in a filtration series or when more than 30 minutes elapses between successive filtrations. The filtration units are sterilized prior to starting the filtration series and between samples. The funnels used for filtration are sterile and disposable. The method blanks are plated onto the same media types used during the filtration process. This demonstrates that the filtration equipment along with filters, sample containers, media and reagents are not contaminated due to improper handling, preparation or adverse environmental exposures.

For pour plate technique, such as heterotrophic plate count, a method blank is made by pouring one uninoculated plate per batch or lot of media.

6.7.3.3 Test Variability/Reproducibility

Monthly Analyst Comparison is performed by doing duplicate counts on one positive sample for each type of media used for membrane filtration. Each analyst counts typical results on the same sample and must be within ten percent difference to be acceptable. The analyst that originally counted the plates should be within 5% difference in counts.

6.7.3.4 Sample Specific Controls (where applicable).

Matrix spike and matrix duplicates are performed per method requirement.

6.7.3.5 Data Reduction

The calculations, data reduction, and statistical interpretations performed are in compliance with method protocols. Refer to sections 4.3, 4.9, 4.11, 4.12 and 4.14 for laboratory's compliance to this policy. Calculations are performed on the raw data by computer or manually performed and retained. Initially, the analyst reviews the data for acceptability of quality control measures and accuracy of final results. The analyst ensures the raw data entered into the computer is correct as well as spot checks computer calculations. Manual calculations require secondary calculation checks by another analyst. Also, calculations performed by Cerner are verified when the analyst calculates their duplicates. Once the data is reviewed it is documented on the COC.

6.7.3.6 Selectivity

All media used for growth or recovery of organisms are checked once per lot or batch to ensure the target organisms respond in an acceptable and predictable manner. This is accomplished by our media verification procedure and by performing completed tests. Refer to *WQL – 119: Membrane Filtration Media Verification*, *WQL -109: Colilert-18* and *WQL – 110: Enterolert.* We obtain our reference cultures used for quality control from ATCC to ensure identity and traceability. The reference culture identity is verified before single-use working stocks are prepared Refer to *WQL – 134: Quality Control Culture Maintenance*.

Culture Controls

- Negative culture controls are used to demonstrate that the medium does not support the growth of non-

target organisms or does not exhibit the typical positive reaction of a target organism.

- Positive culture controls are used to demonstrate that the medium can support the growth of the target organism(s), and that the medium produces the specified or expected reaction to the target organism.
- Prior to first use, each lot or batch of selective media is analyzed with one or more known negative and positive culture controls, as appropriate to the method. Each media has a quality control chart that identifies the culture control organisms.

6.7.3.7 Constant and Consistent Test Conditions

WQL facility has sufficient storage space with non-absorbent floors and work surfaces for easy cleaning and disinfecting. Laboratory equipment maintenance and calibration follow Standard Methods recommendations. Thermometers are used to monitor temperature in incubators, refrigerators and water baths. Thermometers are calibrated according to National Institute of Standard and Technology (NIST) standards biannually by a certified contractor.

Autoclave temperature is recorded on a continuous recording device to ensure the proper sterilization temperature is reached. Biological indicators and temperature sensitive tape are used with each autoclave run to indicate sterilization conditions are met and complete. Autoclave records for each cycle include:

- Date
- Contents
- Maximum temperature
- Pressure
- Sterilization time
- Total run time
- Analyst initial

Autoclave preventive maintenance is performed quarterly and calibration is performed annually by a contracted vendor.

Oven sterilization of loops and pipettes are documented in the same process as the autoclave. Monthly biological indicator and temperature sensitive tape are used to determine sterilization effectiveness.

Volumetric equipment such as dispensers are verified for accuracy with each batch. Accuracy of equipment with volumetric markings such as funnels, pipettes, and collection bottles are verified once per lot prior to initial use. Volume verification is performed using Class A certified glassware. Volume accuracy is acceptable within 2.5% of the expected volume.

Incubators and water baths are monitored for temperature uniformity twice daily, at least four hours apart. The temperature of each shelf in the incubator are documented on the temperature chart. New equipment are monitored to meet specific ranges prior to use.

Lab ware such as glassware and plastic ware are washed according to the Media Room SOP. Sterility and pH QC is performed on lab ware prior to use. Inhibitory Residue testing is performed annually and each time the laboratory changes detergent or washing procedure.

6.7.4 Data Acceptance/Rejection Criteria

The lab follows all data acceptance/rejection criteria listed in Standard Methods 23rd ed. for each method used.

6.7.5 Sample Handling

Receipt of samples complies with Volume 1, Module 2, Sections 5.8.6 and 5.8.7

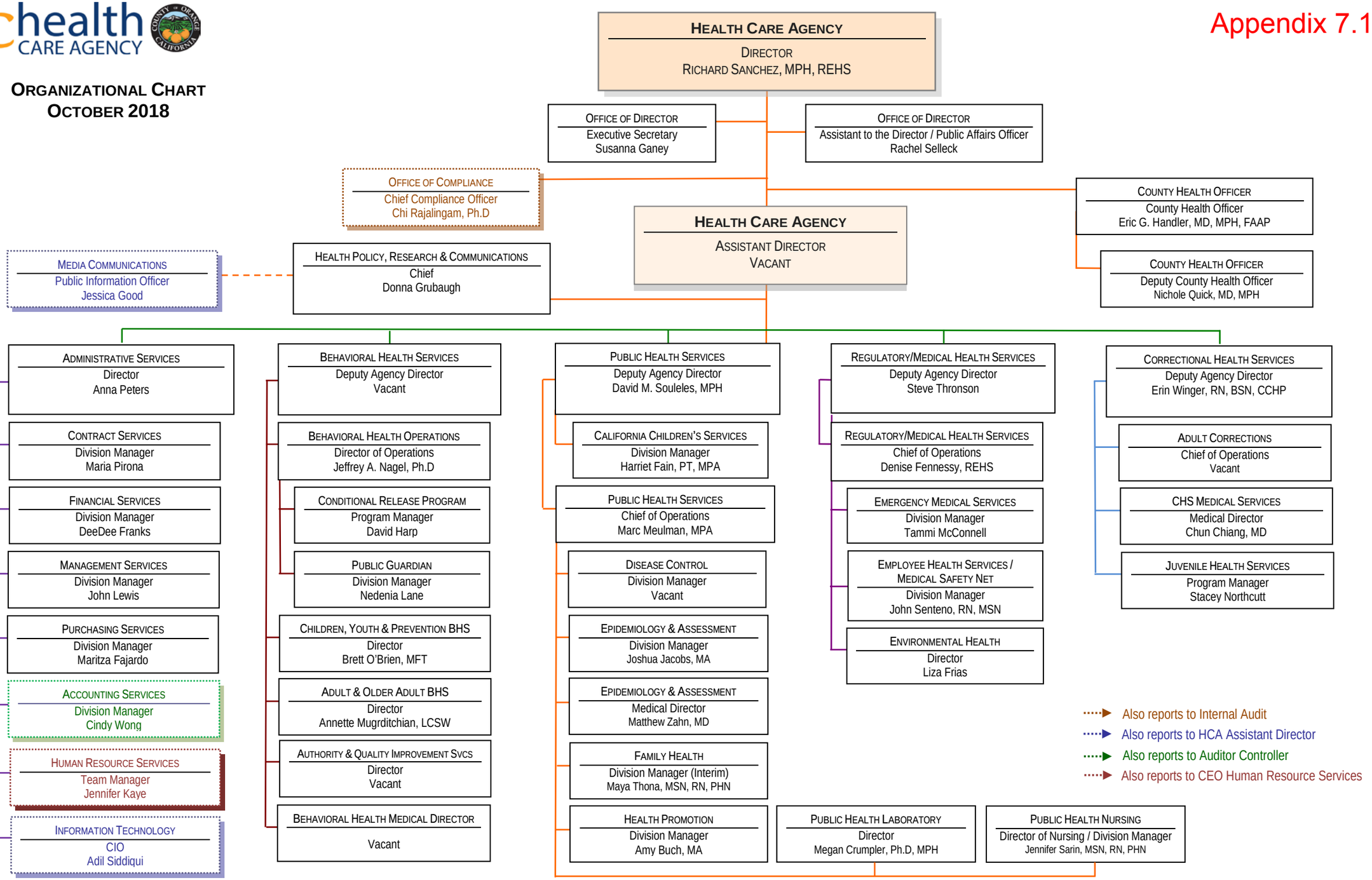
6.7.5.1 Samples that require temperature preservation are accepted if they meet the sample acceptance criteria. Refer to *WQL – 104: Sample: Collection, Acceptance, and Disposal.*

6.7.5.2 Microbiological samples from known chlorinated sources, unknown sources where disinfectant usage is suspected, and all potable water supplies do not require them to be checked for absence of disinfectant residual because we provide our clients with sample containers. The efficacy of the sodium thiosulfate is tested per lot of sample containers and documented. Refer to *WQL – 125: Efficacy of Dechlorination Agent*.

7.0 Appendices

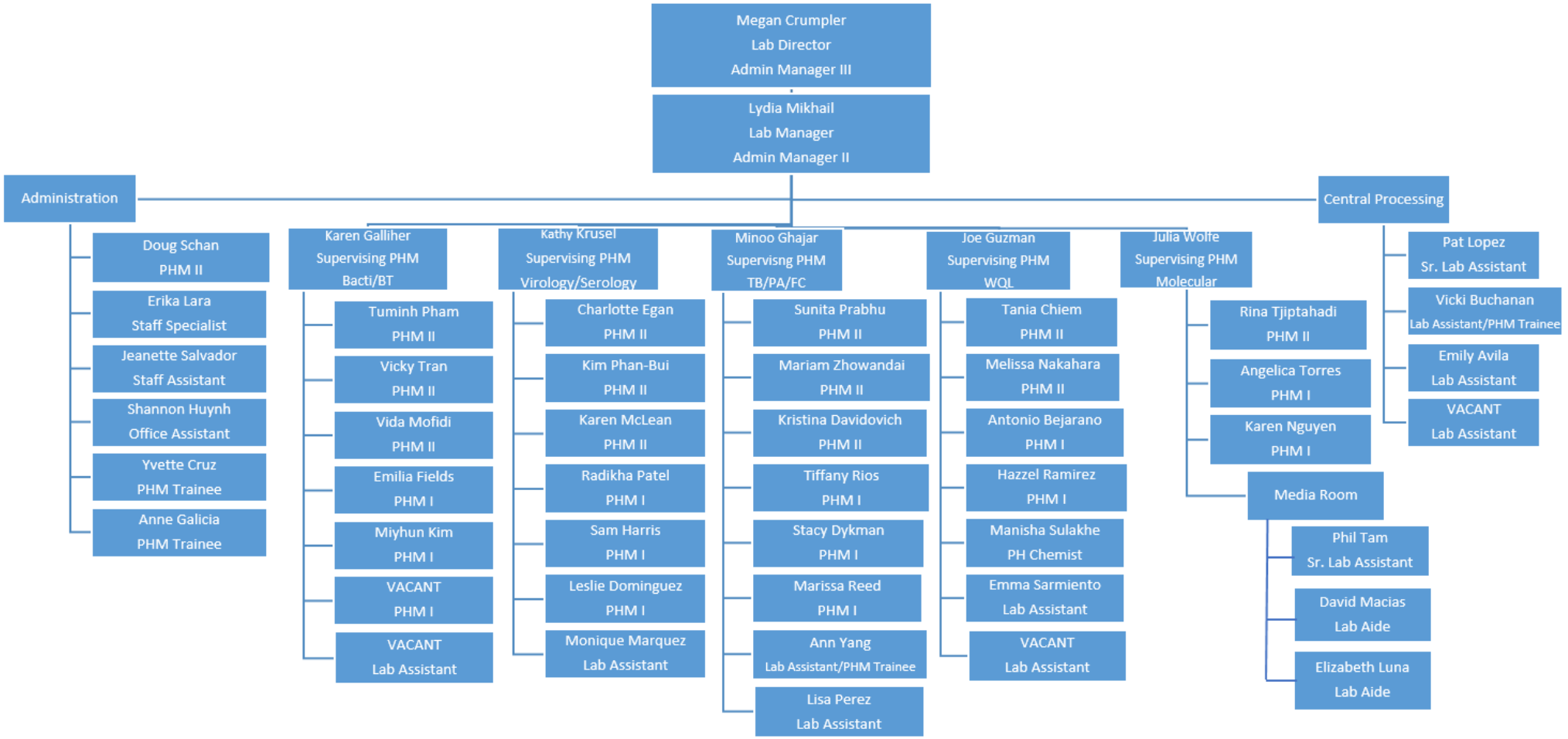
Appendix 7.1.1

ORGANIZATIONAL CHART
OCTOBER 2018



Appendix 7.1.2

Orange County Public Health Laboratory Organization Chart March 2019



Master List

Standard Operating Procedures

Appendix 7.2.1

	Name	Index	Category	Analytes Tested	Reference Method
1	Weekend SOP	WQL - 102	WQL Operations		
2	Sample: Collection, Acceptance, and Disposal	WQL - 104	WQL Operations		SM 9020
3	Creating Standard Operating Procedures (SOP)	WQL - 107	WQL Operations		
4	Membrane Filtration	WQL - 108	WQL Analysis Methods	Total coliforms, Fecal coliforms, enterococci, E. coli	SM 9222A,B, D, EPA 1600, EPA 1603
5	Colilert-18	WQL - 109	WQL Analysis Methods	Total coliforms, E. coli	SM 9223B
6	Enterolert	WQL - 110	WQL Analysis Methods	Enterococci	SM 9230D
7	Heterotropic Plate Count (HPC)	WQL - 111	WQL Analysis Methods	Heterotrophic bacteria	SM 9215A-B
8	EasyPhage Coliphage	WQL - 112	WQL Analysis Methods		Scientific Methods EP100, SM 9224C, EPA 1602
9	Multiple Tube Fermentation (MTF)	WQL - 113	WQL Analysis Methods	Total coliforms, Fecal coliforms	SM 9221A, 9221B, 9221C
11	Membrane Filtration Media Verification	WQL - 119	WQL QA/QC		SM 9020B,9222B,9222D EPA 1600, 1603
12	Method for Enterococci Speciation	WQL - 120	WQL Analysis Methods		
13	Coliphage Enumeration: EPA 1602 Double Agar Layer	WQL - 121	WQL Analysis Methods		EPA 1602
14	Membrane Filtration Media and Daily Quality Control	WQL - 122	WQL QA/QC		SM 9020, EPA 1600, EPA 1603
15	Measurement of Method Precision SM 9020B	WQL - 123	WQL QA/QC		SM 9020B
16	Analyst Comparison of Plate Counts SM 9020B	WQL - 124	WQL QA/QC		SM 9020B
17	Efficacy of Dechlorination Agent	WQL - 125	WQL QA/QC		
18	Measurement of Potential Hydrogen (pH)	WQL - 126	WQL QA/QC		SM 4500H A-B
19	Inhibitory Residue Testing	WQL - 127	WQL QA/QC		
20	Nanodrop 2000	WQL - 128	WQL QA/QC		
21	DNA Quantitation by Qubit 4	WQL - 139	WQL Analysis Methods		
22	HF183 qPCR: DNA Standard and IAC Preparation	WQL - 141	WQL Analysis Methods		EPA: Characterization of Human Fecal Pollution in Water by TaqMan Quantitative Polymerase Chain Reaction (PCR) assays. May 2013 Draft.

LABORATORY EQUIPMENT

Appendix 7.3.1

ITEM	MFG	MODEL_NO
AIR CLEAN, PCR WORKSTATION	AIR CLEAN SYSTEMS	600
AUTOCLAVE	MARGET FORGE	STMEL
BALANCE	SARTORIUS	1475MP8
BALANCE	DENVER INSTRUMENT	APX-200
BEAD BATH	LAB ARMOR	M720
CELLULAR PHONE	APPLE	iPHONE6
CENTRIFUGE	BECKMAN	J6-HC
CENTRIFUGE	HERAEUS	17RS
CENTRIFUGE	EPPENDORF	5430
CENTRIFUGE/MICRO	EPPENDORF	5424
CENTRIFUGE, MINI	VWR	MINISTAR
CENTRIFUGE, MINI	VWR	MINISTAR
CENTRIFUGE, MINI	VWR	MINISTAR
CENTRIFUGE, MINI	VWR	MINISTAR
COLONY COUNTER	QUEBEC	3325
COLONY COUNTER	QUEBEC	3325
COMPUTER	HP	8300 ELITE
COMPUTER	HP	8300 ELITE
COMPUTER	HP	8300 ELITE
COMPUTER	HP	ELITE DESK 8 0 0
COMPUTER	HP	ELITE DESK 8 0 0
COMPUTER	HP	8300 ELITE
COMPUTER	HP	800 ELITE G1
COMPUTER	HP	800 ELITE G1
COMPUTER	HP	ELITE DESK 8 0 0
COMPUTER	HP	ELITE DESK 8 0 0
COMPUTER	HP	ELITE DESK 8 0 0
DISHWASHER	MIELE	G7883 CD
DISPENSER,EZ-PAK	MILLIPORE	FIJNO1213
DISPENSER,EZ-PAK	MILLIPORE	F1PN01556
DISPENSER,EZ-PAK	MILLIPORE	F1PN01556
DISPENSER,EZ-PAK	MILLIPORE	F1PN01556
DISPENSER,EZ-PAK	MILLIPORE	F2BN01794
DRY BATH		17600
FREEZER	SANYO	MDF-U73VC
FREEZER	ISOTEMP	IU2886D
FREEZER	PANASONIC	MDF-U731M-PA
FUNNEL,DISPENSER	MILLIPORE	
FUNNEL,DISPENSER	MILLIPORE	
FUNNEL,DISPENSER	MILLIPORE	
FUNNEL,DISPENSER	MILLIPORE	
HOOD, FUME	KEWAUNEE	H05S5448
HOOD, STERILGARD	BAKER	SG603A
HOT PLATE	CORNING	PC-620

LABORATORY EQUIPMENT

ITEM	MFG	MODEL_NO
HOT PLATE	THERMO SCIENTIFIC	8P88857100
HOT PLATE	THERMO SCIENTIFIC	8P88857100
HYDROMETER, QUANTA	HYDROLAB CORP.	
INCUBATOR	THERMO SCIENTIFIC	3911
INCUBATOR	THERMO SCIENTIFIC	3911
INCUBATOR	MILLIPORE	Dual Chamber
INCUBATOR	MILLIPORE	XX6320000
INCUBATOR	MILLIPORE	XX6320000
INCUBATOR	SANYO	MIR-153 COOLED/HEATED
INCUBATOR,02	FORMA SCIENTIFIC	3960
INCUBATOR,02	FORMA SCIENTIFIC	3960
ISOTEMP OVEN	FISHER	106G
MANIFOLD,3 PLACE	MILLIPORE	F1SN01647
MANIFOLD,3 PLACE	MILLIPORE	F1SN01647
MANIFOLD,3 PLACE	MILLIPORE	F1SN01647
MANIFOLD,3 PLACE	MILLIPORE	F1NN01540
MANIFOLD,3 PLACE	MILLIPORE	# 2
MANIFOLD,3 PLACE	MILLIPORE	3 POSITION MANIFOLD
MICROSCOPE	NIKON	SMZ745
MICROSCOPE	NIKON	SMZ645
MICROSCOPE	NIKON	SMZ645
MICROSCOPE	NIKON	SMZ645
PCR, DROPLET DIGITAL	BIORAD	QX200
PCR, REAL TIME	APPLIED BIOSYSTEMS	7500 FAST
PCR, REAL TIME	APPLIED BIOSYSTEMS	STEPONE PLUS
PLATE SPINNER, MINI	LABNET	MPS-1000
QUANTI-TRAY SEALER	IDEXX	89-10894-00
QUANTI-TRAY SEALER	IDEXX	PLUS
QUBIT FLUOROMETER	THERMOFISHER	4
REFRIG/FREEZER	FRIGIDAIRE	FRT18B4AW2
REFRIG/FREEZER	SANYO	MPR-414F
REFRIGERATOR	SANYO	MPR-1410
REFRIGERATOR	SANYO	MPR-1410
REFRIGERATOR	SANYO	MPR-1410
REFRIGERATOR	SANYO	MPR-1410
REFRIGERATOR	SANYO	MPR-1410
REFRIGERATOR	SANYO	MPR-513
ROUTER	NORTEL	SR2101007E5
SERVER	NORTEL	BAYSTACK5520-48T-PWR
SHAKER, INCUBATOR	BARSTEAD	SHKA4000
SPECTROPHOTOMETER	THERMO SCIENTIFIC	NANODROP 2000
SPECTROPHOTOMETER, SCANNING	VWR	UV-1600PC
TEMP RECORDER	HONEYWELL	
TISSUE LYSER	QIAGEN	TISSUELYSER#2

LABORATORY EQUIPMENT

ITEM	MFG	MODEL_NO
ULTRASONIC CLEANER	BRANSON	
ULTRASONIC SONIFIER	BRANSON	P/S BIO
UV LAMP	CAMAG	29001
VACUUM PUMP	MILLIPORE	XX5500000
VACUUM PUMP	MILLIPORE	XX5500000
VACUUUM PUMP SYSTEM	DEKKAR	RML050T2-40-CS
VORTEX	NEUTEC	F202AO175
VORTEX	FISHER SCIENTIFIC	G-560
VORTEX	SCIENTIFIC INDUSTRIES	G-560
VORTEX	SCIENTIFIC INDUSTRIES	G-560
VORTEX	SCIENTIFIC INDUSTRIES	G-560
VORTEX	VWR	945300
VORTEX, MIXMATE SHAKER	EPPENDORF	NONE
VORTEX, MIXER	VELP SCIENTIFICA	NENKO
WATERBATH	PRECISION	2862
WATERBATH	POLY SCI	8306A11B
WATERBATH	PRECISION	TSCIR89
WATERBATH	THERMO SCIENTIFIC	2862
WEIGHTS, BALANCE	METTLER TOLEDO	

Appendix 7.3.2

THERMOMETER-SERIAL#/LAB#	MANUFACTURER	TYPE (spirit-filled, mercury, digital)	RANGE	DEPT	LOCATION / STATUS	EQUIPMENT (INCUBATOR, waterbath, refrig.)
947	ERTCO	SPIRIT-FILLED	-50C/50C	WL	WL	REFRIGERATOR #9
1027	Tel-Tru	DIAL THERMOMETER	0F/220F	WL	WL	FISHER OVEN 106G
1029	N/A	SPIRIT-FILLED	-100C/50C	WL	WL	THER. DRAWER
1105	ERTCO	SPIRIT-FILLED	-20/110C	WL	WL	BEAD BATH
1710	VWR SCIENTIFIC	MERCURY	34.5C/46C	WL	WL	THER. DRAWER
1764	VWR SCIENTIFIC	MERCURY	34.5C/46C	WL	WL	WATERBATH #3
1770	VWR SCIENTIFIC	MERCURY	35C/46C	WL	WL	THER. DRAWER
1774	VWR SCIENTIFIC	MERCURY	34.5C/46C	WL	WL	WATERBATH #2
1808	VWR SCIENTIFIC	MERCURY	34.5C/46C	WL	WL	THER. DRAWER
1809	ERTCO	MERCURY	34.5C/46.5C	WL	WL	THER. DRAWER
2161	ERTCO	SPIRIT-FILLED	-10C/20C	WL	WL	THER. DRAWER
2564	ERTCO	SPIRIT-FILLED	-10C/20C	WL	WL	FIELD/COOLER THERM.
2709	A&M THER. CORP.	SPIRIT-FILLED	-5C/15C	WL	WL	REF./FREEZER #5
2862	A&M THER. CORP.	SPIRIT-FILLED	-5C/15C	WL	WL	THER. DRAWER
2885	A&M THER. CORP.	SPIRIT-FILLED	-5C/15C	WL	WL	THER. DRAWER
2954	A&M THER. CORP.	SPIRIT-FILLED	-5C/15C	WL	WL	REFRIGERATOR #7
2963	A&M THER. CORP.	SPIRIT-FILLED	-5C/15C	WL	WL	REFRIGERATOR #6
2995	A&M THER. CORP.	SPIRIT-FILLED	-5C/15C	WL	WL	REFRIGERATOR #10
3199	ERTCO	SPIRIT-FILLED	-10C/20C	WL	OCPW	FIELD/COOLER THERM.
3537	ERTCO	SPIRIT-FILLED	-5C/15C	WL	WL	REFRIGERATOR #8
3941	ERTCO	SPIRIT-FILLED	-10C/20C	WL	WL	REFRIGERATOR #4
3971	ERTCO	SPIRIT-FILLED	-10C/20C	WL	OCPW	THER. DRAWER
4282	ERTCO	COOLER THER	-10C/20C	WL	OCPW	FIELD/COOLER THERM.
4428	ERTCO	SPIRIT-FILLED	-10C/20C	WL	OCPW	FIELD/COOLER THERM.
4495	ERTCO	SPIRIT-FILLED	+20C/50C	WL	WL	INCUBATOR #1
4614	ERTCO	SPIRIT-FILLED	-10C/20C	WL	OCPW	FIELD/COOLER THERM.
4637	ERTCO	MERCURY	+20C/50C	WL	WL	THER. DRAWER
4827	ERTCO	SPIRIT-FILLED	-10C/20C	WL	OCPW	FIELD/COOLER THERM.
5229	ERTCO	SPIRIT-FILLED	-10C/20C	WL	OCPW	FIELD/COOLER THERM.
5526	ERTCO	SPIRIT-FILLED	-10C/20C	WL	OCPW	FIELD/COOLER THERM.
5576	ERTCO	SPIRIT-FILLED	-10C/20C	WL	OCPW	FIELD/COOLER THERM.
6196	ERTCO	SPIRIT-FILLED	-10C/20C	WL	OCWD	FIELD/COOLER THERM.
6533	ERTCO	SPIRIT-FILLED	-10C/20C	WL	OCWD	FIELD/COOLER THERM.
6690	ERTCO	SPIRIT-FILLED	-10C/20C	WL	OCWD	THER. DRAWER
6707	ERTCO	SPIRIT-FILLED	-10C/20C	WL	OCWD	THER. DRAWER
6708	ERTCO	SPIRIT-FILLED	-10C/20C	WL	WL	THER. DRAWER
6754	ERTCO	SPIRIT-FILLED	-10C/20C	WL	OCWD	FIELD/COOLER THERM.
6761	ERTCO	SPIRIT-FILLED	+20C/50C	WL	WL	THER. DRAWER
6863	ERTCO	SPIRIT-FILLED	+20C/50C	WL	WL	INCUBATOR #14
6957	ERTCO	SPIRIT-FILLED	+20C/50C	WL	WL	INCUBATOR #14
7040	ERTCO	SPIRIT-FILLED	35C/46C	WL	WL	INCUBATOR #14
7537	ERTCO	MERCURY	35C/46C	WL	WL	THER. DRAWER
8201	ERTCO	SPIRIT-FILLED	-10C/20C	WL	EH	THER. DRAWER
8276	ERTCO	SPIRIT-FILLED	-10C/20C	WL	EH	THER. DRAWER
8405	ERTCO	SPIRIT-FILLED	-10C/20C	WL	EH	FIELD/COOLER THERM.
8407	ERTCO	SPIRIT-FILLED	-10C/20C	WL	WL	FIELD/COOLER THERM.
8408	ERTCO	SPIRIT-FILLED	-10C/20C	WL	WL	FIELD/COOLER THERM.
8431	ERTCO	SPIRIT-FILLED	-10C/20C	WL	EH	FIELD/COOLER THERM.
8454	ERTCO	SPIRIT-FILLED	-10C/20C	WL	EH	THER. DRAWER
8475	ERTCO	SPIRIT-FILLED	-10C/20C	WL	WL	FIELD/COOLER THERM.
8491	ERTCO	SPIRIT-FILLED	-10C/20C	WL	EH	FIELD/COOLER THERM.
8497	ERTCO	SPIRIT-FILLED	-10C/20C	WL	EH	FIELD/COOLER THERM.
8500	ERTCO	SPIRIT-FILLED	-10C/20C	WL	EH	FIELD/COOLER THERM.
10399	ERTCO	MERCURY	+20C/50C	WL	WL	THER. DRAWER
18428	ERTCO	SPIRIT-FILLED	+20C/50C	WL	WL	INCUBATOR #1
19426	ERTCO	SPIRIT-FILLED	+20C/50C	WL	WL	INCUBATOR #1
19845	ERTCO	SPIRIT-FILLED	+20C/50C	WL	WL	INCUBATOR #14
20093	ERTCO	SPIRIT-FILLED	+20C/50C	WL	WL	INCUBATOR #1
20166	ERTCO	SPIRIT-FILLED	+20C/50C	WL	WL	THER. DRAWER
20368	ERTCO	SPIRIT-FILLED	+20C/50C	WL	WL	THER. DRAWER
20424	ERTCO	SPIRIT-FILLED	+20C/50C	WL	WL	THER. DRAWER
20461	ERTCO	SPIRIT-FILLED	+20C/50C	WL	WL	INCUBATOR #1
20502	ERTCO	SPIRIT-FILLED	+20C/50C	WL	WL	
171908	EVER-SAFE	SPIRIT-FILLED	-10C/50C	WL	WL	MAX Q4000
172035	ERTCO	SPIRIT-FILLED	0C/50C	WL	WL	INCUBATOR #10
0518	SPER-SCIENTIFIC	MERCURY	35C/46C	WL	WL	WATER BATH #2
A 01383	H B INSTRUMENT	ALCOHOL	0C/50C	WL	WL	THER. DRAWER
B02-100	MILLIPORE	MERCURY	28C/44.8C	WL	WL	EMERGENCY INCUBATOR #7
B02-102	MILLIPORE	MERCURY	28C/44.8C	WL	WL	EMERGENCY INCUBATOR #6
H01-331	MILLIPORE	MERCURY	28C/44.8C	WL	WL	EMERGENCY INCUBATOR #5
H01-335	MILLIPORE	MERCURY	28C/44.8C	WL	WL	EMERGENCY INCUBATOR #5
J01-515	MILLIPORE	MERCURY	28C/44.8C	WL	WL	EMERGENCY INCUBATOR #6
7	XANAX	SPIRIT-FILLED	-40C/110C	WL	WL	DRI-BATH 1760
122277721	VWR SCIENTIFIC	INFRARED	-60C/500C	WL	WL	RECEIVING AREA
150697409	FISHER BRAND	INFRARED	-60C/500C	WL	WL	RECEIVING AREA
140006	VWR SCIENTIFIC			WL	WL	

THERMOMETER-SERIAL#/LAB#	MANUFACTURER	TYPE (spirit-filled, mercury, digital)	RANGE	DEPT	LOCATION / STATUS	EQUIPMENT (INCUBATOR, waterbath, refrig.)
4324562	VWR SCIENTIFIC	H-B Instrument		WL	WL	**INCUBATOR #13**
3144672	VWR SCIENTIFIC	H-B Instrument	**41.5 C**	WL	WL	**THER. DRAWER**
24542	VWR SCIENTIFIC	H-B Instrument	**41.5 C**	WL	WL	**THER. DRAWER**
3144672	VWR SCIENTIFIC	H-B Instrument		WL	WL	**INCUBATOR #13**
2507	VWR SCIENTIFIC	H-B Instrument		WL	WL	**FIELD/COOLER THERM.**
5104117	VWR SCIENTIFIC	H-B Instrument	**41.5 C**	WL	WL	**INCUBATOR #13**
4324549	VWR SCIENTIFIC	H-B Instrument		WL	WL	**THER. DRAWER**
3144670	VWR SCIENTIFIC	H-B Instrument		WL	WL	**THER. DRAWER**
4182096	VWR SCIENTIFIC	H-B Instrument	44.5 C	WL	WL	**INCUBATOR #12**
3144644	VWR SCIENTIFIC	H-B Instrument	44.5 C	WL	WL	**INCUBATOR #12**
3144677	VWR SCIENTIFIC	H-B Instrument	44.5 C	WL	WL	**INCUBATOR #12**
8454	VWR SCIENTIFIC				Newport	

PART B PERSONNEL QUALIFICATIONS PRINCIPAL ANALYST

Please make photocopies of this form and provide the information for additional personnel.

1. Name (Last, First, Middle Initial): _____

2. Title: _____

[ ] Supervisor of Section _____ Operates Device _____

3. Education:

Month/Year From - To	College/University	Major	Degree	Year Completed

4. Technical Training:

Month/Year From - To	Technical Trade or Service School	Subject Certificate	Year Completed

5. Relevant Experience: (Last 5 years)

Month/Year From - To	Name and Address of Employer	Job Title

6. Briefly describe your experience relevant to this employment on a separate sheet of paper. Be sure to identify the laboratory, person's name and position.

7. Certificate(s): (Analyst)

[ ] CAL Nevada Section American Water Works Association

Grade:_____ Expiration date:_____

[ ] California Water Environment Association (CWEA)

Grade:_____ Expiration date: _____

Appendix 7.5.2a

Personnel Training and Competency Record
Microbiologist

Section: Water Quality Laboratory Period _____ to _____

Employee Name

	Training			Competency		
Procedure	Review Date	Employee Initials	Supv. Initials	Procedure Type*	Date Reviewed	Supv Initials
Monitoring equipment temperature						
Sample receiving						
Supplies receiving						
Setting up/labeling MF media						
Perform Membrane Filtration						
Set-up duplicate						
Precision Criteria entry						
Reading Les Endo						
Reading mFC						
Reading mEI						
Reading mTEC						
MF/duplicate calculations						
Fill out MF membrane sterility QC						
E-mailing reports						
Faxing reports						
COC Data Entry						
Discarding water samples						
Scan/File COCs						
Initiate requisitions						
Filing requisitions						
Harvesting QC organisms						
Setting up Quality Control						
Setting up daily media QC						
Reading/recording QC						
Freezing cultures						
Multiple Tube Fermentation (MTF)						
Media Verification						
Setting up Colilert 18/Enterolert						
Reading Colilert 18/Enterolert						
Colilert 18/Enterolert Completed test						
Reporting positive domestics						
HPC Set-up/Reading/Reporting						
Coliphage Set-up/Reading/Reportig						
PCR Filtering						
PCR Extraction						
Canine qPCR						
HF183 qPCR						
Enterococcus qPCR						
ELAP proficiency samples						

*Procedure type; Personal Observation (PO), Written exam (EX), Feedback (FB), Review of Record (ROR), Review of documentation (ROD)

Appendix 7.5.2b

Personnel Training and Competency Record
Lab Assistant

Section: Water Quality Laboratory Period _____ to _____

Employee Name

	Training			Competency		
Procedure	Review Date	Employee Initials	Supv. Initials	Procedure Type*	Date Reviewed	Supv Initials
Monitoring equipment temperature						
Equipment maintenance						
Sample receiving						
Supplies receiving						
Setting up/labeling media for MF						
Perform Membrane Filtration						
Set-up duplicate						
Precision Criteria entry						
Reading Les Endo						
Reading mFC						
Reading mEI						
Reading mTEC						
MF/duplicate calculation						
Fill out MF membrane sterility QC						
E-mailing reports						
Faxing reports						
COC Data Entry						
Discarding water samples						
Scanning/File COCs						
Initiate requisitions						
File requisitions/packing slips						
Inventory						
Harvesting QC organisms						
Setting up Quality Control						
Setting up Daily media QC						
Freezing cultures						
Multiple Tube Fermentation (MTF)						
Media Verification						
Setting up Colilert 18/Enterolert						
Reading Colilert 18/Enterolert						
Colilert 18/Enterolert Completed test						
Reporting positive domestics						
HPC Set-up/Reading/Reporting						
Coliphage Set-up/Reading/Reportig						
PCR Filtering						
PCR Extraction						
ELAP proficiency samples						

*Procedure type; Personal Observation (PO), Written exam (EX), Feedback (FB), Review of Record (ROR), Review of documentation (ROD)

Appendix 7.5.3

ORDER PROCEDURE	Guzman, J.	Bejarano, A.	Chiem, T.	Dominguez, L.	Dykman, S.	Nakahara, M.	Ramirez, H.	Sarmiento, E.	Sulakhe, M.
WQL-TCMF (Total Coliforms)	✓	✓	✓		✓	✓		✓	✓
WQL-FCMF (Fecal Coliforms)	✓	✓	✓		✓	✓		✓	✓
WQL-ENTMF (Enterococcus)	✓	✓	✓		✓	✓		✓	✓
WQL-ECMF (E. coli)	✓	✓	✓		✓	✓		✓	✓
WQL-TCSED (Total Coliforms)	✓		✓		✓				
WQL-FCSED (Fecal Coliforms)	✓		✓		✓				
WQL-ENTSED (Enterococcus)	✓		✓		✓				
WQL-ECSED (E. coli)	✓		✓		✓				
WQL-TCIDEXX (Total Coliforms)	✓	✓	✓		✓	✓		✓	✓
WQL-ECIDEXX (E. coli)	✓	✓	✓		✓	✓		✓	✓
WQL-ENTIDEXX (Enterococcus)	✓	✓	✓		✓	✓		✓	✓
WQL-TCMTF (Total Coliforms)	✓		✓		✓	✓			
WQL-FCMTF (Fecal Coliforms)	✓		✓		✓	✓			
WQL-HPC	✓	✓	✓		✓	✓		✓	✓
WQL-Coliphage		✓	✓		✓	✓			
WQL-qPCR Human		✓	✓		✓	✓			
WQL-qPCR Canine		✓	✓		✓	✓			

County of Orange
HEALTH CARE AGENCY
PUBLIC HEALTH WATER QUALITY LABORATORY

Policy Statement: Laboratory Ethics

It is the policy of the Orange County Public Health Water Quality Laboratory (OCPHWQL) to conduct all business with integrity and in an ethical manner. It is a basic and expected responsibility of all staff and managers to hold to the highest ethical standard of professional conduct in the performance of all duties.

Staff at the OCPHWQL are charged with:

- Providing accountability for the quality and integrity of the laboratory services they provide. This responsibility requires that employees properly document pertinent laboratory functions and that data produced by them are of known, documented quality.

- Striving to maintain and improve their technical knowledge and professional competence. This responsibility requires that employees become familiar with all the tools and information necessary for the performance of their assigned duties.

- Maintaining cooperative, professional working relationships with colleagues and laboratory clients.

I understand the laboratory's requirements regarding Laboratory Ethics and my responsibility to follow the policy in my role as an OCPHWQL employee.

Name_____
(*Please Print*)

Signature_____ Date:_____

Change Log

Date	Description	Approved By