#### SECTION 10. COMPLAINTS (NELAC 5.4.8)

#### 10.1 <u>OVERVIEW</u>

The laboratory considers an effective client complaint handling processes to be of significant business and strategic value. Listening to and documenting client concerns captures 'client knowledge' that enables our operations to continually improve processes and client satisfaction. An effective client complaint handling process also provides assurance to the data user that the laboratory will stand behind its data, service obligations and products.

A client complaint is any expression of dissatisfaction with any aspect of our business services (e.g., communications, responsiveness, data, reports, invoicing and other functions) expressed by any party, whether received verbally or in written form. Client inquiries, complaints or noted discrepancies are documented, communicated to management, and addressed promptly and thoroughly.

The laboratory has procedures for addressing both external and internal complaints with the goal of providing satisfactory resolution to complaints in a timely and professional manner.

The nature of the complaint is identified, documented and investigated, and an appropriate action is determined and taken. In cases where a client complaint indicates that an established policy or procedure was not followed, the QA Department must evaluate whether a special audit must be conducted to assist in resolving the issue. A written confirmation or letter to the client, outlining the issue and response taken is recommended as part of the overall action taken.

The process of complaint resolution and documentation utilizes the procedures outlined in Section 12 (Corrective Actions) and is documented in the laboratory's corrective action database in accordance with procedures specified in laboratory SOP No. IR-QA-CAR, *Corrective Actions*.

#### 10.2 EXTERNAL COMPLAINTS

An employee that receives a complaint initiates the complaint resolution process by first documenting the complaint according to IR-QA-CAR.

Complaints fall into two categories: correctable and non-correctable. An example of a correctable complaint would be one where a report re-issue would resolve the complaint. An example of a non-correctable complaint would be one where a client complains that their data was repeatedly late. Non-correctable complaints should be reviewed for preventive action measures to reduce the likelihood of future occurrence and mitigation of client impact.

The general steps in the complaint handling process are:

- Receiving and Documenting Complaints
- Complaint Investigation and Service Recovery
- Process Improvement

The laboratory shall inform the initiator of the complaint of the results of the investigation and the corrective action taken, if any.

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# 10.3 INTERNAL COMPLAINTS

Internal complaints include, but are not limited to: errors and non-conformances, training issues, internal audit findings, and deviations from methods. Corrective actions may be initiated by any staff member who observes a nonconformance and shall follow the procedures outlined in Section 12. In addition, Corporate Management, Sales and Marketing and IT may initiate a complaint by contacting the laboratory or through the corrective action system described in Section 12.

# 10.4 MANAGEMENT REVIEW

The number and nature of client complaints is reported by the QA Manager to the laboratory and QA Director in the QA Monthly report. Monitoring and addressing the overall level and nature of client complaints and the effectiveness of the solutions is part of the Annual Management Review (Section 16).

# SECTION 11. CONTROL OF NON-CONFORMING WORK (NELAC 5.4.9)

# 11.1 <u>OVERVIEW</u>

When data discrepancies are discovered or deviations and departures from laboratory SOPs, policies and/or client requests have occurred, corrective action is taken immediately. First, the laboratory evaluates the significance of the nonconforming work. Then, a corrective action plan is initiated based on the outcome of the evaluation. If it is determined that the nonconforming work is an isolated incident, the plan could be as simple as adding a qualifier to the final results and/or making a notation in the case narrative. If it is determined that the nonconforming work is a systematic or improper practices issue, the corrective action plan could include a more in depth investigation and a possible suspension of an analytical method. In all cases, the actions taken are documented using the laboratory's corrective action system (refer to Section 12).

Due to the frequently unique nature of environmental samples, sometimes departures from documented policies and procedures are needed. When an analyst encounters such a situation, the problem is presented to the supervisor for resolution. The supervisor may elect to discuss it with the Technical Director or have a representative contact the client to decide on a logical course of action. Once an approach is agreed upon, the analyst documents it using the laboratories corrective action system described in Section 12. This information can then be supplied to the client in the form of a footnote or a case narrative with the report.

Project Management may encounter situations where a client may request that a special procedure be applied to a sample that is not standard lab practice. Based on a technical evaluation, the lab may accept or opt to reject the request based on technical or ethical merit. An example might be the need to report a compound that the lab does not normally report. The lab would not have validated the method for this compound following the procedures in Section 19. The client may request that the compound be reported based only on the calibration. Such a request would need to be approved by the Technical Director and QA Manager, documented and included in the project folder. Deviations **must** also be noted on the final report with a statement that the compound is not reported in compliance with NELAC (or the analytical method) requirements and the reason. Data being reported to a non-NELAC state would need to note the change made to how the method is normally run.

# 11.2 RESPONSIBILITIES AND AUTHORITIES

TestAmerica's Corporate SOP entitled Internal Investigation of Potential Data Discrepancies and Determination for Data Recall (SOP No. CA-L-S-001), outlines the general procedures for the reporting and investigation of data discrepancies and alleged incidents of misconduct or violations of TestAmerica's data integrity policies as well as the policies and procedures related to the determination of the potential need to recall data.

Under certain circumstances, the Laboratory Director, the Operations Manager, a Lab Supervisor, or a member of the QA team may authorize departures from documented procedures or policies. The departures may be a result of procedural changes due to the nature of the sample; a one-time procedure for a client; QC failures with insufficient sample to reanalyze, etc.. In most cases, the client will be informed of the departure prior to the reporting of the data. Any departures must be well documented using the laboratory's corrective action procedures. This information may also be documented in logbooks and/or data review

checklists as appropriate. Any impacted data must be referenced in a case narrative and/or flagged with an appropriate data qualifier.

Any misrepresentation or possible misrepresentation of analytical data discovered by any laboratory staff member must be reported to facility Senior Management within 24-hours. The Senior Management staff is comprised\_of the Laboratory Director, the QA Manager, and the Department Managers. The reporting of issues involving alleged violations of the company's Data Integrity or Manual Integration procedures <u>must</u> be conveyed to an Ethics and Compliance Officer (ECO), Director of Quality & Client Advocacy and the laboratory's Quality Director within 24 hours of discovery.

Whether an inaccurate result was reported due to calculation or quantitation errors, data entry errors, improper practices, or failure to follow SOPs, the data must be evaluated to determine the possible effect.

The Laboratory Director, QA Manager, ECOs, Corporate Quality, the COO, General Managers and the Quality Directors have the authority and responsibility to halt work, withhold final reports, or suspend an analysis for due cause as well as authorize the resumption of work.

#### 11.3 EVALUATION OF SIGNIFICANCE AND ACTIONS TAKEN

For each nonconforming issue reported, an evaluation of its significance and the level of management involvement needed is made. This includes reviewing its impact on the final data, whether or not it is an isolated or systematic issue, and how it relates to any special client requirements.

TestAmerica's Corporate Data Investigation & Recall Procedure (SOP No. CA-L-S-001) distinguishes between situations when it would be appropriate for laboratory management to make the decision on the need for client notification (written or verbal) and data recall (report revision) and when the decision must be made with the assistance of the ECO's and Corporate Management. Laboratory level decisions are documented and approved using the laboratory's standard nonconformance/corrective action reporting in lieu of the data recall determination form contained in TestAmerica's Corporate SOP No. CA-L-S-001.

#### 11.4 PREVENTION OF NONCONFORMING WORK

If it is determined that the nonconforming work could recur, further corrective actions must be made following the laboratory's corrective action system. On a monthly basis, the QA Department evaluates non-conformances to determine if any nonconforming work has been repeated multiple times. If so, the laboratory's corrective action process may be followed.

# 11.5 METHOD SUSPENSION/RESTRICTION (STOP WORK PROCEDURES)

In some cases, it may be necessary to suspend/restrict the use of a method or target compound which constitutes significant risk and/or liability to the laboratory. Suspension/restriction procedures can be initiated by any of the persons noted in Section 11.2, Paragraph 5.

Prior to suspension/restriction, confidentiality will be respected, and the problem with the required corrective and preventive action will be stated in writing and presented to the Laboratory Director.

The Laboratory Director shall arrange for the appropriate personnel to meet with the QA Manager as needed. This meeting shall be held to confirm that there is a problem, that suspension/restriction of the method is required and will be concluded with a discussion of the steps necessary to bring the method/target or test fully back on line. In some cases, that may not be necessary if all appropriate personnel have already agreed there is a problem and there is agreement on the steps needed to bring the method, target or test fully back on line.

The QA Manager will also initiate a corrective action report as described in Section 12 if one has not already been started. A copy of any meeting notes and agreed upon steps should be faxed or e-mailed by the laboratory to the appropriate General Manager and member of Corporate QA. This fax/e-mail acts as notification of the incident.

After suspension/restriction, the lab will hold all reports to clients pending review. No faxing, mailing or distributing through electronic means may occur. The report must not be posted for viewing on the internet. It is the responsibility of the Laboratory Director to hold all reporting and to notify all relevant laboratory personnel regarding the suspension/restriction (e.g., Project Management, Log-in, etc...). Clients will NOT generally be notified at this time. Analysis may proceed in some instances depending on the non-conformance issue.

Within 72 hours, the QA Manager will determine if compliance is now met and reports can be released, OR determine the plan of action to bring work into compliance, and release work. A team, with all principals involved (Laboratory Director, Technical Director, QA Manager, Supervisor) can devise a start-up plan to cover all steps from client notification through compliance and release of reports. Project Management, and the Directors of Client Services and Sales and Marketing must be notified if clients must be notified or if the suspension/restriction affects the laboratory's ability to accept work. The QA Manager must approve start-up or elimination of any restrictions after all corrective action is complete. This approval is given by final signature on the completed corrective action report.

# SECTION 12. CORRECTIVE ACTION (NELAC 5.4.10)

# 12.1 <u>OVERVIEW</u>

A major component of TestAmerica's Quality Assurance (QA) Program is the problem investigation and feedback mechanism designed to keep the laboratory staff informed on quality related issues and to provide insight to problem resolution. When nonconforming work or departures from policies and procedures in the quality system or technical operations are identified, the corrective action procedure provides a systematic approach to assess the issues, restore the laboratory's system integrity, and prevent reoccurrence. Corrective actions are documented using Non-Conformance Reports (NCR) and Corrective Action Reports (CAR) (refer to Figures 12-1 and 12-2).

# 12.2 <u>GENERAL</u>

Problems within the quality system or within analytical operations may be discovered in a variety of ways, such as QC sample failures, internal or external audits, proficiency testing (PT) performance, client complaints, staff observation, etc..

The purpose of a corrective action system is to:

- Identify non-conformance events and assign responsibility(s) for investigating.
- Resolve non-conformance events and assign responsibility for any required corrective action.
- Identify Systematic Problems before they become serious.
- Identify and track client complaints and provide resolution.

**12.2.1** <u>Non-Conformance Report (NCR)</u> - is used to document the following types of corrective actions:

- Deviations from an established procedure or SOP
- QC outside of limits (non-matrix related)
- Isolated reporting / calculation errors
- Client complaints
- Discrepancies in materials / goods received vs. manufacturer packing slips.

**12.2.2** <u>Corrective Action Report (CAR)</u> - is used to document the following types of corrective actions:

- Questionable trends that are found in the monthly review of NCRs
- Issues found while reviewing NCRs that warrant further investigation.
- Internal audit findings
- Failed or unacceptable PT results
- Corrective actions that cross multiple departments in the laboratory
- Systematic reporting / calculation errors
- · Health and Safety violations

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# 12.3 <u>CLOSED LOOP CORRECTIVE ACTION PROCESS</u>

Any employee in the company can initiate a corrective action. There are four main components to a closed-loop corrective action process once an issue has been identified: Cause Analysis, Selection and Implementation of Corrective Actions (both short and long term), Monitoring of the Corrective Actions, and Follow-up.

# 12.3.1 <u>Cause Analysis</u>

- Upon discovery of a non-conformance event, the event must be defined and documented. An NCR or CAR must be initiated, someone is assigned to investigate the issue and the event is investigated for cause. Table 12-1 provides some general guidelines on determining responsibility for assessment.
- The cause analysis step is the key to the process as a long term corrective action cannot be determined until the cause is determined.
- If the cause is not readily obvious, the Supervisor, Laboratory Director, or QA Manager (or QA designee) is consulted.

#### 12.3.2 <u>Selection and Implementation of Corrective Actions</u>

- Where corrective action is needed, the laboratory shall identify potential corrective actions. The action(s) most likely to eliminate the problem and prevent recurrence are selected and implemented. Responsibility for implementation is assigned.
- Corrective actions shall be to a degree appropriate to the magnitude of the problem identified through the cause analysis.
- Whatever corrective action is determined to be appropriate, the laboratory shall document and implement the changes. The NCR or CAR is used for this documentation.

#### 12.3.3 Root Cause Analysis

Root Cause Analysis is a class of problem solving (investigative) methods aimed at identifying the basic or causal factor(s) that underlie variation in performance or the occurrence of a significant failure. The root cause may be buried under seemingly innocuous events, many steps preceding the perceived failure. At first glance, the immediate response is typically directed at a symptom and not the cause. Typically, root cause analysis would be best with three or more incidents to triangulate a weakness.

Systematically analyze and document the Root Causes of the more significant problems that are reported. Identify, track, and implement the corrective actions required to reduce the likelihood of recurrence of significant incidents. Trend the Root Cause data from these incidents to identify Root Causes that, when corrected, can lead to dramatic improvements in performance by eliminating entire classes of problems.

Identify the one event associated with problem and ask why this event occurred. Brainstorm the root causes of failures by asking why events occurred or conditions existed; and then why the cause occurred 5 consecutive times until you get to the root cause. For each of these sub

events or causes, ask why it occurred. Repeat the process for the other events associated with the incident.

Root cause analysis does not mean the investigation is over. Look at technique, or other systems outside the normal indicators. Often creative thinking will find root causes that ordinarily would be missed, and continue to plague the laboratory or operation.

#### 12.3.4 Monitoring of the Corrective Actions

- The Department Manager/Supervisor and QA Manager are responsible to ensure that the corrective action taken was effective.
- Ineffective actions are documented and re-evaluated until acceptable resolution is achieved. Department Managers are accountable to the Laboratory Director to ensure final acceptable resolution is achieved and documented appropriately.
- Each NCR and CAR is entered into a database for tracking purposes and a monthly summary of all corrective actions is printed out for review to aid in ensuring that the corrective actions have taken effect.
- The QA Manager reviews monthly NCRs and CARs for trends. Highlights are included in the QA monthly report (refer to Section 16). If a significant trend develops that adversely affects quality, an audit of the area is performed and corrective action implemented.
- Any out-of-control situations that are not addressed acceptably at the laboratory level may be reported to the Corporate Quality Director by the QA Manager, indicating the nature of the outof-control situation and problems encountered in solving the situation.

#### 12.3.5 Follow-up Audits

- Follow-up audits may be initiated by the QA Manager and shall be performed as soon as possible when the identification of a nonconformance casts doubt on the laboratory's compliance with its own policies and procedures, or on its compliance with state or federal requirements.
- These audits often follow the implementation of the corrective actions to verify effectiveness. An additional audit would only be necessary when a critical issue or risk to business is discovered.

(Also refer to Section 15.1.4, Special Audits.)

# 12.4 TECHNICAL CORRECTIVE ACTIONS

In addition to providing acceptance criteria and specific protocols for technical corrective actions in the method SOPs, the laboratory has general procedures to be followed to determine when departures from the documented policies and procedures and quality control have occurred (refer to Section 11). The documentation of these procedures is through the use of an NCR or CAR.

Table 12-1 includes examples of general technical corrective actions. For specific criteria and corrective actions, refer to the analytical methods or specific method SOPs. The laboratory may also maintains Work Instructions on these items that are available upon request.

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Table 12-1 provides some general guidelines for identifying the individual(s) responsible for assessing each QC type and initiating corrective action. The table also provides general guidance on how a data set should be treated if associated QC measurements are unacceptable. Specific procedures are included in Method SOPs, Work Instructions, QAM Sections 19 and 20. All corrective actions are reviewed monthly, at a minimum, by the QA Manager and highlights are included in the QA monthly report.

To the extent possible, samples shall be reported only if all quality control measures are acceptable. If the deficiency does not impair the usability of the results, data will be reported with an appropriate data qualifier and/or the deficiency will be noted in the case narrative. Where sample results may be impaired, the Project Manager is notified by an NCR and appropriate corrective action (e.g., reanalysis) is taken and documented.

# 12.5 BASIC CORRECTIONS

When mistakes occur in records, each mistake shall be crossed-out, [not obliterated (e.g. no white-out)], and the correct value entered alongside. All such corrections shall be initialed (or signed) and dated by the person making the correction. In the case of records stored electronically, the original "uncorrected" file must be maintained intact and a second "corrected" file is created.

This same process applies to adding additional information to a record. All additions made later than the initial must also be initialed (or signed) and dated.

When corrections are due to reasons other than obvious transcription errors, the reason for the corrections (or additions) shall also be documented.

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# Figure 12-1. Example – NCR/CAR Data Entry Screen

🖉 Corrective Action Report: tailims.Irvine - Dave Dawes	- U ×
Corrective Action Supervisor QA PM Print Exit	
CAR No.       16306       Status       Review       Client Complaint       Edit         Entered By       Nikki Huynh       Date Entered       1 /20/2011       NCR:       Done	
Issue Batch/Work Order Information Supervisor Quality Assurance Project Manangement	
Issue Information	
C Employee None Specified  Date of Occurrence 1/20/2011  Additional Issue Notes	
© Department Metals	
Issue Cause	
QC out of limits	
Description The blank for Co was high but the sample is 10x higher.	
Employee Oversight	
None None, sample data were not affected	<b>_</b>
Description  Description	4
	<b>V</b>

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# Figure 12-2. *Example – Client CAR*

CORRECTIVE ACTION REPORT		
Department: GC-SV Drinking Water Method: EPA 515.4 Lab Sample ID: ISJ1328-01 Identification and Definition of Problem: The positive result originally reported for	Date: 08/27/2010 Matrix: Water Dalapon by EPA 515.4 was incorrect and should have been ND.	
Determination of the Cause of the Problem: The lab did not correctly verify the prese	nce of Dalapon on the confirmation channel.	
	sed result for Dalapon. A full investigation of all other samples that could conducted. As a corrective action, lab procedures have been updated and	
Quality Assurance Approval:	Date: 10/14/2010 03:36 PM	
Car #16,138, Work Order: N/A	Printed on 10/14/2010	

# Table 12-1.

# Example – General Corrective Action Procedures Something like this table is needed to meet 5.4.10.5 of the NELAC standard.

QC Activity (Individual Responsible for Initiation/Assessment)	Acceptance Criteria	Recommended Corrective Action
Initial Instrument Blank	- Instrument response < MDL.	<ul> <li>Prepare another blank.</li> <li>If same response, determine cause of contamination: reagents, environment,</li> </ul>
(Analyst)	ICON	instrument equipment failure, etc
Initial Calibration Standards (Analyst, Supervisor)	<ul> <li>Correlation coefficient &gt; 0.99 or standard concentration value.</li> <li>% Recovery within acceptance range.</li> <li>See details in Method SOP.</li> </ul>	<ul> <li>Reanalyze standards.</li> <li>If still unacceptable, remake standards and recalibrate instrument.</li> </ul>
Independent Calibration Verification (Second Source) <i>(Analyst, Supervisor)</i>	- % Recovery within control limits.	<ul> <li>Remake and reanalyze standard.</li> <li>If still unacceptable, then remake calibration standards or use new primary standards and recalibrate instrument.</li> </ul>
Continuing Calibration Standards (Analyst, Data Reviewer)	% Recovery within control limits.	<ul> <li>Reanalyze standard.</li> <li>If still unacceptable, then recalibrate and rerun affected samples.</li> </ul>
Matrix Spike / Matrix Spike Duplicate (MS/MSD) (Analyst, Data Reviewer)	- % Recovery within limits documented in LIMS	<ul> <li>If the acceptance criteria for duplicates or matrix spikes are not met because of matrix interferences, the acceptance of the analytical batch is determined by the validity of the LCS.</li> <li>If the LCS is within acceptable limits the batch is acceptable.</li> <li>The results of the duplicates, matrix spikes and the LCS are reported with the data set.</li> </ul>
Laboratory Control Sample (LCS) (Analyst, Data Reviewer)	- % Recovery within limits specified in LIMs.	- Batch must be re-prepared and re- analyzed. <b>Note:</b> If there is insufficient sample or the holding time cannot be met, contact client and report with flags.
Surrogates (Analyst, Data Reviewer)	- % Recovery within limits of method or within three standard deviations of the historical mean.	- Individual sample must be repeated. Place comment in LIMS.

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QC Activity (Individual Responsible for Initiation/Assessment)	Acceptance Criteria	Recommended Corrective Action
Method Blank (MB_ (Analyst, Data Reviewer)	< Reporting Limit <sup>1</sup>	<ul> <li>Reanalyze blank.</li> <li>If still positive, determine source of contamination. If necessary, reprocess (i.e. digest or extract) entire sample batch. Report blank results.</li> </ul>
Proficiency Testing (PT) Samples (QA Manager, Department Manager/Supervisor)	- Criteria supplied by PT Supplier.	- Any failures or warnings must be investigated for cause. Failures may result in the need to repeat a PT sample to show the problem is corrected.
Internal / External Audits (QA Manager, Department Manager/Supervisor, Laboratory Director)	- Defined in Quality System documentation such as SOPs, QAM, etc	- Non-conformances must be investigated through CAR system and necessary corrections must be made.
Reporting / Calculation Errors (Depends on issue – possible individuals include: Analysts, Data Reviewers, Project Managers, Department Manager/ Supervisor, QA Manager, Corporate QA, Corporate Management)	- SOP CA-L-S-001, Internal Investigation of Potential Data Discrepancies and Determination for Data Recall.	- Corrective action is determined by type of error. Follow the procedures in SOP CA-L-S-001 or your lab's CA SOP.
Client Complaints (Project Managers, Lab Director/Manager, Sales and Marketing)	-	- Corrective action is determined by the type of complaint. For example, a complaint regarding an incorrect address on a report will result in the report being corrected and then follow- up must be performed on the reasons the address was incorrect (e.g., database needs to be updated).
QA Monthly Report (Refer to Section 16 for an example) (QA Manager, Lab Director/Manager, Department Supervisors/Managers)	- QAM, SOPs.	- Corrective action is determined by the type of issue. For example, CARs for the month are reviewed and possible trends are investigated.

QC Activity (Individual Responsible for Initiation/Assessment)	Acceptance Criteria	Recommended Corrective Action
Health and Safety Violation (Safety Officer, Lab Director/Manager, Department Supervisor/Manager)	- Environmental Health and Safety (EHS) Manual.	- Non-conformance is investigated and corrected through CAR system.

#### Note:

1. Except as noted below for certain compounds or if specified otherwise by the client, the method blank should be below the detection limit. Concentrations up to five times the reporting limit will be allowed for the ubiquitous laboratory and reagent contaminants: methylene chloride, toluene, acetone, 2-butanone and phthalates **provided** they appear in similar levels in the reagent blank and samples. This allowance presumes that the detection limit is significantly below any regulatory limit to which the data are to be compared and that blank subtraction will not occur. For benzene and ethylene dibromide (EDB) and other analytes for which regulatory limits are extremely close to the detection limit, the method blank must be below the method detection limit.

#### SECTION 13. PREVENTIVE ACTION (NELAC 5.4.11)

#### 13.1 <u>OVERVIEW</u>

The laboratory's preventive action programs improve, or eliminate potential causes of nonconforming product and/or nonconformance to the quality system. This preventive action process is a proactive continuous process improvement activity that can be initiated through feedback from clients, employees, business providers, and affiliates. The QA Department has the overall responsibility to ensure that the preventive action process is in place, and that relevant information on actions is submitted for management review.

Dedicating resources to an effective preventive action system emphasizes the laboratory's commitment to its Quality Program. It is beneficial to identify and address negative trends before they develop into complaints, problems and corrective actions. Additionally, customer service and satisfaction can be improved through continuous improvements to laboratory systems.

Opportunities for improvement may be discovered during management reviews, the QA Metrics Report, internal or external audits, proficiency testing performance, client complaints, staff observation, etc..

The monthly QA Metrics Report shows performance indicators in all areas of the quality system. These areas include revised reports, corrective actions, audit findings, internal auditing and data authenticity audits, client complaints, PT samples, holding time violations, SOPs, ethics training, etc. These metrics are used to help evaluate quality system performance on an ongoing basis and provide a tool for identifying areas for improvement.

The laboratory's corrective action process is integral to implementation of preventive actions. A critical piece of the corrective action process is the implementation of actions to prevent further occurrence of a non-compliance event. Historical review of corrective action provides a valuable mechanism for identifying preventive action opportunities.

**13.1.1** The following elements are part of a preventive action system:

- <u>Identification</u> of an opportunity for preventive action.
- <u>Process</u> for the preventive action.
- <u>Define the measurements</u> of the effectiveness of the process once undertaken.
- <u>Execution</u> of the preventive action.
- Evaluation of the plan using the defined measurements.
- <u>Verification</u> of the effectiveness of the preventive action.
- <u>Close-Out</u> by documenting any permanent changes to the Quality System as a result of the Preventive Action. Documentation of Preventive Action is incorporated into the monthly QA reports, corrective action process and management review.

**13.1.2** Any Preventive Actions undertaken or attempted shall be taken into account during the Annual Management Review (Section 16). A highly detailed recap is not required; a simple

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recount of success and failure within the preventive action program will provide management a measure for evaluation.

# 13.2 MANAGEMENT OF CHANGE

The Management of Change process is designed to manage significant events and changes that occur within the laboratory. Through these procedures, the potential risks inherent with a new event or change are identified and evaluated. The risks are minimized or eliminated through pre-planning and the development of preventive measures. The types of changes covered under this system include: Facility Changes, Major Accreditation Changes, Addition or Deletion to Division's Capabilities or Instrumentation, Key Personnel Changes, Laboratory Information Management System (LIMS) changes.



# SECTION 14. CONTROL OF RECORDS (NELAC 5.4.12)

The laboratory maintains a record system appropriate to its needs and that complies with applicable standards or regulations as required. The system produces unequivocal, accurate records that document all laboratory activities. The laboratory retains all original observations, calculations and derived data, calibration records and a copy of the analytical report for a minimum of five years after it has been issued.

# 14.1 <u>OVERVIEW</u>

The laboratory has established procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records. A record index is listed in Table 14-1. Quality records are maintained by the QA department in a database, which is backed up as part of the regular laboratory backup. Records are of two types; either electronic or hard copy paper formats depending on whether the record is computer or hand generated (some records may be in both formats). Technical records are maintained by the individual department managers.

#### Table 14-1. Record Index<sup>1</sup>

	Record Types <sup>1</sup> :	Retention Time:
Technical Records	<ul> <li>Raw Data</li> <li>Logbooks<sup>2</sup></li> <li>Standards</li> <li>Certificates</li> <li>Analytical Records</li> <li>Lab Reports</li> </ul>	5 Years from analytical report issue*
Official Documents	<ul> <li>Quality Assurance Manual (QAM)</li> <li>Work Instructions</li> <li>Policies</li> <li>SOPs</li> <li>Policy Memorandums</li> <li>Manuals</li> </ul>	5 Years from document retirement date*
QA Records	<ul> <li>Internal &amp; External Audits/Responses</li> <li>Certifications</li> <li>Corrective/Preventive Actions</li> <li>Management Reviews</li> <li>Method &amp; Software Validation / Verification Data</li> <li>Data Investigation</li> </ul>	5 Years from archival* <u><b>Data Investigation:</b></u> 5 years or the life of the affected raw data storage whichever is greater (beyond 5 years if ongoing project or pending investigation)
Project Records	<ul> <li>Sample Receipt &amp; COC</li> <li>Documentation</li> <li>Contracts and Amendments</li> <li>Correspondence</li> <li>QAPP</li> <li>SAP</li> <li>Telephone Logbooks</li> <li>Lab Reports</li> </ul>	5 Years from analytical report issue*
Administrative Records	Finance and Accounting	10 years

Record Types <sup>1</sup> :	Retention Time:
EH&S Manual, Permits, Disposal Records	7 years
Employee Handbook	Indefinitely
Personnel files, Employee Signature & Initials, Administrative Training Records (e.g., Ethics)	7 Years (HR Personnel Files must be maintained indefinitely)
Administrative Policies Technical Training Records	7 years

<sup>1</sup> Record Types encompass hardcopy and electronic records.

<sup>2</sup> Examples of Logbook types: Maintenance, Instrument Run, Preparation (standard and samples), Standard and Reagent Receipt, Archiving, Balance Calibration, Temperature (hardcopy or electronic records).

\* Exceptions listed in Table 14-2.

**14.1.1** All records are stored and retained in such a way that they are secure and readily retrievable at the laboratory facility or from the Corodata off-site data storage service that provides a suitable environment to prevent damage or deterioration and to prevent loss. All records shall be protected against fire, theft, loss, environmental deterioration, and vermin. In the case of electronic records, electronic or magnetic sources, storage media are protected from deterioration caused by magnetic fields and/or electronic deterioration.

Access to the data is limited to laboratory and company employees. Records archived off-site are stored in a secure location where a record is maintained of any entry into the storage facility. Whether on-site or off-site storage is used, logs are maintained in each storage box to note removal and return of records. Retention of records are maintained on-site at the laboratory for approximately six months after their generation and moved offsite for the remainder of the required storage time. Records are maintained for a minimum of five years unless otherwise specified by a client or regulatory requirement.

Tracking of stored records both on-site and off-site is accomplished using the laboratory's Archived Records database. Details on the use of this database are addressed in the laboratory's SOP on document control, IR-QA-DOC.

For raw data and project records, record retention shall be calculated from the date the project report is issued. For other records, such as Controlled Documents, QA, or Administrative Records, the retention time is calculated from the date the record is formally retired. Records related to the programs listed in Table 14-2 have lengthier retention requirements and are subject to the requirements in Section 14.1.3.

# 14.1.2 <u>Programs with Longer Retention Requirements</u>

Some regulatory programs have longer record retention requirements than the standard record retention time. These are detailed in Table 14-2 with their retention requirements. In these cases, the longer retention requirement is enacted. If special instructions exist such that client data cannot be destroyed prior to notification of the client, the container or box containing that data is marked as to who to contact for authorization prior to destroying the data.

Program	<sup>1</sup> Retention Requirement
Drinking Water – All States	10 years (project records)
Drinking Water Lead and Copper Rule	12 years (project records)
Commonwealth of MA – All environmental data 310 CMR 42.14	10 years
FIFRA – 40 CFR Part 160	Retain for life of research or marketing permit for pesticides regulated by EPA
Housing and Urban Development (HUD) Environmental Lead Testing	10 years
Alaska	10 years
Louisiana – All	10 years
Michigan Department of Environmental Quality – all environmental data	10 years
Navy Facilities Engineering Service Center (NFESC)	10 years
NY Potable Water NYCRR Part 55-2	10 years
Ohio VAP	10 years and State contacted prior to disposal
TSCA - 40 CFR Part 792	10 years after publication of final test rule or negotiated test agreement

# Table 14-2. Example: Special Record Retention Requirements

<sup>1</sup>Note: Extended retention requirements must be noted with the archive documents or addressed in facility-specific records retention procedures.

**14.1.3** The laboratory has procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records. All analytical data is maintained as hard copy or in a secure readable electronic format. For analytical reports that are maintained as copies in PDF format, refer to Section 19.14.1 for more information.

**14.1.4** The record keeping system allows for historical reconstruction of all laboratory activities that produced the analytical data, as well as rapid recovery of historical data (Records stored off site should be accessible within 2 days of a request for such records). The history of the sample from when the laboratory took possession of the samples must be readily understood through the documentation. This shall include inter-laboratory transfers of samples and/or extracts.

The records include the identity of personnel involved in sampling, sample receipt, preparation, or testing. All analytical work contains the initials (at least) of the personnel involved. The laboratory's copy of the COC is stored with the invoice and the work order sheet generated by the LIMS. The chain of custody would indicate the name of the sampler. If any sampling notes are provided with a work order, they are kept with this package.

- All information relating to the laboratory facilities equipment, analytical test methods, and related laboratory activities, such as sample receipt, sample preparation, or data verification are documented.
- The record keeping system facilitates the retrieval of all working files and archived records for inspection and verification purposes (e.g., set format for naming electronic files, set format for what is included with a given analytical data set) is detailed in each method SOP, as necessary. Instrument data is stored sequentially by instrument. A given day's analyses are maintained in the order of the analysis. Run logs are maintained for each instrument or method; a copy of each day's run long or instrument sequence is stored with the data to aid in re-constructing an analytical sequence. Where an analysis is performed without an instrument, bound logbooks or bench sheets are used to record and file data. Standard and reagent information is recorded in logbooks or entered into the LIMS for each method as required.
- Changes to hardcopy records shall follow the procedures outlined in Section 12 and 19. Changes to electronic records in LIMS or instrument data are recorded in audit trails.
- The reason for a signature or initials on a document is clearly indicated in the records such as "sampled by," "prepared by," "reviewed by", or "analyzed by".
- All generated data except those that are generated by automated data collection systems, are recorded directly, promptly and legibly in permanent dark ink.
- Hard copy data may be scanned into PDF format for record storage as long as the scanning process can be verified in order to ensure that no data is lost and the data files and storage media must be tested to verify the laboratory's ability to retrieve the information prior to the destruction of the hard copy that was scanned. The procedure for this verification can be found in laboratory SOP No. IR-PM-DATA, *Project Management Data Reporting, Validation and Distribution in Element LIMS*.
- Also refer to Section 19.14.1 'Computer and Electronic Data Related Requirements'.

#### 14.2 TECHNICAL AND ANALYTICAL RECORDS

**14.2.1** The laboratory retains records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each analytical report issued, for a minimum of five years unless otherwise specified by a client or regulatory requirement. The records for each analysis shall contain sufficient information to enable the analysis to be repeated under conditions as close as possible to the original. The records shall include the identity of laboratory personnel responsible for the sampling, performance of each analysis and reviewing results.

**14.2.2** Observations, data and calculations are recorded real-time and are identifiable to the specific task.

**14.2.3** Changes to hardcopy records shall follow the procedures outlined in Section 12 and 19. Changes to electronic records in LIMS or instrument data are recorded in audit trails.

The essential information to be associated with analysis, such as strip charts, tabular printouts, computer data files, analytical notebooks, and run logs, include:

- laboratory sample ID code;
- Date of analysis; Time of Analysis is also required if the holding time is seventy-two (72) hours or less, or when time critical steps are included in the analysis (e.g., drying times, incubations, etc.); instrumental analyses have the date and time of analysis recorded as part of their general operations. Where a time critical step exists in an analysis, location for such a time is included as part of the documentation in a specific logbook or on a benchsheet.
- Instrumentation identification and instrument operating conditions/parameters. Operating conditions/parameters are typically recorded in instrument maintenance logs where available.
- analysis type;
- all manual calculations and manual integrations;
- analyst's or operator's initials/signature;
- sample preparation including cleanup, separation protocols, incubation periods or subculture, ID codes, volumes, weights, instrument printouts, meter readings, calculations, reagents;
- test results;
- standard and reagent origin, receipt, preparation, and use;
- calibration criteria, frequency and acceptance criteria;
- data and statistical calculations, review, confirmation, interpretation, assessment and reporting conventions;
- quality control protocols and assessment;
- electronic data security, software documentation and verification, software and hardware audits, backups, and records of any changes to automated data entries; and
- Method performance criteria including expected quality control requirements. These are indicated both in the LIMS and on specific analytical report formats.

#### 14.3 LABORATORY SUPPORT ACTIVITIES

In addition to documenting all the above-mentioned activities, the following are retained QA records and project records (previous discussions in this section relate where and how these data are stored):

- all original raw data, whether hard copy or electronic, for calibrations, samples and quality control measures, including analysts' work sheets and data output records (chromatograms, strip charts, and other instrument response readout records);
- a written description or reference to the specific test method used which includes a
  description of the specific computational steps used to translate parametric observations into
  a reportable analytical value;
- copies of final reports;

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- archived SOPs;
- correspondence relating to laboratory activities for a specific project;
- all corrective action reports, audits and audit responses;
- proficiency test results and raw data; and
- results of data review, verification, and crosschecking procedures

#### 14.3.1 Sample Handling Records

Records of all procedures to which a sample is subjected while in the possession of the laboratory are maintained. These include but are not limited to records pertaining to:

- sample preservation including appropriateness of sample container and compliance with holding time requirement;
- sample identification, receipt, acceptance or rejection and login;
- sample storage and tracking including shipping receipts, sample transmittal / COC forms; and
- procedures for the receipt and retention of samples, including all provisions necessary to protect the integrity of samples.

# 14.4 ADMINISTRATIVE RECORDS

The laboratory also maintains the administrative records in either electronic or hard copy form. Refer to Table 14-1.

# 14.5 RECORDS MANAGEMENT, STORAGE AND DISPOSAL

All records (including those pertaining to test equipment), certificates and reports are safely stored, held secure and in confidence to the client. Certification related records are available upon request.

All information necessary for the historical reconstruction of data is maintained by the laboratory. Records that are stored only on electronic media must be supported by the hardware and software necessary for their retrieval.

Records that are stored or generated by computers or personal computers have hard copy, write-protected backup copies, or an electronic audit trail controlling access.

The laboratory has a record management system (a.k.a., document control) for control of laboratory notebooks, instrument logbooks, standards logbooks, and records for data reduction, validation, storage and reporting. Laboratory notebooks are issued on a per analysis basis, and are numbered sequentially. All data are recorded sequentially within a series of sequential notebooks. Bench sheets are filed sequentially. Standards are maintained in the LIMS – no logbooks are used to record that data. Records are considered archived when noted as such in the records management system (a.k.a., document control.)

# 14.5.1 Transfer of Ownership

In the event that the laboratory transfers ownership or goes out of business, the laboratory shall ensure that the records are maintained or transferred according to client's instructions. Upon ownership transfer, record retention requirements shall be addressed in the ownership transfer agreement and the responsibility for maintaining archives is clearly established. In addition, in cases of bankruptcy, appropriate regulatory and state legal requirements concerning laboratory records must be followed. In the event of the closure of the laboratory, all records will revert to the control of the corporate headquarters. Should the entire company cease to exist, as much notice as possible will be given to clients and the accrediting bodies who have worked with the laboratory during the previous 5 years of such action.

# 14.5.2 <u>Records Disposal</u>

Records are removed from the archive and destroyed after 5 years unless otherwise specified by a client or regulatory requirement. On a project specific or program basis, clients may need to be notified prior to record destruction. Records are destroyed in a manner that ensures their confidentiality such as shredding, mutilation or incineration. (Refer to Tables 14-1 and 14-2).

Electronic copies of records must be destroyed by erasure or physically damaging off-line storage media so no records can be read.

If a third party records management company is hired to dispose of records, a "Certificate of Destruction" is required.

# SECTION 15. AUDITS (NELAC 5.4.13)

# 15.1 INTERNAL AUDITS

Internal audits are performed to verify that laboratory operations comply with the requirements of the lab's quality system and with the external quality programs under which the laboratory operates. Audits are planned and organized by the QA staff. Personnel conducting the audits should be independent of the area being evaluated. Auditors will have sufficient authority, access to work areas, and organizational freedom necessary to observe all activities affecting quality and to report the assessments to laboratory management and when requested to corporate management.

Audits are conducted and documented as described in the TestAmerica Corporate SOP on performing Internal Audits, SOP No. CA-Q-S-004. The types and frequency of routine internal audits are shown in Table 15-1. Special or ad hoc assessments may be conducted as needed under the direction of the QA staff.

Description	Performed by	Frequency
Quality Systems	QA Department or Designee	All areas of the laboratory annually
<ul> <li>QA Technical Audits</li> <li>Evaluate raw data versus final reports</li> <li>Analyst integrity</li> <li>Data authenticity</li> </ul>	QA Department or Designee	All methods within a 2-year period, with at least 15% of methods every quarter
SOP Method Compliance	Technical Director	<ul> <li>All SOPs within a 2-year period</li> <li>All new analysts or new analyst/methods within 3 months of IDOC</li> </ul>
Special	QA Department or Designee	Surveillance or spot checks performed as needed
Performance Testing	Analysts with QA oversight	Two successful per year for each NELAC field of testing or as dictated by regulatory requirements

#### Table 15-1. Types of Internal Audits and Frequency

# 15.1.1 Annual Quality Systems Audit

An annual quality systems audit is required to ensure compliance to analytical methods and SOPs, the laboratory's Data Integrity and Ethics Policies, NELAC quality systems, client and state requirements, and the effectiveness of the internal controls of the analytical process, including but not limited to data review, quality controls, preventive action and corrective action. The completeness of earlier corrective actions is assessed. The audit is divided into modules for each operating or support area of the lab, and each module is comprehensive for a given area. The area audits may be done on a rotating schedule throughout the year to ensure

adequate coverage of all areas. This schedule may change as situations in the laboratory warrant.

# 15.1.2 QA Technical Audits

QA technical audits are based on client projects, associated sample delivery groups, and the methods performed. Reported results are compared to raw data to verify the authenticity of results. The validity of calibrations and QC results are compared to data qualifiers, footnotes, and case narratives. Documentation is assessed by examining run logs and records of manual integrations. Manual calculations are checked. Where possible, MintMiner is used to identify unusual manipulations of the data deserving closer scrutiny. QA technical audits will include all methods within a two-year period.

# 15.1.3 SOP Method Compliance

Compliance of all SOPs with the source methods and compliance of the operational groups with the SOPs will be assessed by the Technical Director at least every two years. The work of each newly hired analyst is assessed within 3 months of working independently, (e.g., completion of method IDOC). In addition, as analysts add methods to their capabilities, (new IDOC) reviews of the analyst work products will be performed within 3 months of completing the documented training.

# 15.1.4 Special Audits

Special audits are conducted on an as needed basis, generally as a follow up to specific issues such as client complaints, corrective actions, PT results, data audits, system audits, validation comments, regulatory audits or suspected ethical improprieties. Special audits are focused on a specific issue, and report format, distribution, and timeframes are designed to address the nature of the issue.

# 15.1.5 <u>Performance Testing</u>

The laboratory participates in performance audits conducted through the analysis of PT samples provided by a third party. These are performed either annually or semi-annually based on the laboratory's accreditation requirements (e.g. NELAP and Nevada DEP are semi-annual, Arizona DHS and California ELAP are annual). The laboratory generally participates in the following types of PT studies: Drinking Water (WS), Non-potable Water (WP), Underground Storage Tank (UST), and Soil (HW).

It is TestAmerica's policy that PT samples be treated as typical samples in the production process. Furthermore, where PT samples present special or unique problems, in the regular production process they may need to be treated differently, as would any special or unique request submitted by any client. The QA Manager must be consulted and in agreement with any decisions made to treat a PT sample differently due to some special circumstance.

Written responses to unacceptable PT results are required. In some cases it may be necessary for blind QC samples to be submitted to the laboratory to show a return to control.

# 15.2 EXTERNAL AUDITS

External audits are performed when certifying agencies or clients conduct on-site inspections or submit performance testing samples for analysis. It is TestAmerica's policy to cooperate fully with regulatory authorities and clients. The laboratory makes every effort to provide the auditors with access to personnel, documentation, and assistance. Laboratory supervisors are responsible for providing corrective actions to the QA Manager who coordinates the response for any deficiencies discovered during an external audit. Audit responses are due in the time allotted by the client or agency performing the audit. When requested, a copy of the audit report and the labs corrective action plan will be forwarded to Corporate Quality.

The laboratory cooperates with clients and their representatives to monitor the laboratory's performance in relation to work performed for the client. The client may only view data and systems related directly to the client's work. All efforts are made to keep other client information confidential.

# 15.2.1 <u>Confidential Business Information (CBI) Considerations</u>

During on-site audits, auditors may come into possession of information claimed as business confidential. A business confidentiality claim is defined as "a claim or allegation that business information is entitled to confidential treatment for reasons of business confidentiality or a request for a determination that such information is entitled to such treatment." When information is claimed as business confidential, the laboratory must place on (or attach to) the information at the time it is submitted to the auditor, a cover sheet, stamped or typed legend or other suitable form of notice, employing language such as "trade secret", "proprietary" or "company confidential". Confidential portions of documents otherwise non-confidential must be clearly identified. CBI may be purged of references to client identity by the responsible laboratory official at the time of removal from the laboratory. However, sample identifiers may not be obscured from the information. Additional information regarding CBI can be found in within the 2003 NELAC standards.

# 15.3 AUDIT FINDINGS

Audit findings are documented using the external audit finding database. The laboratory's corrective action responses for both types of audits may include action plans that could not be completed within a predefined timeframe. In these instances, a completion date must set and agreed to by operations management and the QA Manager.

Developing and implementing corrective actions to findings is the responsibility of the Department Manager where the finding originated. Findings that are not corrected by specified due dates are reported monthly to management in the QA monthly report. When requested, a copy of the audit report and the labs corrective action plan will be forwarded to Corporate Quality.

If any audit finding casts doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test results, the laboratory shall take timely corrective action, and shall notify clients in writing if the investigations show that the laboratory results have been affected. Once corrective action is implemented, a follow-up audit is scheduled to ensure that the problem has been corrected.

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Clients must be notified promptly in writing, of any event such as the identification of defective measuring or test equipment that casts doubt on the validity of results given in any test report or amendment to a test report. The investigation must begin within 24-hours of discovery of the problem and all efforts are made to notify the client within two weeks after the completion of the investigation.



# SECTION 16. MANAGEMENT REVIEWS (NELAC 5.4.14)

# 16.1 QUALITY ASSURANCE REPORT

A comprehensive QA Report shall be prepared each month by the laboratory's QA Department and forwarded to the Laboratory Director, Technical Directors, Operation Manager, their Quality Director as well as the General Manager. All aspects of the QA system are reviewed to evaluate the suitability of policies and procedures. During the course of the year, the Laboratory Director, General Manager or Corporate QA may request that additional information be added to the report.

On a monthly basis, Corporate QA compiles information from all the monthly laboratory reports. The Corporate Quality Directors prepare a report that includes a compilation of all metrics and notable information and concerns regarding the QA programs within the laboratories. The report also includes a listing of new regulations that may potentially impact the laboratories. This report is presented to the Senior Management Team and General Managers.

#### 16.2 ANNUAL MANAGEMENT REVIEW

The senior lab management team (Laboratory Director, Operations Manager, Customer Services Manager, Technical Directors, QA Manager) conducts a review annually of its quality systems and LIMS to ensure its continuing suitability and effectiveness in meeting client and regulatory requirements and to introduce any necessary changes or improvements. It will also provide a platform for defining quality goals & objectives. Corporate Operations and Corporate QA personnel is be included in this meeting at the discretion of the Laboratory Director. The LIMS review consists of examining any audits, complaints or concerns that have been raised through the year that are related to the LIMS. The laboratory will summarize any critical findings that can not be solved by the lab and report them to Corporate IT.

This management systems review (Corporate SOP No. CA-Q-S-008 & Work Instruction No. CA-Q-WI-020) uses information generated during the preceding year to assess the "big picture" by ensuring that routine actions taken and reviewed on a monthly basis are not components of larger systematic concerns. The monthly review should keep the quality systems current and effective, therefore, the annual review is a formal senior management process to review specific existing documentation. Significant issues from the following documentation are compiled or summarized by the QA Manager prior to the review meeting:

- Matters arising from the previous annual review.
- Prior Monthly QA Reports issues.
- Laboratory QA Metrics.
- Review of report reissue requests.
- Review of client feedback and complaints.
- Issues arising from any prior management or staff meetings.
- Minutes from prior senior lab management meetings. Issues that may be raised from these meetings include:
  - Adequacy of staff, equipment and facility resources.

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- Adequacy of policies and procedures.
- Future plans for resources and testing capability and capacity.
- The annual internal double blind PT program sample performance (if performed),
- Compliance to the Ethics Policy and Data Integrity Plan. Including any evidence/incidents of inappropriate actions or vulnerabilities related to data Integrity.

A report is generated by the QA Manager and management. The report is distributed to the appropriate General Manager and the Quality Director. The report includes, but is not limited to:

- The date of the review and the names and titles of participants.
- A reference to the existing data quality related documents and topics that were reviewed.
- Quality system or operational changes or improvements that will be made as a result of the review [e.g., an implementation schedule including assigned responsibilities for the changes (Action Table)].

Changes to the quality systems requiring update to the laboratory QA Manual shall be included in the next revision of the QA Manual.

#### 16.3 POTENTIAL INTEGRITY RELATED MANAGERIAL REVIEWS

Potential integrity issues (data or business related) must be handled and reviewed in a confidential manner until such time as a follow-up evaluation, full investigation, or other appropriate actions have been completed and issues clarified. TestAmerica's Corporate Data Investigation/Recall SOP shall be followed (SOP No. CA-L-S-001). All investigations that result in finding of inappropriate activity are documented and include any disciplinary actions involved, corrective actions taken, and all appropriate notifications of clients.

TestAmerica's COO, VP of Client & Technical Services, General Managers and Quality Directors receive a monthly report from the Director of Quality & Client Advocacy summarizing any current data integrity or data recall investigations. The General Manager's are also made aware of progress on these issues for their specific labs.

# SECTION 17. PERSONNEL (NELAC 5.5.2)

# 17.1 <u>OVERVIEW</u>

The laboratory's management believes that its highly qualified and professional staff is the single most important aspect in assuring a high level of data quality and service. The staff consists of professionals and support personnel as outlined in the organization chart in Figure 4-1.

All personnel must demonstrate competence in the areas where they have responsibility. Any staff that is undergoing training shall have appropriate supervision until they have demonstrated their ability to perform their job function on their own. Staff shall be qualified for their tasks based on appropriate education, training, experience and/or demonstrated skills as required.

The laboratory employs sufficient personnel with the necessary education, training, technical knowledge and experience for their assigned responsibilities.

All personnel are responsible for complying with all QA/QC requirements that pertain to the laboratory and their area of responsibility. Each staff member must have a combination of experience and education to adequately demonstrate a specific knowledge of their particular area of responsibility. Technical staff must also have a general knowledge of lab operations, test methods, QA/QC procedures and records management.

Laboratory management is responsible for formulating goals for lab staff with respect to education, training and skills and ensuring that the laboratory has a policy and procedures for identifying training needs and providing training of personnel. The training shall be relevant to the present and anticipated responsibilities of the lab staff.

The laboratory only uses personnel that are employed by or under contract to, the laboratory. Contracted personnel, when used, must meet competency standards of the laboratory and work in accordance to the laboratory's quality system.

#### 17.2 <u>EDUCATION AND EXPERIENCE REQUIREMENTS FOR TECHNICAL</u> <u>PERSONNEL</u>

The laboratory makes every effort to hire analytical staffs that possess a college degree (AA, BA, BS) in an applied science with some chemistry in the curriculum. Exceptions can be made based upon the individual's experience and ability to learn. Selection of qualified candidates for laboratory employment begins with documentation of minimum education, training, and experience prerequisites needed to perform the prescribed task. Minimum education and training requirements for TestAmerica employees are outlined in job descriptions and are generally summarized for analytical staff in the table below.

The laboratory maintains job descriptions for all personnel who manage, perform or verify work affecting the quality of the environmental testing the laboratory performs. Job Descriptions are located on the TestAmerica intranet site's Human Resources web-page (Also see Section 4 for position descriptions/responsibilities).

Experience and specialized training are occasionally accepted in lieu of a college degree (basic lab skills such as using a balance, colony counting, aseptic or quantitation techniques, etc., are also considered).

As a general rule for analytical staff:

Specialty	Education	Experience
Extractions, Digestions, some electrode methods (pH, DO, Redox, etc.), or Titrimetric and Gravimetric Analyses	H.S. Diploma	On the job training (OJT)
GFAA, CVAA, FLAA, Single component or short list Chromatography (e.g., Fuels, BTEX-GC, IC	A college degree in an applied science or 2 years of college and at least 1 year of college chemistry	Or 2 years prior analytical experience is required
ICP, ICPMS, Long List or complex chromatography (e.g., Pesticides, PCB, Herbicides, HPLC, etc.), GCMS	A college degree in an applied science or 2 years of college chemistry	or 5 years of prior analytical experience
Spectra Interpretation	A college degree in an applied science or 2 years of college chemistry	And 2 years relevant experience Or 5 years of prior analytical experience
Technical Directors/Department Managers – General	Bachelors Degree in an applied science or engineering with 24 semester hours in chemistry An advanced (MS, PhD.) degree may substitute for one year of experience	And 2 years experience in environmental analysis of representative analytes for which they will oversee
Technical Director – <u>Wet Chem</u> only (no advanced instrumentation)	Associates degree in an applied science or engineering or 2 years of college with 16 semester hours in chemistry	And 2 years relevant experience
Technical Director - Microbiology	Bachelors degree in applied science with at least 16 semester hours in general microbiology and biology An advanced (MS,	And 2 years of relevant experience
	PhD.) degree may substitute for one year of experience	

When an analyst does not meet these requirements, they can perform a task under the direct supervision of a qualified analyst, peer reviewer or Department Manager, and are considered an analyst in training. The person supervising an analyst in training is accountable for the quality of the analytical data and must review and approve data and associated corrective actions.

# 17.3 TRAINING

The laboratory is committed to furthering the professional and technical development of employees at all levels.

Orientation to the laboratory's policies and procedures, in-house method training, and employee attendance at outside training courses and conferences all contribute toward employee proficiency. Below are examples of various areas of required employee training:

Required Training	Time Frame	Employee Type
Environmental Health & Safety	Prior to lab work	All
Ethics – New Hires	1 week of hire	All
Ethics – Comprehensive	90 days of hire	All
Data Integrity	30 days of hire	Technical and PMs
Quality Assurance	90 days of hire	All
Ethics – Comprehensive	Annually	All
Refresher		
Initial Demonstration of Capability (DOC)	Prior to unsupervised method performance	Technical

The laboratory maintains records of relevant authorization/competence, education, professional qualifications, training, skills and experience of technical personnel (including contracted personnel) as well as the date that approval/authorization was given. These records are kept on file at the laboratory. Also refer to "Demonstration of Capability" in Section 19.

The training of technical staff is kept up to date by:

- Each employee must have documentation in their training file that they have read, understood and agreed to follow the most recent version of the laboratory QA Manual and SOPs in their area of responsibility. This documentation is updated as SOPs are updated.
- Documentation from any training courses or workshops on specific equipment, analytical techniques or other relevant topics are maintained in their training file.
- Documentation of proficiency (refer to Section 19).
- An Ethics Agreement signed by each staff member (renewed each year) and evidence of annual ethics training.
- A Confidentiality Agreement signed by each staff member signed at the time of employment.
- Human Resources maintains documentation and attestation forms on employment status & records; benefit programs; timekeeping/payroll; and employee conduct (e.g., ethics). This information is maintained in the employee's secured personnel file.

Evidence of successful training could include such items as:

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- Adequate documentation of training within operational areas, including one-on-one technical training for individual technologies, and particularly for people cross-trained.
- Analysts knowledge to refer to QA Manual and QA SOPs for quality issues.
- Analysts following SOPs, i.e., practice matches SOPs.
- Analysts regularly communicate to supervisors and QA if SOPs need revision, rather than waiting for auditors to find problems.

Further details of the laboratory's training program are described in laboratory SOP No. IR-QA-TRAIN, *Training and Documentation*.

# 17.4 DATA INTEGRITY AND ETHICS TRAINING PROGRAM

Establishing and maintaining a high ethical standard is an important element of a Quality System. Ethics and data integrity training is integral to the success of TestAmerica and is provided for each employee at TestAmerica. It is a formal part of the initial employee orientation within 1 week of hire followed by technical data integrity training within 30 days, comprehensive training within 90 days, and an annual refresher for all employees. Senior management at each facility performs the ethics training for their staff.

In order to ensure that all personnel understand the importance TestAmerica places on maintaining high ethical standards at all times; TestAmerica has established a Corporate Ethics Policy (Policy No. CA-L-P-001) and an Ethics Statement. All initial and annual training is documented by signature on the signed Ethics Statement demonstrating that the employee has participated in the training and understands their obligations related to ethical behavior and data integrity.

Violations of this Ethics Policy will not be tolerated. Employees who violate this policy will be subject to disciplinary actions up to and including termination. Criminal violations may also be referred to the Government for prosecution. In addition, such actions could jeopardize TestAmerica's ability to do work on Government contracts, and for that reason, TestAmerica has a Zero Tolerance approach to such violations.

Employees are trained as to the legal and environmental repercussions that result from data misrepresentation. Key topics covered in the presentation include:

- Organizational mission and its relationship to the critical need for honesty and full disclosure in all analytical reporting.
- Ethics Policy
- How and when to report ethical/data integrity issues. Confidential reporting.
- Record keeping.
- Discussion regarding data integrity procedures.
- Specific examples of breaches of ethical behavior (e.g. peak shaving, altering data or computer clocks, improper macros, etc., accepting/offering kickbacks, illegal accounting practices, unfair competition/collusion)
- Internal monitoring. Investigations and data recalls.

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- Consequences for infractions including potential for immediate termination, debarment, or criminal prosecution.
- Importance of proper written narration / data qualification by the analyst and project manager with respect to those cases where the data may still be usable but are in one sense or another partially deficient.

Additionally, a data integrity hotline (1-800-736-9407) is maintained by TestAmerica and administered by the Corporate Quality Department.

# SECTION 18. ACCOMMODATIONS AND ENVIRONMENTAL CONDITIONS (NELAC 5.5.3)

# 18.1 <u>OVERVIEW</u>

The Irvine laboratory is a 45,000 ft<sup>2</sup> secure laboratory facility with controlled access and designed to accommodate an efficient workflow and to provide a safe and comfortable work environment for employees. All visitors sign in and are escorted by laboratory personnel. Access is controlled by various measures. The Ontario laboratory is a 1,500 ft<sup>2</sup> laboratory with similar security and design accommodations.

The laboratories are equipped with structural safety features. Each employee is familiar with the location, use, and capabilities of general and specialized safety features associated with their workplace. The laboratory provides and requires the use of protective equipment including safety glasses, protective clothing, gloves, etc., OSHA and other regulatory agency guidelines regarding required amounts of bench and fume hood space, lighting, ventilation (temperature and humidity controlled), access, and safety equipment are met or exceeded.

Traffic flow through sample preparation and analysis areas is minimized to reduce the likelihood of contamination. Adequate floor space and bench top area is provided to allow unencumbered sample preparation and analysis space. Sufficient space is also provided for storage of reagents and media, glassware, and portable equipment. Ample space is also provided for refrigerated sample storage before analysis and archival storage of samples after analysis. Laboratory HVAC and deionized water systems are designed to minimize potential trace contaminants.

The Irvine laboratory is separated into specific areas for sample receiving, sample preparation, volatile organic sample analysis, non-volatile organic sample analysis, inorganic sample analysis, microbiological sample analysis, and administrative functions.

The Ontario laboratory is separated into specific areas for sample receiving, microbiological sample analysis, and administrative functions.

#### 18.2 <u>ENVIRONMENT</u>

Laboratory accommodation, test areas, energy sources, lighting are adequate to facilitate proper performance of tests. The facility is equipped with heating, ventilation, and air conditioning (HVAC) systems appropriate to the needs of environmental testing performed at this laboratory.

The environment in which these activities are undertaken does not invalidate the results or adversely affect the required accuracy of any measurements.

The laboratory provides for the effective monitoring, control and recording of environmental conditions that may affect the results of environmental tests as required by the relevant specifications, methods, and procedures. Such environmental conditions include humidity, voltage, temperature, and vibration levels in the laboratory.

When any of the method or regulatory required environmental conditions change to a point where they may adversely affect test results, analytical testing will be discontinued until the environmental conditions are returned to the required levels.

Environmental conditions of the facility housing the computer network and LIMS are regulated to protect against raw data loss.

# 18.3 WORK AREAS

There is effective separation between neighboring areas when the activities therein are incompatible with each other. Examples include:

- Microbiological culture handling and sample incubation areas.
- Volatile organic chemical handling areas, including sample preparation and waste disposal, and volatile organic chemical analysis areas.

Access to and use of all areas affecting the quality of analytical testing is defined and controlled by secure access to the laboratory building as described below in the Building Security section.

Adequate measures are taken to ensure good housekeeping in the laboratory and to ensure that any contamination does not adversely affect data quality. These measures include regular cleaning to control dirt and dust within the laboratory. Work areas are available to ensure an unencumbered work area. Work areas include:

- Access and entryways to the laboratory.
- Sample receipt areas.
- Sample storage areas.
- Chemical and waste storage areas.
- Data handling and storage areas.
- Sample processing areas.
- Sample analysis areas.

Refer to Standard Methods, 20<sup>th</sup> Ed., 9020B, Section 2 for specific requirements for microbiological laboratory facility requirements.

# 18.4 FLOOR PLAN

A floor plan for both facilities can be found in Appendix 1.

# 18.5 BUILDING SECURITY

Building keys and alarm codes are distributed to employees as necessary.

Visitors to the laboratory sign in and out in a visitor's logbook. A visitor is defined as any person who visits a specific laboratory location who is not an employee of that specific laboratory location. In addition to signing into the laboratory, the Environmental, Health and Safety Manual contains requirements for visitors and vendors. There are specific safety forms that must be reviewed and signed. Visitors (with the exception of company employees) are escorted by

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laboratory personnel at all times, or the location of the visitor is noted in the visitor's logbook. Signs are posted in the laboratory designating employee only areas - "Authorized employees beyond this point".

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### SECTION 19. TEST METHODS AND METHOD VALIDATION (NELAC 5.5.4)

## 19.1 <u>OVERVIEW</u>

The laboratory uses methods that are appropriate to meet our clients' requirements and that are within the scope of the laboratory's capabilities. These include sampling, handling, transport, storage and preparation of samples, and, where appropriate, an estimation of the measurement of uncertainty as well as statistical techniques for analysis of environmental data.

Instructions are available in the laboratory for the operation of equipment as well as for the handling and preparation of samples. All instructions, Standard Operating Procedures (SOPs), reference methods and manuals relevant to the working of the laboratory are readily available to all staff. Deviations from published methods are documented (with justification) in the laboratory's approved SOPs. SOPs are submitted to clients for review at their request. Significant deviations from published methods and regulatory approval where applicable.

## 19.2 STANDARD OPERATING PROCEDURES (SOPS)

The laboratory maintains SOPs that accurately reflect all phases of the laboratory such as assessing data integrity, corrective actions, handling customer complaints as well as all analytical methods and sampling procedures. The method SOPs are derived from the most recently promulgated/approved, published methods and are specifically adapted to the laboratory facility. Modifications or clarifications to published methods are clearly noted in the SOPs. All SOPs are controlled in the laboratory.

- All SOPs contain a revision number, effective date, and appropriate approval signatures. Controlled copies are available to all staff.
- Procedures for writing an SOP are incorporated by reference to TestAmerica's Corporate SOP entitled 'Writing a Standard Operating Procedure', No. CW-Q-S-002.
- SOPs are reviewed at a minimum of every 2 years (annually for Drinking Water and DoD SOPs), and where necessary, revised to ensure continuing suitability and compliance with applicable requirements.

# 19.3 LABORATORY METHODS MANUAL

For each test method, the laboratory shall have available the published referenced method as well as the laboratory developed SOP.

**Note:** If more stringent standards or requirements are included in a mandated test method or regulation than those specified in this manual, the laboratory shall demonstrate that such requirements are met. If it is not clear which requirements are more stringent, the standard from the method or regulation is to be followed. Any exceptions or deviations from the referenced methods or regulations are noted in the specific analytical SOP.

The laboratory maintains an SOP Index for both technical and non-technical SOPs. Technical SOPs are maintained to describe a specific test method. Non-technical SOPs are maintained to describe functions and processes not related to a specific test method. Table 19-1 for SOP index.

# 19.4 SELECTION OF METHODS

Since numerous methods and analytical techniques are available, continued communication between the client and laboratory is imperative to assure the correct methods are utilized. Once client methodology requirements are established, this and other pertinent information is summarized by the Project Manager. These mechanisms ensure that the proper analytical methods are applied when the samples arrive for log-in. For non-routine analytical services (e.g., special matrices, non-routine compound lists), the method of choice is selected based on client needs and available technology. The methods selected should be capable of measuring the specific parameter of interest, in the concentration range of interest, and with the required precision and accuracy.

## 19.4.1 Sources of Methods

Routine analytical services are performed using standard EPA-approved methodology. In some cases, modification of standard approved methods may be necessary to provide accurate analyses of particularly complex matrices. When the use of specific methods for sample analysis is mandated through project or regulatory requirements, only those methods shall be used.

When clients do not specify the method to be used or methods are not required, the methods used will be clearly validated and documented in an SOP and available to clients and/or the end user of the data.

The analytical methods used by the laboratory are those currently accepted and approved by the U. S. EPA and the state or territory from which the samples were collected. Reference methods include:

- <u>Guidelines Establishing Test Procedures for the Analysis of Pollutants Under the Clean Water Act,</u> and Appendix A-C; 40 CFR Part 136, USEPA Office of Water. <u>Revised as of July 1, 1995, Appendix</u> <u>A to Part 136 - Methods for Organic Chemical Analysis of Municipal and Industrial Wastewater (EPA 600 Series)</u>
- Methods for Chemical Analysis of Water and Wastes, EPA 600 (4-79-020), 1983.
- <u>Methods for the Determination of Inorganic Substances in Environmental Samples</u>, EPA-600/R-93/100, August 1993.
- <u>Methods for the Determination of Metals in Environmental Samples</u>, EPA/600/4-91/010, June 1991. Supplement I: EPA-600/R-94/111, May 1994.
- <u>Methods for the Determination of Organic Compounds in Drinking Water</u>, EPA-600/4-88-039, December 1988, Revised, July 1991, Supplement I, EPA-600-4-90-020, July 1990, Supplement II, EPA-600/R-92-129, August 1992. <u>Supplement III EPA/600/R-95/131 - August 1995 (EPA 500 Series</u>) (EPA 500 Series methods)
- Technical Notes on Drinking Water Methods, EPA-600/R94-173, October 1994
- <u>Standard Methods for the Examination of Water and Wastewater</u>, 20<sup>th</sup> and on-line editions; Eaton, A.D. Clesceri, L.S. Greenberg, A.E. Eds; American Water Works Association, Water Pollution Control Federation, American Public Health Association: Washington, D.C.
- <u>Test Methods for Evaluating Solid Waste Physical/Chemical Methods (SW846)</u>, Third Edition, September 1986, Final Update I, July 1992, Final Update IIA, August 1993, Final Update II,

September 1994; Final Update IIB, January 1995; Final Update III, December 1996; Final Update IV, January 2008.

- <u>Annual Book of ASTM Standards</u>, American Society for Testing & Materials (ASTM), Philadelphia, PA.
- <u>Manual for the Certification of Laboratories Analyzing Drinking Water (EPA 815-R-05-004, January 2005)</u>
- Code of Federal Regulations (CFR) 40, Parts 136, 141, 172, 173, 178, 179 and 261

The laboratory reviews updated versions to all the aforementioned references for adaptation based upon capabilities, instrumentation, etc., and implements them as appropriate. As such, the laboratory strives to perform only the latest versions of each approved method as regulations allow or require.

Other reference procedures for non-routine analyses may include methods established by specific states (e.g., Underground Storage Tank methods), ASTM or equipment manufacturers. Sample type, source, and the governing regulatory agency requiring the analysis will determine the method utilized.

The laboratory shall inform the client when a method proposed by the client may be inappropriate or out of date. After the client has been informed, and they wish to proceed contrary to the laboratory's recommendation, it will be documented.

# 19.4.2 <u>Demonstration of Capability</u>

Before the laboratory may institute a new method and begin reporting results, the laboratory shall confirm that it can properly operate the method. In general, this demonstration does not test the performance of the method in real world samples, but in an applicable and available clean matrix sample. If the method is for the testing of analytes that are not conducive to spiking, demonstration of capability may be performed on quality control samples.

A demonstration of capability (DOC, Lab SOP # IR-QA-TRAIN) is performed whenever there is a change in instrument type (e.g., new instrumentation), method or personnel.

The initial demonstration of capability must be thoroughly documented and approved by the Technical Director and QA Manager prior to independently analyzing client samples. All associated documentation must be retained in accordance with the laboratories archiving procedures.

The laboratory must have an approved SOP, demonstrate satisfactory performance, and conduct an MDL study (when applicable). There may be other requirements as stated within the published method or regulations (i.e., retention time window study).

**Note:** In some instances, a situation may arise where a client requests that an unusual analyte be reported using a method where this analyte is not normally reported. If the analyte is being reported for regulatory purposes, the method must meet all procedures outlined within this QA Manual (SOP, MDL, and Demonstration of Capability). If the client states that the information is not for regulatory purposes, the result may be reported as long as the following criteria are met:

- The instrument is calibrated for the analyte to be reported using the criteria for the method and ICV/CCV criteria are met (unless an ICV/CCV is not required by the method or criteria are per project DQOs).
- The laboratory's nominal or default reporting limit (RL) is equal to the quantitation limit (QL), must be at or above the lowest non-zero standard in the calibration curve and must be reliably determined. Project RLs are client specified reporting levels which may be higher than the QL. Results reported below the QL must be qualified as estimated values. Also see Section 19.6.1.3, Relationship of Limit of Detection (LOD) to Quantitation Limit (QL).
- The client request is documented and the lab informs the client of its procedure for working with unusual compounds. The final report must be footnoted: *Reporting Limit based on the low standard of the calibration curve.*

# 19.4.3 Initial Demonstration of Capability (IDOC) Procedures

**19.4.3.1** The spiking standard used must be prepared independently from those used in instrument calibration.

**19.4.3.2** The analyte(s) shall be diluted in a volume of clean matrix sufficient to prepare four aliquots at the concentration specified by a method or the laboratory SOP.

**19.4.3.3** At least four aliquots shall be prepared (including any applicable clean-up procedures) and analyzed according to the test method (either concurrently or over a period of days).

**19.4.3.4** Using all of the results, calculate the mean recovery in the appropriate reporting units and the standard deviations for each parameter of interest.

**19.4.3.5** When it is not possible to determine the mean and standard deviations, such as for presence, absence and logarithmic values, the laboratory will assess performance against criteria described in the Method SOP.

**19.4.3.6** Compare the information obtained above to the corresponding acceptance criteria for precision and accuracy in the test method (if applicable) or in laboratory generated acceptance criteria (LCS or interim criteria) if there is no mandatory criteria established. If any one of the parameters do not meet the acceptance criteria, the performance is unacceptable for that parameter.

**19.4.3.7** When one or more of the tested parameters fail at least one of the acceptance criteria, the analyst must proceed according to either option listed below:

- Locate and correct the source of the problem and repeat the test for all parameters of interest beginning with 19.4.3.3 above.
- Beginning with 19.4.3.3 above, repeat the test for all parameters that failed to meet criteria. Repeated failure, however, will confirm a general problem with the measurement system. If this occurs, locate and correct the source of the problem and repeat the test for all compounds of interest beginning with 19.4.3.1 above.

Note: Results of successive LCS analyses can be used to fulfill the DOC requirement.

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A certification statement (refer to Figure 19-1 as an example) shall be used to document the completion of each initial demonstration of capability. A copy of the certification is archived in the analyst's training folder.

Methods on line prior to the effective date of this Section shall be updated to the procedures outlined above as new analysts perform their demonstration of capability. A copy of the new record will replace that which was used for documentation in the past. At a minimum, the precision and accuracy of four mid-level laboratory control samples must have been compared to the laboratory's quality control acceptance limits.

# 19.5 LABORATORY DEVELOPED METHODS AND NON-STANDARD METHODS

Any new method developed by the laboratory must be fully defined in an SOP and validated by qualified personnel with adequate resources to perform the method. Method specifications and the relation to client requirements must be clearly conveyed to the client if the method is a non-standard method (not a published or routinely accepted method). The client must also be in agreement to the use of the non-standard method.

# 19.6 VALIDATION OF METHODS

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

All non-standard methods, laboratory designed/developed methods, standard methods used outside of their scope, and major modifications to published methods must be validated to confirm they are fit for their intended use. The validation will be as extensive as necessary to meet the needs of the given application. The results are documented with the validation procedure used and contain a statement as to the fitness for use.

# 19.6.1 <u>Method Validation and Verification Activities for All New Methods</u>

While method validation can take various courses, the following activities can be required as part of method validation. Method validation records are designated QC records and are archived accordingly.

# 19.6.1.1 Determination of Method Selectivity

Method selectivity is the demonstrated ability to discriminate the analyte(s) of interest from other compounds in the specific matrix or matrices from other analytes or interference. In some cases to achieve the required selectivity for an analyte, a confirmation analysis is required as part of the method.

#### 19.6.1.2 Determination of Method Sensitivity

Sensitivity can be both estimated and demonstrated. Whether a study is required to estimate sensitivity depends on the level of method development required when applying a particular measurement system to a specific set of samples. Where estimations and/or demonstrations of sensitivity are required by regulation or client agreement, such as the procedure in 40 CFR Part 136 Appendix B, under the Clean Water Act, these shall be followed.

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## 19.6.1.3 <u>Relationship of Limit of Detection (LOD) to the Quantitation Limit (QL)</u>

An important characteristic of expression of sensitivity is the difference in the LOD and the QL. The LOD is the minimum level at which the presence of an analyte can be reliably concluded. The QL is the minimum concentration of analyte that can be quantitatively determined with acceptable precision and bias. For most instrumental measurement systems, there is a region where semi-quantitative data is generated around the LOD (both above and below the estimated MDL or LOD) and below the QL. In this region, detection of an analyte may be confirmed but quantification of the analyte is unreliable within the accuracy and precision guidelines of the measurement system. When an analyte is detected below the QL, and the presence of the analyte is confirmed by meeting the qualitative identification criteria for the analyte, the analyte can be reliably reported, but the amount of the analyte can only be estimated. If data is to be reported in this region, it must be done so with a qualification that denotes the semi-quantitative nature of the result.

#### 19.6.1.4 Determination of Interferences

A determination that the method is free from interferences in a blank matrix is performed.

## 19.6.1.5 <u>Determination of Range</u>

Where appropriate to the method, the quantitation range is determined by comparison of the response of an analyte in a curve to established or targeted criteria. Generally the upper quantitation limit is defined by highest acceptable calibration concentration. The lower quantitation limit or QL cannot be lower than the lowest non-zero calibration level, and can be constrained by required levels of bias and precision.

#### 19.6.1.6 Determination of Accuracy and Precision

Accuracy and precision studies are generally performed using replicate analyses, with a resulting percent recovery and measure of reproducibility (standard deviation, relative standard deviation) calculated and measured against a set of target criteria.

#### 19.6.1.7 Documentation of Method

The method is formally documented in an SOP. If the method is a minor modification of a standard laboratory method that is already documented in an SOP, an SOP Attachment describing the specific differences in the new method is acceptable in place of a separate SOP.

#### 19.6.1.8 <u>Continued Demonstration of Method Performance</u>

Continued demonstration of Method Performance is addressed in the SOP. Continued demonstration of method performance is generally accomplished by batch specific QC samples such as LCS, method blanks or PT samples.

# 19.7 METHOD DETECTION LIMITS (MDL)/ LIMITS OF DETECTION (LOD)

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Method detection limits (MDL) are initially determined in accordance with <u>40 CFR Part 136</u>, <u>Appendix B</u> or alternatively by other technically acceptable practices that have been accepted by regulators. MDL is also sometimes referred to as Limit of Detection (LOD). The MDL theoretically represents the concentration level for each analyte within a method at which the Analyst is 99% confident that the true value is not zero. The MDL is determined for each analyte initially during the method validation process and updated as required in the analytical methods, whenever there is a significant change in the procedure or equipment, or based on project specific requirements. Generally, the analyst prepares at least seven replicates of solution spiked at one to five times the estimated method detection limit (most often at the lowest standard in the calibration curve) into the applicable matrix with all the analytes of interest. Each of these aliquots is extracted (including any applicable clean-up procedures) and analyzed in the same manner as the samples. Where possible, the seven replicates should be analyzed over 2-4 days to provide a more realistic MDL.

Refer to the Corporate SOP No. CA-Q-S-006 or laboratory SOP No. IR-QA-MDL, *Determination of Method Detection Limits*.

# 19.8 INSTRUMENT DETECTION LIMITS (IDL)

The IDL is sometimes used to assess the reasonableness of the MDLs or in some cases required by the analytical method or program requirements. IDLs are most used in metals analyses but may be useful in demonstration of instrument performance in other areas.

IDLs are calculated to determine an instrument's sensitivity independent of any preparation method. IDLs are calculated either using 7 replicate spike analyses, like MDL but without sample preparation, or by the analysis of 10 instrument blanks and calculating 3 x the absolute value of the standard deviation.

If IDL is > than the MDL, it may be used as the reported MDL.

# 19.9 VERIFICATION OF DETECTION AND REPORTING LIMITS

Once an MDL is established, it must be verified, on each instrument, by analyzing a quality control sample (prepared as a sample) at approximately 2-3 times the calculated MDL for single analyte analyses (e.g. most wet chemistry methods, Atomic Absorption, etc.) and 1-4 times the calculated MDL for multiple analyte methods (e.g. GC, GCMS, ICP, etc.). The analytes must be qualitatively identified. This verification does not apply to methods that are not readily spiked (e.g. pH, turbidity, etc.) or where the lab does not report to the MDL. If the MDL does not verify, then the lab will not report to the MDL, or redevelop their MDL or use the level where qualitative identification is established. MDLs must be verified at least annually.

When the laboratory establishes a quantitation limit, it must be initially verified by the analysis of a low level standard or QC sample at 1-2 the reporting limit and annually thereafter. The annual requirement is waved for methods that have an annually verified MDL. The laboratory will comply with any regulatory requirements.

# 19.10 RETENTION TIME WINDOWS

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Most organic analyses and some inorganic analyses use chromatography techniques for qualitative and quantitative determinations. For every chromatography analysis or as specific in the reference method, each analyte will have a specific time of elution from the column to the detector. This is known as the analyte's retention time. The variance in the expected time of elution is defined as the retention time window. As the key to analyte identification in chromatography, retention time windows must be established on every column for every analyte used for that method. These records are kept with the files associated with an instrument for later quantitation of the analytes. Complete details are available in the laboratory SOPs.

# 19.11 EVALUATION OF SELECTIVITY

The laboratory evaluates selectivity by following the checks within the applicable analytical methods, which include mass spectral tuning, second column confirmation, ICP interelement interference checks, chromatography retention time windows, sample blanks, spectrochemical, atomic absorption or fluorescence profiles, co-precipitation evaluations and specific electrode response factors.

# 19.12 ESTIMATION OF UNCERTAINTY OF MEASUREMENT

**19.12.1** Uncertainty is "a parameter associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand" (as defined by the International Vocabulary of Basic and General Terms in Metrology, ISO Geneva, 1993, ISBN 92-67-10175-1). Knowledge of the uncertainty of a measurement provides additional confidence in a result's validity. Its value accounts for all the factors which could possibly affect the result, such as adequacy of analyte definition, sampling, matrix effects and interferences, climatic conditions, variances in weights, volumes, and standards, analytical procedure, and random variation. Some national accreditation organizations require the use of an "expanded uncertainty": the range within which the value of the measurand is believed to lie within at least a 95% confidence level with the coverage factor k=2.

**19.12.2** Uncertainty is not error. Error is a single value, the difference between the true result and the measured result. On environmental samples, the true result is never known. The measurement is the sum of the unknown true value and the unknown error. Unknown error is a combination of systematic error, or bias, and random error. Bias varies predictably, constantly, and independently from the number of measurements. Random error is unpredictable, assumed to be Gaussian in distribution, and reducible by increasing the number of measurements.

**19.12.3** The minimum uncertainty associated with results generated by the laboratory can be determined by using the Laboratory Control Sample (LCS) accuracy range for a given analyte. The LCS limits are used to assess the performance of the measurement system since they take into consideration all of the laboratory variables associated with a given test over time (except for variability associated with the sampling and the variability due to matrix effects). The percent recovery of the LCS is compared either to the method-required LCS accuracy limits or to the statistical, historical, in-house LCS accuracy limits.

**19.12.4** To calculate the uncertainty for the specific result reported, multiply the result by the decimal of the lower end of the LCS range percent value for the lower end of the uncertainty range, and multiply the result by the decimal of the upper end of the LCS range percent value

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for the upper end of the uncertainty range. These calculated values represent a 99%-certain range for the reported result. As an example, suppose that the result reported is 1.0 mg/l, and the LCS percent recovery range is 50 to 150%. The uncertainty range would be 0.5 to 1.5 mg/l, which could also be written as 1.0 + 0.5 mg/l.

**19.12.5** In the case where a well recognized test method specifies limits to the values of major sources of uncertainty of measurement (e.g., 524.2, 525, etc.) and specifies the form of presentation of calculated results, no further discussion of uncertainty is required.

# 19.13 SAMPLE REANALYSIS GUIDELINES

Because there is a certain level of uncertainty with any analytical measurement, a sample reanalysis may result in either a higher or lower value from an initial sample analysis. There are also variables that may be present (e.g., sample homogeneity, analyte precipitation over time, etc.) that may affect the results of a reanalysis. Based on the above comments, the laboratory will reanalyze samples at a client's request with the following caveats. Client specific Contractual Terms & Conditions for reanalysis protocols may supersede the following items.

- Homogenous samples: If a reanalysis agrees with the original result to within the RPD limits for MS/MSD or Duplicate analyses, or within <u>+</u> 1 reporting limit for samples ≤ 5x the reporting limit, the original analysis will be reported. At the client's request, both results may be reported on the same report but not on two separate reports.
- If the reanalysis does not agree (as defined above) with the original result, then the laboratory will investigate the discrepancy and reanalyze the sample a third time for confirmation if sufficient sample is available.
- Any potential charges related to reanalysis are discussed in the contract terms and conditions or discussed at the time of the request. The client will typically be charged for reanalysis unless it is determined that the lab was in error.
- Due to the potential for increased variability, reanalysis may not be applicable to Nonhomogenous, Encore, and Sodium Bisulfate preserved samples. See the Area Supervisor or Laboratory Director if unsure.

# 19.14 <u>CONTROL OF DATA</u>

The laboratory has policies and procedures in place to ensure the authenticity, integrity, and accuracy of the analytical data generated by the laboratory.

# 19.14.1 <u>Computer and Electronic Data Related Requirements</u>

The three basic objectives of our computer security procedures and policies are shown below. More detail is outlined in SOP No. IR-IT-COMPSEC, *Computer Security*. The laboratory is currently running Element which is a 3<sup>rd</sup> party LIMS system that has been highly customized to meet the needs of the laboratory. It is referred to as LIMS for the remainder of this section. The LIMS utilizes SQL which is an industry standard relational database platform. It is referred to as Database for the remainder of this section.

- **19.14.1.1** <u>Maintain the Database Integrity:</u> Assurance that data is reliable and accurate through data verification (review) procedures, password-protecting access, anti-virus protection, data change requirements, as well as an internal LIMS permissions procedure.
  - LIMS Database Integrity is achieved through data input validation, internal user controls, and data change requirements.
  - Spreadsheets and other software developed in-house must be verified with documentation through hand calculations prior to use.
- **19.14.1.2** Ensure Information Availability: Protection against loss of information or service is ensured through scheduled back-ups, stable file server network architecture, secure storage of media, line filter, Uninterruptible Power Supply (UPS), and maintaining older versions of software as revisions are implemented.
- **19.14.1.3** <u>Maintain Confidentiality:</u> Ensure data confidentiality through physical access controls when electronically transmitting data.

# 19.14.2 Data Reduction

The complexity of the data reduction depends on the analytical method and the number of discrete operations involved (e.g., extractions, dilutions, instrument readings and concentrations). The analyst calculates the final results from the raw data or uses appropriate computer programs to assist in the calculation of final reportable values.

For manual data entry, e.g., Wet Chemistry, the data is reduced by the analyst and then verified by the Department Manager or alternate analyst prior to updating the data in LIMS. The spreadsheets, or any other type of applicable documents, are signed by both the analyst and alternate reviewer to confirm the accuracy of the manual entry(s).

Manual integration of peaks will be documented and reviewed and the raw data will be flagged in accordance with the TestAmerica Corporate SOP No. CA-Q-S-002, *Acceptable Manual Integration Practices*.

Analytical results are reduced to appropriate concentration units specified by the analytical method, taking into account factors such as dilution, sample weight or volume, etc. Blank correction will be applied only when required by the method or per manufacturer's indication; otherwise, it should not be performed. Calculations are independently verified by appropriate laboratory staff. Calculations and data reduction steps for various methods are summarized in the respective analytical SOPs or program requirements.

- **19.14.2.1** All raw data must be retained in the sequence file folder, computer file (if appropriate), and/or logbook. All criteria pertinent to the method must be recorded. The documentation is recorded at the time observations or calculations are made and must be signed or initialed/dated (month/day/<u>year</u>). It must be easily identifiable who performed which tasks if multiple people were involved.
- **19.14.2.2** In general, concentration results are reported in milligrams per liter (mg/l) or micrograms per liter (µg/l) for liquids and milligrams per kilogram (mg/kg) or

micrograms per kilogram ( $\mu$ g/kg) for solids. For values greater than 10,000 mg/l, results can be reported in percent, i.e., 10,000 mg/l = 1%. Units are defined in each lab SOP.

- **19.14.2.3** In reporting, the analyst or the instrument output records the raw data result using values of known certainty plus one uncertain digit. If final calculations are performed external to LIMS, the results should be entered in LIMS with at least three significant figures. In general, results are reported to 2 significant figures on the final report.
- **19.14.2.4** For those methods that do not have an instrument printout or an instrumental output compatible with the LIMS System, the raw results and dilution factors are entered directly into LIMS by the analyst, and the software calculates the final result for the analytical report. LIMS has a defined significant figure criterion for each analyte.
- **19.14.2.5** The laboratory strives to import data directly from instruments or calculation spreadsheets to ensure that the reported data are free from transcription and calculation errors. For those analyses with an instrumental output compatible with the LIMS, the raw results and dilution factors are transferred into LIMS electronically after reviewing the quantitation report, and removing unrequested or poor spectrally-matched compounds. The analyst prints a copy of what has been entered to check for errors. This printout and the instrument's printout of calibrations, concentrations, retention times, chromatograms, and mass spectra, if applicable, are retained with the data file. The data file is stored in a monthly folder on the instrument computer; periodically, this file is transferred to the server and, eventually, to a tape file.

# 19.14.3 Logbook / Worksheet Use Guidelines

Logbooks and worksheets are filled out 'real time' and have enough information on them to trace the events of the applicable analysis/task. (e.g. calibrations, standards, analyst, sample ID, date, time on short holding time tests, temperatures when applicable, calculations are traceable, etc.)

- Corrections are made following the procedures outlined in Section 12.
- Logbooks are controlled by the QA department. A record is maintained of all logbooks in the lab.
- Unused portions of pages must be "Z"'d out, signed and dated.
- Worksheets are created with the approval of the Technical Director/QA Manager at the facility. The QA Manager controls all worksheets following the procedures in Section 6.

# 19.14.4 <u>Review / Verification Procedures</u>

Review procedures are outlined in the following laboratory SOPs:

- IR-SC-LOGIN, Sample Control [for sample receipt and login]
- IR-PM-DATA, Project Management Data Reporting, Validation and Distribution in Element LIMS [for PM review of final report]
- IR-QA-REV, *General Data Review* [for laboratory technical review]

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These have been put in place to ensure that reported data are free from calculation and transcription errors, that QC parameters have been reviewed and evaluated before data is reported. The general review concepts are discussed below, more specific information can be found in the SOPs.

- **19.14.4.1** The data review process at the laboratory starts at the Sample Control level. Sample Control personnel review chain-of-custody forms and input the sample information and required analyses into a computer LIMS. The Sample Control Supervisor reviews the transaction of the chain-of-custody forms and the inputted information. The Project Managers perform final review of the chain-of-custody forms and inputted information.
- **19.14.4.2** The next level of data review occurs with the Analysts. As results are generated, analysts review their work to ensure that the results generated meet QC requirements and relevant EPA methodologies. The Analysts transfer the data into the LIMS and add data qualifiers if applicable. To ensure data compliance, a different analyst performs a second level of review. Second level review is accomplished by checking reported results against raw data and evaluating the results for accuracy. During the second level review, blank runs, QA/QC check results, initial and continuing calibration results, laboratory control samples, sample data, qualifiers and spike information are evaluated. Where calibration is not required on a daily basis, secondary review of the initial calibration results may be conducted at the time of calibration. 100% of sample data from manual methods (BOD, titrations, etc.), GC/MS spectra and manual integrations are reviewed. All GCMS calibrations are also electronically reviewed utilizing auditing software to help ensure compliance to ethics and manual integration policies. Issues that deem further review include the following:
  - QC data are outside the specified control limits for accuracy and precision
  - Reviewed sample data does not match with reported results
  - Unusual detection limit changes are observed
  - Samples having unusually high results
  - Samples exceeding a known regulatory limit
  - Raw data indicating some type of contamination or poor technique
  - Inconsistent peak integration
  - Transcription errors
  - Results outside of calibration range
- **19.14.4.3** Unacceptable analytical results may require reanalysis of the samples. Any problems are brought to the attention of the Laboratory Director, Project Manager, Quality Assurance Manager, Operations Manager, or Supervisor for further investigation. Corrective action is initiated whenever necessary.
- **19.14.4.4** The results are then entered or directly transferred into the computer database and a hard copy (or .pdf) is printed for the client.

- **19.14.4.5** As a final review prior to the release of the report, the Project Manager reviews the results for appropriateness and completeness. This review and approval ensures that client requirements have been met and that the final report has been properly completed. The process includes, but is not limited to, verifying that chemical/logical relationships are evaluated, COC is followed, cover letters/ narratives are present, flags are appropriate, and project specific requirements are met.
- **19.14.4.6** Any project that requires a data package is subject to a tertiary data review for transcription errors and acceptable quality control requirements. The Project Manager then signs the final report. The PMs also check the report for any clerical or invoicing errors. When complete, the report is sent out to the client.
- **19.14.4.7** A visual summary of the flow of samples and information through the laboratory, as well as data review and validation, is presented in Figure 19-2.

# 19.14.5 <u>Manual Integrations</u>

Computerized data systems provide the analyst with the ability to re-integrate raw instrument data in order to optimize the interpretation of the data. Though manual integration of data is an invaluable tool for resolving variations in instrument performance and some sample matrix problems, when used improperly, this technique would make unacceptable data appear to meet quality control acceptance limits. Improper re-integrations lead to legally indefensible data, a poor reputation, or possible laboratory decertification. Because guidelines for re-integration of data are not provided in the methods and most methods were written prior to widespread implementation of computerized data systems, the laboratory trains all analytical staff on proper manual integration techniques using TestAmerica's Corporate SOP (CA-Q-S-002).

- **19.14.5.1** The analyst must adjust baseline or the area of a peak in some situations, for example when two compounds are not adequately resolved or when a peak shoulder needs to be separated from the peak of interest. The analyst must use professional judgment and common sense to determine when manual integrating is required. Analysts are encouraged to ask for assistance from a senior analyst or manager when in doubt.
- **19.14.5.2** Analysts shall not increase or decrease peak areas to for the sole purpose of achieving acceptable QC recoveries that would have otherwise been unacceptable. The intentional recording or reporting of incorrect information (or the intentional omission of correct information) is against company principals and policy and is grounds for immediate termination.
- **19.14.5.3** Client samples, performance evaluation samples, and quality control samples are all treated equally when determining whether or not a peak area or baseline should be manually adjusted.
- **19.14.5.4** All manual integrations receive a second level review. Manual integrations must be indicated on an expanded scale "after" chromatograms such that the integration performed can be easily evaluated during data review. Expanded scale "before" chromatograms are also required for all manual integrations on QC parameters (calibrations, calibration verifications, laboratory control samples, internal standards,

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surrogates, etc.) unless the laboratory has another documented corporate approved procedure in place that can demonstrate an active process for detection and deterrence of improper integration practices.

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Figure 19-1a.	Example - Demonstration of Capability Che	cklist (page 1 of 2)
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Emple	oyee: Training Start Date: Training	Finish Date:	
Train	er: Procedure(s):	Matrix:	
Denar	rtment: SOP:		
Jepa	Filename revisio	n#	Date
	Task	Initials /	Date Complete
1	I have read and understood the published procedure(s).		
	(i.e. the EPA, Standard Methods, ASTM or other organization)	Traince initials	
	The published methods(s) read applicable to this procedure are:		
2	The SOP contains no deviations from the Source method(s) (above) that are not		
2	documented in the Method Deviations section of the SOP. If deviations are		7
	discovered, notify the area Supervisor and the QA Manager before proceeding	Traince initials	Date
	further.		
3	I have read, understood and agree to follow this SOP without deviation.		
		Traince initials	/
4	Using the SOP as a step-by-step reference, the trainer has demonstrated the entire		
	procedure to me. If deviations are discovered, notify the area Supervisor and the		/
	QA Manager before proceeding further.	Traince initials	Date
5	I have performed the following procedure under the direct supervision of an		
	experienced staff member:		7
	Preparation of standards and reagents. (List Element # and description/conc.):	Traince initials	Date
	Preparation of samples and QC for analysis (List Element Batch #):	Trainer initials	Date
	Performance of a calibration (List file ID and/or date):		
	Analysis of a complete sequence (List file ID and/or date):		
6	To demonstrate understanding of the SOP/method, complete the following for the		7
0	analysis of: (for multi-analyte methods select one analyte)	Traince initials	Date
	Type of calibration curve:Acceptance criteria:		
	Calibration range: %R limits for ICV: %R limits for CCV:		
	CCV frequency: Method Blank criteria:		
	%R limits for LCS: %R & RPD limits for MS/MSD:		
	Associated IS: %R limits for IS:		
	Associated Surr: %R limits for Surr:		
	Associated SPCC: SPCC criteria:		
	Associated CCC: CCC criteria:		
7	Employee has independently performed the procedure and results have been		7
	reviewed and confirmed by experienced staff member.	Traince initials	Date

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	<u>OA only</u> (Note when the training took place.)		U
8	Trainer completed a DOC for this method on:		1
0	Trainer compreted a DOC for this method on.	QA initials	Date
9	Employee has had annual Manual Integration training on		7
	INU	QA initials	Date
10	Employee has had annual Ethics and Data Integrity training on	QA initials	/
11	Employee has demonstrated capability by generating acceptable results* c	on:	
	4 Duplicates Other:	QA initials	/
	*DOC sample type depends on test performed, see SOP	QA muas	Date
	employee named above has successfully demonstrated proficiency to per-	form the above-mentioned	procedure,
main	tain applicable QA/QC requirements, and report results on his or her own.		
Emp	loyee Signature:	Date:	
Trair	er Signature:	Date:	
Supe	rvisory Signature:	Date:	
	Director/QA approval:	Date:	

Figure 19-1b. Example - Demonstration of Capability Checklist (page 2 of 2)

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Figure 19	9-2.	Example - De	monstration of (	Capability Form (NEL	_AP)
Labo Anal Matr SOP	pratory Name: pratory Address yst(s) Name(s):	CERTIFICA	TION OF CAPABI TION STATEMEN	Л	
We, t	the undersigned,	CERTIFY that:			
	this f	acility for the analyses	of samples under the Na	ethod(s), which is in use at tional Environmental nonstration of Capability.	
		est method(s) was per ication.	formed by the analyst(s)	identified on this	
		oy of the test method(s ersonnel on-site.	) and the laboratory-spec	tific SOPs are available for	
		data associated with the lete, and self explanato	e demonstration capabilit	y are true, accurate,	
	recor and t	nstruct and validate the	y of this certification form se analyses have been r rmation is well organized sors.	etained at the facility,	
Te	echnical Director	's Name and Title	Signature	Date	
Q	uality Assurance	Manager	Signature	Date	
Acc prin Cor Selt	urate: Based o ciples/practices nplete: Include f-Explanatory:	s. es the results of all su	ractices consistent with		

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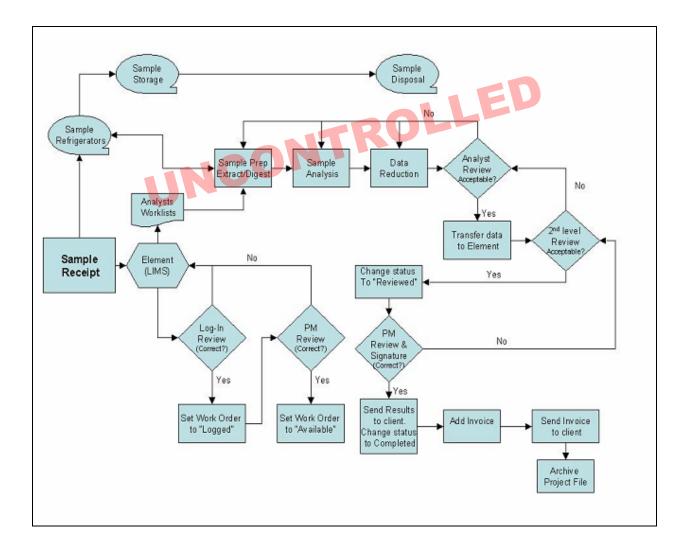


Figure 19-3.

**Example: Work Flow** 

#### Table 19-1: SOP Index

DEPARTMENT	FILENAME	TITLE	TYPE
Administrative	IR-ADMIN-SOFT	SOFTWARE MAINTENANCE	NON-TECHNICAL
Administrative	IR-ADM-POW	POWER OUTAGES	NON-TECHNICAL
Administrative	IR-IT-COMPUSEC	COMPUTER SECURITY	NON-TECHNICAL
EXTRACTIONS	IR-EXT-1664	GRAVIMETRIC DETERMINATION OF N-HEXANE EXTRACTABLE MATERIAL AND SILICA GEL TREATED N-HEXANE EXTRACTABLE MATERIAL IN WATER	TECHNICAL
EXTRACTIONS	IR-EXT-3510_D	EPA METHOD 3510C (DIESEL EXTRACTION FOR WATER)	TECHNICAL
EXTRACTIONS	IR-EXT-3510_P	EPA METHOD 3510C AND 608 (ORGANOCHLORINE PESTICIDES AND PCBS EXTRACTION FOR WATER)	TECHNICAL
EXTRACTIONS	IR-EXT-3520C	EPA METHOD 3520C AND EPA METHOD 625 (CONTINUOUS LIQUID-LIQUID EXTRACTION)	TECHNICAL
EXTRACTIONS	IR-EXT-3545_SV	EPA METHOD 3545 ( PRESSURIZED FLUID EXTRACTION [PFE], SEMI-VOLATILE EXTRACTION FOR SOIL)	TECHNICAL
EXTRACTIONS	IR-EXT-3545P	EPA METHOD 3545 (PRESSURIZED FLUID EXTRACTION [PFE], PESTICIDE AND PCB EXTRACTION FOR SOIL)	TECHNICAL
EXTRACTIONS	IR-EXT-3546	EPA METHOD 3546 MICROWAVE EXTRACTION OF SOLIDS	TECHNICAL
EXTRACTIONS	IR-EXT-3580A	EPA METHOD 3580A Waste Dilution	TECHNICAL
EXTRACTIONS	IR-EXT-418_413	EPA METHOD 413.2 AND 418.1 (TOTAL RECOVERABLE PETROLEUM HYDROCARBONS, OIL AND GREASE FOR WATER AND SOIL)	TECHNICAL
EXTRACTIONS	IR-EXT-9071	HEM and STG-HEM IN SOLID SAMPLES, EPA 9071B MOD/EPA 3550C MOD	TECHNICAL
EXTRACTIONS	IR-EXT-CALUFT	DIESEL EXTRACTION FOR SOIL, CA LUFT METHOD	TECHNICAL
EXTRACTIONS	IR-EXT-IGNITE	IGNITABILITY IN SOIL	TECHNICAL
EXTRACTIONS	IR-EXT-NA2SO4	PREPARATION OF SODIUM SULFATE FOR EXTRACTIONS	TECHNICAL
EXTRACTIONS	IR-PREP-ORP	STANDARD METHOD 2580B (OXIDATION REDUCTION POTENTIAL)	TECHNICAL
EXTRACTIONS	IR-WET-COLOR	EPA METHOD 110.2 & SM 2120B (COLOR, COLORIMETRIC-PLATINUM-COBALT)	TECHNICAL
EXTRACTIONS	IR-WET-FE2	FERROUS IRON BY SM 3500Fe-D MODIFIED	TECHNICAL
EXTRACTIONS	IR-WET-ODOR	THRESHOLD ODOR (SM 2150B & EPA 140.1)	TECHNICAL
EXTRACTIONS	IR-WET-PH	EPA METHOD 150.1/ 9040B/9040C/ 9041A/9045C/SM4500-H+B (ELECTROMETRIC pH)	TECHNICAL
EXTRACTIONS	IR-WET-SETT	SETTLEABLE MATTER (EPA METHOD 160.5 / SM2540F)	TECHNICAL
EXTRACTIONS	IR-WET-TURB	TURBIDITY, NEPHELOMETRIC (EPA METHOD 180.1 AND STANDARD METHOD 2130B)	TECHNICAL
GC_GCMS_SEMI_DW	IR-GCS-505	EPA 505 (DETERMINATION OF ORGANOHALIDE PESTICIDES AND POLYCHLORINATED BIPHENYL (PCBs)	TECHNICAL
GC_GCMS_SEMI_DW	IR-GCS-508.1	EPA 508.1 (DETERMINATION OF CHLORINATED PESTICIDES, HERBICIDES AND ORGANOHALIDES)	TECHNICAL

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DEPARTMENT	FILENAME	TITLE	TYPE
GC_GCMS_SEMI_DW	IR-GCS-515.4	EPA METHOD 515.4 (DETERMINATION OF CHLORINATED ACIDS IN DW BY 515.4)	TECHNICAL
GC_GCMS_SEMI_DW	IR-GCS-552_2	EPA METHOD 552.2 (DETERMINATION OF HALOACETIC ACIDS IN DW BY LIQUID-LIQUID EXTRACTION, DERIVATIZATIONS BY GC)	TECHNICAL
GC_GCMS_SEMI_DW	IR-GCV-504	EPA METHOD 504.1 (EDB, DBCP, AND 123TCP IN WATER BY MICROEXTRACTION AND GAS CHROMATOGRAPHY)	TECHNICAL
GC_GCMS_SEMI_DW	IR-MSS-525_2	EPA METHOD 525.2 (ORGANIC COMPOUNDS BY LIQUID-SOLID EXTRACTION AND GAS CHROMATOGRAPGY/MASS SPECTROMETRY)	TECHNICAL
GC_GCMS_SEMI_DW	IR-MSS-548_1	EPA METHOD 548.1( DETERMINATION OF ENDOTALL IN DRINKING WATER BY ION EXCHANGE EXTRACTION, ACIDIC METHANOL METHYLATION AND GCMS)	TECHNICAL
GC-BTEX	IR-GCV-8015_8021	GASOLINE RANGE ORGANICS (GRO) / BTEX AND MTBE/MINERAL SPIRITS	TECHNICAL
GC-BTEX	IR-GCV-AIR	EPA METHOD 8015/8020, MODIFIED FOR AIR AND CARB METHOD 410A (BTEX, MTBE AND FUEL HYDROCARBONS AS GASOLINE)	TECHNICAL
GC-BTEX	IR-GCV-FIX	ASTM 1946-92 (FIXED GASES)	TECHNICAL
GC-BTEX	IR-GCV-RSK	METHANE, ETHANE AND ETHYLENE BY GC HEADSPACE (RSK-175)	TECHNICAL
GCMS-SEMI	IR-MSS-14DIOX	1,4-DIOXANE BY 8270C MODIFIED SCAN MODE	TECHNICAL
GCMS-SEMI	IR-MSS-8270C_625	EPA METHOD 8270C (SEMI-VOLATILE ORGANIC COMPOUNDS)/EPA METHOD 625 (BASE/NEUTRALS AND ACIDS)	TECHNICAL
GCMS-SEMI	IR-MSS-CHLOR	DICHLOROACETALDEHYDE AND TRICHLOROACETALDEHYDE BY EPA 8270C MOD, SELECTIVE ION MONITORING (SIM) MODE	TECHNICAL
GCMS-SEMI	IR-MSS-NITROSA	NITROSAMINES BY GC/MS USING CHEMICAL IONIZATION (EPA 1625C MODIFIED)	TECHNICAL
GCMS-SEMI	IR-MSS-PAHSIM	PAHS COMPOUNDS BY EPA 8270C SELECTIVE ION MONITORING (SIM) MODE	TECHNICAL
GCMS-SEMI	IR-MSS-TEL	TETRAETHYLLEAD BY GCMS EPA 8270C MOD	TECHNICAL
GCMS-VOL	IR-MSV-123TCP	1,2,3-Trichloropropane by GCMS SIM MODE, EPA 524.2	TECHNICAL
GCMS-VOL	IR-MSV-524	EPA METHOD 524.2 (PURGEABLE ORGANIC COMPOUNDS)	TECHNICAL
GCMS-VOL	IR-MSV-8260_624	EPA METHOD 8260B/624/TPH BY GCMS (VOLATILE ORGANIC COMPOUNDS)	TECHNICAL
GCMS-VOL	IR-MSV-PREP	VOLATILE ORGANIC PREPARATION (EPA 5030B, 5030C & 5035A)	TECHNICAL
GCMS-VOL	IR-MSV-SIM	Volatile Organic Compounds by GCMS-SIM	TECHNICAL
GC-SEMI	IR-GCS-8015_AZ	C10 -C32 HYDROCARBONS IN SOIL (ADHS METHOD 8015AZ R1)	TECHNICAL
GC-SEMI	IR-GCS-8015_D	EPA METHOD 8015B AND MODIFIED FOR DHS LUFT (TOTAL PETROLOLEUM HYDROCARBONS AS DIESEL )	TECHNICAL
GC-SEMI	IR-GCS-PCBs	EPA METHOD 8082/608 (POLYCHLORINATED BIPHENYLS (PCBS) BY GC)	TECHNICAL

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DEPARTMENT	FILENAME	TITLE	TYPE
GC-SEMI	IR-GCS-PEST	ORGANOCHLORINE PESTICIDES BY GC (EPA METHODS 608 & 8081A)	TECHNICAL
GC-SEMI	IR-GCV-ALC	EPA METHOD 8015B ( METHANOL AND ETHANOL BY GC)	TECHNICAL
HEALTH & SAFETY	IR-EHS-RESP	RESPIRATORY PROTECTION PLAN - VOLUNTARY	NON-TECHNICAL
HEALTH & SAFETY	IR-EHS-WASTE	HAZARDOUS WASTE DISPOSAL	NON-TECHNICAL
HPLC-DW	IR-HP-531.1	EPA 531.1 (Measurement of Carbamates in Water by Direct Aqueous Injection HPLC with Post Column Derivatization)	TECHNICAL
HPLC-DW	IR-HP-547	EPA 547 (DETERMINATION OF GLYPHOSATE IN DW DIRECT-AQUEOUS INJECTION HPLC W/POST COLUMN DERIVATIZATION & FLUORESCENCE DETECTION)	TECHNICAL
HPLC-DW	IR-HP-549_2	EPA 549.2 (DETERMINATION OF DIQUAT & PARAQUAT IN DW BY LIQUID-SOLID EXTRACTION AND HPLC-UV DETECTION)	TECHNICAL
INORGANIC PREP	IR-EXT-1010	EPA METHOD 1010 (PENSKY-MARTENS CLOSED- CUP METHOD FOR DETERMINING IGNITABILITY)	TECHNICAL
INORGANIC PREP	IR-MET-PREP_W	ACID DIGESTION OF WATER FOR TOTAL RECOVERABLE OR DISSOLVED METALS BY ICP AND ICP/MS (EPA METHODS 200.2, 3005A AND 3010A)	TECHNICAL
INORGANIC PREP	IR-PREP-1311-12- TI22	TCLP, SPLP (EPA METHOD 1311 & 1312) AND STLC/ WET EXTRACTION (TITLE 22, SECTION 66261.126, APPENDIX III)	TECHNICAL
INORGANIC PREP	IR-PREP-3050	ACID DIGESTION FOR TOTAL METALS BY GFAA AND ICP IN SOIL (EPA METHOD 3050B)	TECHNICAL
INORGANIC PREP	IR-PREP-LFR_Leach	LFR Special Leachate Procedure	TECHNICAL
INORGANIC PREP	IR-PREP-WASH	GLASSWARE WASHING	NON-TECHNICAL
METALS	IR-MET-1640	TRACE ELEMENTS IN WATER BY PRE- CONCENTRATION AND ICP/MS (EPA 1640)	TECHNICAL
METALS	IR-MET-CEC	EPA METHOD 9081A CATION-EXCHANGE CAPACITY OF SOILS (SODIUM ACETATE)	TECHNICAL
METALS	IR-MET-HG	MERCURY, COLD-VAPOR ATOMIC ABSORPTION SPECTROMETRY (EPA METHODs 245.1/7470A/7471)	TECHNICAL
METALS	IR-MET-ICP	ICP METALS ANALYSES (EPA METHOD 6010B, EPA METHOD 200.7)	TECHNICAL
METALS	IR-MET-ICPMS	METALS BY ICP/MS (EPA METHOD 200.8 & EPA 6020)	TECHNICAL
METALS	IR-MET-ORG-PB	ORGANIC LEAD BY GRAPHITE FURNACE AA (CA DTSC 939-M)	TECHNICAL
MICRO	IR-MICRO-9221-DW	TOTAL COLIFORMS, FECAL COLIFORMS, AND E. COLI IN DRINKING WATER BY MULTIPLE TUBE FERMENTATION (MTF) / MOST PROBABLE NUMBER (MPN) STANDARD METHODS 9221 B, C, E, AND F	TECHNICAL
MICRO	IR-MICRO-9221-WW	TOTAL COLIFORMS, FECAL COLIFORMS, AND E. COLI IN NON-POTABLE WATERS, BIOSOLIDS, SOIL AND SLUDGE BY MULTIPLE TUBE FERMENTATION (MTF) / MOST PROBABLE NUMBER (MPN) STANDARD METHODS 9221 B, C, E, AND F	TECHNICAL

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DEPARTMENT	FILENAME	TITLE	TYPE
MICRO	IR-MICRO-9223B	TOTAL COLIFORM AND E. COLI PRESENCE/ABSENCE OR (Quanti-Tray) MPN BY COLILERT, COLILERT 18, COLISURE OR COLITAG SM 9223B	TECHNICAL
MICRO	IR-MICRO-9230-FSE	FECAL STREPTOCOCCUS AND ENTEROCOCCUS GROUP IN UNTREATED WATERS BY MULTIPLE TUBE FERMENTATION SM 9230B AND SM 9230D	TECHNICAL
MICRO	IR-MICRO- AUTOCLAVE	MICROBIOLOGICAL STERILIZATION EQUIPMENT - AUTOCLAVE AND HOT AIR OVEN	NON-TECHNICAL
MICRO	IR-MICRO-GLP	MICROBIOLOGICAL GOOD LABORATORY PRACTICE (GLP)	NON-TECHNICAL
MICRO	IR-MICRO-HPC- POUR	HETEROTROPHIC PLATE COUNT – (HPC) POUR PLATE BY SM 9215B	TECHNICAL
MICRO	IR-MICRO-HPC-SIM	HETEROTROPHIC PLATE COUNT – (HPC SIM) BY IDEXX SIM PLATE	TECHNICAL
MICRO	IR-MICRO-MRQS	MICROBIOLOGICAL MEDIA, REAGENTS AND QUANTITATION SUPPLIES – RECEIVING, PREPARATION AND QUALITY CONTROL CHECK	NON-TECHNICAL
MICRO	IR-MICRO- PURE_CULTURES	MICROBIOLOGICAL - PURE CULTURE PREPARATION AND MAINTENANCE	NON-TECHNICAL
MICRO	IR-MICRO- QC_EQUIP- ENVIRONMENT	MICROBIOLOGICAL QUALITY CONTROL CHECKS FOR LABORATORY EQUIPMENTS AND LABORATORY ENVIRONMENT	NON-TECHNICAL
MICRO	IR-MICRO-RGW	MICROBIOLOGY - REAGENT GRADE WATER	NON-TECHNICAL
MICRO	IR-MICRO-WASH	MICROBIOLOGY - GLASSWARE WASHING	NON-TECHNICAL
РМ	IR-PM-CLIENT	PROJECT MANAGEMENTCLIENT/PROJECT SET- UP	NON-TECHNICAL
РМ	IR-PM-DATA	PROJECT MANAGEMENT DATA REPORTING, VALIDATION AND DISTRIBUTION IN ELEMENT LIMS	NON-TECHNICAL
PM	IR-PM-DATAPACK	DATA PACKAGE GENERATION	NON-TECHNICAL
РМ	IR-PM-DOC	PROJECT MANAGEMENTCOMMUNICATION AND DOCUMENTATION	NON-TECHNICAL
PM	IR-PM-EDF	EDF (ELECTRONIC DATA FORMAT)	NON-TECHNICAL
РМ	IR-PM-WIP	WELL INVESTIGATION PROGRAM (WIP) Package Generation	NON-TECHNICAL
QA	IR-QA-ARCH	RECORD ARCHIVING	NON-TECHNICAL
QA	IR-QA-BAL	BALANCE CALIBRATION VERIFICATION AND DOCUMENTATION	NON-TECHNICAL
QA	IR-QA-BPREQ	BP LaMP Technical Requirements	NON-TECHNICAL
QA	IR-QA-CAR	CORRECTIVE ACTIONS	NON-TECHNICAL
QA	IR-QA-CNTRLLIM	CONTROL CHARTS AND STATISTICAL PROCESS CONTROL	NON-TECHNICAL
QA	IR-QA-DATAQUAL	USE OF DATA QUALIFIERS	NON-TECHNICAL
QA	IR-QA-DOC	DOCUMENT CONTROL	NON-TECHNICAL
QA	IR-QA-DW_REQ	DRINKING WATER PROGRAM REQUIREMENTS	NON-TECHNICAL
QA	IR-QA-ETEDW	EARTH TECH/EDWARDS AFB PROJECT REQUIREMENTS	NON-TECHNICAL
QA	IR-QA-ICOC	LEGAL CUSTODY PROCEDURES	NON-TECHNICAL
QA	IR-QA-LOGBOOK	LOGBOOKS, DOCUMENTATION, AND LABORATOARY COMMUNICATION	NON-TECHNICAL

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DEPARTMENT	FILENAME	TITLE	TYPE
QA	IR-QA-LOTTEST	CONTAINER AND REAGENT VERIFICATION BY LOT TESTING	NON-TECHNICAL
QA	IR-QA-MDL	DETERMINATION OF METHOD DETECTION LIMITS	NON-TECHNICAL
QA	IR-QA-PIPET	PIPET CALIBRATION	NON-TECHNICAL
QA	IR-QA-QAD	QUALITY ASSURANCE DEPARTMENT	NON-TECHNICAL
QA	IR-QA-QAPP_REV	REVIEW AND COMMUNICATION OF CLIENT QUALITY REQUIREMENTS	NON-TECHNICAL
QA	IR-QA-REFRBLANK	REFRIGERATOR STORAGE BLANKS	NON-TECHNICAL
QA	IR-QA-REV	GENERAL DATA REVIEW	NON-TECHNICAL
QA	IR-QA-SIGFIG	SIGNIFICANT FIGURES	NON-TECHNICAL
QA	IR-QA-SOPS	CREATION AND MAINTENANCE OF SOPS	NON-TECHNICAL
QA	IR-QA-SPEC	WAVELENGTH CHECK FOR SPECTROPHOTOMETERS	NON-TECHNICAL
QA	IR-QA-STDCNTRL	REAGENT AND STANDARD CONTROL AND DOCUMENTATION	NON-TECHNICAL
QA	IR-QA-SUBSAMP	SUBSAMPLING	NON-TECHNICAL
QA	IR-QA-THERMA	THERMOMETER CALIBRATION, TEMPERATURE MONITORING, AND DOCUMENTATION	NON-TECHNICAL
QA	IR-QA-TRAIN	TRAINING AND DOCUMENTATION	NON-TECHNICAL
QA	IR-QA-WATER	LABORATORY WATER QUALITY	NON-TECHNICAL
SAMPLE CONTROL	IR-SC-BPRESER	BOTTLE PRESERVATION	NON-TECHNICAL
SAMPLE CONTROL	IR-SC-COURIER	COURIER PROCEDURES	NON-TECHNICAL
SAMPLE CONTROL	IR-SC-FIELD	FIELD SAMPLING	NON-TECHNICAL
SAMPLE CONTROL	IR-SC-LOGIN	SAMPLE CONTROL	NON-TECHNICAL
SAMPLE CONTROL	IR-SC-MLOG	MANUAL ENTRY OF SAMPLES FOR SAMPLE CONTROL	NON-TECHNICAL
SAMPLE CONTROL	IR-SC- OBLIT_LABELS	OBLITARATION OF CLIENT LABELS	NON-TECHNICAL
WETCHEM	IR-WET-2540G	STANDARD METHOD 2540G (TOTAL FIXED AND VOLATILE SOLIDS IN SOLIDS AND SEMISOLIDS)	TECHNICAL
WETCHEM	IR-WET-300	EPA METHOD 300.0 and EPA SW9056 (THE DETERMINATION OF INORGANIC ANIONS BY ION CHROMATOGRAPHY)	TECHNICAL
WETCHEM	IR-WET-3001	EPA METHOD 300.1 (THE DETERMINATION OF INORGANIC ANIONS BY ION CHROMATOGRAPHY)	TECHNICAL
WETCHEM	IR-WET-3060A	ALKALINE DIGESTION PROCEDURE FOR HEXAVALENT CHROMIUM EPA 3060A (FOR METHOD EPA 7196 & EPA 7199)	TECHNICAL
WETCHEM	IR-WET-314.0	Determination of Perchlorate by Ion Chromatography- -EPA 314.0	TECHNICAL
WETCHEM	IR-WET-351_2	TOTAL KJELDAHL NITROGEN ( EPA METHOD 351.2)	TECHNICAL
WETCHEM	IR-WET-420	EPA METHOD 420.1/9065 (PHENOLICS, TOTAL RECOVERABLE)	TECHNICAL
WETCHEM	IR-WET-5310C	TOTAL AND DISSOLVED ORGANIC CARBON (STANDARD METHOD 5310C)	TECHNICAL
WETCHEM	IR-WET-5560C	SM 5560C (VOLATILE ORGANIC ACIDS BY DISTILLATION)	TECHNICAL
WETCHEM	IR-WET-5710B	TRIHALOMETHANE FORMATION POTENTIAL SM5710B	TECHNICAL

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DEPARTMENT	FILENAME	TITLE	TYPE
WETCHEM	IR-WET-7196	EPA METHOD 7196A/STANDARD METHODS 3500- CR D (HEXAVALENT CHROMIUM, COLORIMETRIC + ALKALINE DIGEST (EPA 3060A)	TECHNICAL
WETCHEM	IR-WET-ACID	ACIDITY, TITRIMETRIC (EPA METHOD 305.1/SM 2310B)	TECHNICAL
WETCHEM	IR-WET-ALK	ALKALINITY BY SM2320B	TECHNICAL
WETCHEM	IR-WET-AMENCN	STANDARD METHOD 4500-CN-G/9010B (CYANIDES, AMENABLE TO CHLORINATION)	TECHNICAL
WETCHEM	IR-WET-BOD	BIOCHEMICAL OXYGEN DEMAND / CARBONACEOUS BIOLOGICAL OXYGEN DEMAND (SM 5210B)	TECHNICAL
WETCHEM	IR-WET-CN_WAD	STANDARD METHODS 4500-CN, I - WEAK ACID DISSOCIABLE CYANIDE	TECHNICAL
WETCHEM	IR-WET-CO2	STANDARD METHOD 4500-CO2 (TITRIMETRIC METHOD FOR FREE CARBON DIOXIDE)	TECHNICAL
WETCHEM	IR-WET-COD	EPA METHOD 410.4/SM 5520D (CHEMICAL OXYGEN DEMAND)	TECHNICAL
WETCHEM	IR-WET-COND	SPECIFIC ELECTRICAL CONDUCTANCE (EPA METHOD 120.1 / STANDARD METHOD 2510B )	TECHNICAL
WETCHEM	IR-WET-CRIC	Determination of Hexavalent Chromium by Ion ChromatographyEPA Methods 7199 and 218.6	TECHNICAL
WETCHEM	IR-WET-FLUOR_ISE	EPA METHOD 9214/SM 4500F (FLUORIDE BY POTENTIOMETRIC, ION SELECTIVE ELECTRODE)	TECHNICAL
WETCHEM	IR-WET-HARD	HARDNESS BY TITRATION SM2340C	TECHNICAL
WETCHEM	IR-WET-ICMS	Determination of Perchlorate by Ion Chromatography/Mass Spectrometry, EPA 332.0	TECHNICAL
WETCHEM	IR-WET-INORG-CAL	Inorganic Calculations for Ion Balance, Langlier, Aggressive Index, Hardness, Unionized Sulfide, Larson-Skold Index, Sodium Absorption Ratio, Salinity	TECHNICAL
WETCHEM	IR-WET-MBAS	SM 5540C (ANION SURFACTANTS AS METHYLENE BLUE ACTIVE SUBSTANCES)	TECHNICAL
WETCHEM	IR-WET-MERCAP	MERCAPTANS, TOTALS (LACSD 258)	TECHNICAL
WETCHEM	IR-WET-NH3_KONE	AMMONIADETERMINATION BY AUTOMATED PHENATE METHOD (Konelab) EPA 350.1 AND SM4500 NH3-G	TECHNICAL
WETCHEM	IR-WET-NH3_TITR	NITROGEN AMMONIA (TITRIMETRIC) (SM4500- NH3-B, C)	TECHNICAL
WETCHEM	IR-WET-NH3ISE	AMMONIA POTENTIOMETRIC, ION SELECTIVE ELECTRODE (SM4500-NH3 D)	TECHNICAL
WETCHEM	IR-WET-OXY	STANDARD METHOD 4500-O-G (DISSOLVED OXYGEN)	TECHNICAL
WETCHEM	IR-WET-PAINT	PAINT FILTER LIQUIDS TEST, EPA 9095A AND EPA 9095B	TECHNICAL
WETCHEM	IR-WET-PCBSA	EPA 314.0 MOD. (DETERMINATION OF 4- CHLOROBENZENESULFONIC ACID (PCBSA) BY ION CHROMATOGRAPHY)	TECHNICAL
WETCHEM	IR-WET-PERM	STANDARD METHOD 4500-KMnO4 (POTASSIUM PERMANGANATE)	TECHNICAL
WETCHEM	IR-WET-PHOSP	EPA METHOD 365.3 (PHOSPHORUS, ALL FORMS)	TECHNICAL
WETCHEM	IR-WET-SPECGRAV	SPECIFIC GRAVITY BY MASS RATIO (SM2710F)	TECHNICAL
WETCHEM	IR-WET- SULFIDE_SPEC	SULFIDE, COLORIMETRIC, METHYLENE BLUE (STANDARD METHOD 4500 S2-)	TECHNICAL

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DEPARTMENT	FILENAME	TITLE	TYPE
WETCHEM	IR-WET- SULFIDE_TITR	EPA METHOD 9030B/9031/9034 - ACID SOLUBLE SULFIDES	TECHNICAL
WETCHEM	IR-WET-TDS	TOTAL DISSOLVED SOLIDS, FILTERABLE RESIDUE (SM2540C)	TECHNICAL
WETCHEM	IR-WET-THIO	THIOSULFATE BY TITRATION (LACSD 253B)	TECHNICAL
WETCHEM	IR-WET-TOC	EPA METHOD 415.1/SM 5310B OR EPA METHOD SW 9060 (TOTAL ORGANIC CARBON)	TECHNICAL
WETCHEM	IR-WET-TOTALCN	EPA 9010B, 9014 & SM 4500-CN~-B,C,E (CYANIDES, TOTAL)	TECHNICAL
WETCHEM	IR-WET-TRC	SM 4500-CI G ( CHLORINE AND CHLORAMINES)	TECHNICAL
WETCHEM	IR-WET-TS	SM2540B AND SM2540G (TOTAL SOLIDS / PERCENT SOLIDS / PERCENT MOISTURE, GRAVIMETRIC, DRIED AT 103-105 C)	TECHNICAL
WETCHEM	IR-WET-TSS	EPA METHOD 160.2/SM 2540D (TOTAL SUSPENDED SOLIDS; NON-FILTERABLE RESIDUE)	TECHNICAL
WETCHEM	IR-WET-TVS	EPA METHOD 160.4/SM2540E (FIXED AND VOLATILES RESIDUE IN WATERS)	TECHNICAL

## SECTION 20. EQUIPMENT (AND CALIBRATIONS) (NELAC 5.5.5)

### 20.1 <u>OVERVIEW</u>

The laboratory purchases the most technically advanced analytical instrumentation for sample analyses. Instrumentation is purchased on the basis of accuracy, dependability, efficiency and sensitivity. Each laboratory is furnished with all items of sampling, preparation, analytical testing and measurement equipment necessary to correctly perform the tests for which the laboratory has capabilities. Each piece of equipment is capable of achieving the required accuracy and complies with specifications relevant to the method being performed. Before being placed into use, the equipment (including sampling equipment) is calibrated and checked to establish that it meets its intended specification. The calibration routines for analytical instruments establish the range of quantitation. Calibration procedures are specified in laboratory SOPs. A list of laboratory instrumentation is presented in Table 20-1.

Equipment is only operated by authorized and trained personnel. Manufacturers instructions for equipment use are readily accessible to all appropriate laboratory personnel.

#### 20.2 PREVENTIVE MAINTENANCE

The laboratory follows a well-defined maintenance program to ensure proper equipment operation and to prevent the failure of laboratory equipment or instrumentation during use. This program of preventive maintenance helps to avoid delays due to instrument failure.

Routine preventive maintenance procedures and frequency, such as cleaning and replacements, should be performed according to the procedures outlined in the manufacturer's manual. Qualified personnel must also perform maintenance when there is evidence of degradation of peak resolution, a shift in the calibration curve, loss of sensitivity, or failure to continually meet one of the quality control criteria.

Table 20-2 lists examples of scheduled routine maintenance. It is the responsibility of each Department Manager to ensure that instrument maintenance logs are kept for all equipment in his/her department. Preventative maintenance procedures may be / are also outlined in analytical SOPs or instrument manuals. (Note: for some equipment, the log used to monitor performance is also the maintenance log. Multiple pieces of equipment may share the same log as long as it is clear as to which instrument is associated with an entry.)

Instrument maintenance logs are controlled and are used to document instrument problems, instrument repair and maintenance activities. Maintenance logs shall be kept for all major pieces of equipment. Instrument maintenance logs may also be used to specify instrument parameters.

- Documentation must include all major maintenance activities such as contracted preventive maintenance and service and in-house activities such as the replacement of electrical components, lamps, tubing, valves, columns, detectors, cleaning and adjustments.
- Each entry in the instrument log includes the Analyst's initials, the date, a detailed description of the problem (or maintenance needed/scheduled), a detailed explanation of the solution or maintenance performed, and a verification that the equipment is functioning properly (state what was used to determine a return to control. e.g. CCV run on *'date'* was acceptable, or

instrument recalibrated on 'date' with acceptable verification, etc.) must also be documented in the instrument records.

• When maintenance or repair is performed by an outside agency, service receipts detailing the service performed can be affixed into the logbooks adjacent to pages describing the maintenance performed. This stapled in page must be signed across the page entered and the logbook so that it is clear that a page is missing if only half a signature is found in the logbook.

If an instrument requires repair (subjected to overloading or mishandling, gives suspect results, or otherwise has shown to be defective or outside of specified limits) it shall be taken out of operation and tagged as out-of-service or otherwise isolated until such a time as the repairs have been made and the instrument can be demonstrated as operational by calibration and/or verification or other test to demonstrate acceptable performance. The laboratory shall examine the effect of this defect on previous analyses.

In the event of equipment malfunction that cannot be resolved, service shall be obtained from the instrument vendor manufacturer, or qualified service technician, if such a service can be tendered. If on-site service is unavailable, arrangements shall be made to have the instrument shipped back to the manufacturer for repair. Back up instruments, which have been approved, for the analysis shall perform the analysis normally carried out by the malfunctioning instrument. If the back up is not available and the analysis cannot be carried out within the needed timeframe, the samples shall be subcontracted.

If an instrument is sent out for service or transferred to another facility, it must be recalibrated and verified (including new initial MDL study) prior to return to lab operations.

# 20.3 <u>SUPPORT EQUIPMENT</u>

This section applies to all devices that may not be the actual test instrument, but are necessary to support laboratory operations. These include but are not limited to: balances, ovens, refrigerators, freezers, incubators, water baths, field sampling devices, temperature measuring devices, thermal/pressure sample preparation devices and volumetric dispensing devices if quantitative results are dependent on their accuracy, as in standard preparation and dispensing or dilution into a specified volume. All raw data records associated with the support equipment are retained to document instrument performance.

#### 20.3.1 <u>Weights and Balances</u>

The accuracy of the balances used in the laboratory is checked every working day, before use. All balances are placed on stable counter tops.

Each balance is checked prior to initial serviceable use with at least two certified ASTM type 1 weights spanning its range of use (weights that have been calibrated to ASTM type 1 weights may also be used for daily verification). ASTM type 1 weights used only for calibration of other weights (and no other purpose) are inspected for corrosion, damage or nicks at least annually and if no damage is observed, they are calibrated at least every 5 years by an outside calibration laboratory. Any weights (including ASTM Type 1) used for daily balance checks or other purposes are recalibrated/recertified annually to NIST standards (this may be done internally if laboratory maintains "calibration only" ASTM type 1 weights).

All balances are serviced annually by a qualified service representative, who supplies the laboratory with a certificate that identifies traceability of the calibration to the NIST standards.

All of this information is recorded in logs, and the recalibration/recertification certificates are kept on file. See laboratory SOP No. IR-QA-BAL, *Balance Calibration, Verification and Documentation*.

### 20.3.2 pH, Conductivity, and Turbidity Meters

The pH meters used in the laboratory are accurate to  $\pm$  0.1 pH units, and have a scale readability of at least 0.05 pH units. The meters automatically compensate for the temperature, and are calibrated with at least two working range buffer solutions before each use.

Conductivity meters are also calibrated before each use with a known standard to demonstrate the meters do not exceed an error of 1% or one umhos/cm.

Turbidity meters are also calibrated before each use. All of this information is documented in logs.

Consult pH and Conductivity, and Turbidity SOPs for further information.

#### 20.3.3 <u>Thermometers</u>

All thermometers are calibrated on an annual basis with a NIST-traceable thermometer. IR thermometers, digital probes and thermocouples are calibrated quarterly.

The NIST thermometer is recalibrated every five years (unless thermometer has been exposed to temperature extremes or apparent separation of internal liquid) by an approved outside service and the provided certificate of traceability is kept on file. The NIST thermometer(s) have increments of 1 degree (0.5 degree or less increments are required for drinking water microbiological laboratories), and have ranges applicable to method and certification requirements. The NIST traceable thermometer is used for no other purpose than to calibrate other thermometers.

All of this information is documented in logbooks. Monitoring method-specific temperatures, including incubators, heating blocks, water baths, and ovens, is documented in method-specific logbooks. See laboratory SOP No., IR-QA-THERMA, *Thermometer Calibration/Temperature Monitoring and Documentation*.

#### 20.3.4 <u>Refrigerators/Freezer Units, Waterbaths, Ovens and Incubators</u>

The temperatures of all refrigerator units and freezers used for sample and standard storage are monitored once each working day (twice for microbiology).

Ovens, waterbaths and incubators are monitored once each working day (twice for microbiology).

All of this equipment has a unique identification number, and is assigned a unique thermometer for monitoring.

Sample storage refrigerator temperatures are kept between >  $0^{\circ}$ C and  $\leq 6^{\circ}$ C.

Specific temperature settings/ranges for other refrigerators, ovens waterbaths, and incubators can be found in method specific SOPs.

All of this information is documented in Daily Temperature Logbooks and method-specific logbooks.

## 20.3.5 Autopipettors, Dilutors, and Syringes

Mechanical volumetric dispensing devices including burettes (except Class A Glassware) are given unique identification numbers and the delivery volumes are verified gravimetrically, at a minimum, on a quarterly basis. Glass micro-syringes with volumes of 20  $\mu$ L or greater are checked for accuracy every six months

For those dispensers that are not used for analytical measurements, a label is / can be applied to the device stating that it is not calibrated. Any device not regularly verified can not be used for any quantitative measurements.

#### 20.3.6 <u>Autoclaves</u>

Autoclaves are used to sterilize biological contaminants.

A maximum-registering thermometer is used to document the sterilization temperature of the autoclave with each use. Temperature sensitive tape is also used each cycle to indicate the contents have been processed. A biological indicator is processed monthly to determine that sterilization has been effective.

The build-in timer for the autoclave is verified against a stopwatch quarterly.

The pressure and temperature of the autoclave are verified yearly by an approved outside service technician annually.

#### 20.3.7 Field Sampling Devices (Isco Auto Samplers)

Each Auto Sampler (ISCO) is assigned a unique identification number and is recorded on the sampling documentation.

The Auto Sampler is calibrated each day of use based on the sample volume required for the specific sampling event. The results are recorded on the field sampling request form. The technican will adjust the delivery volume prior final set-up to ensure the correct aliquot is collected.

#### 20.4 INSTRUMENT CALIBRATIONS

Calibration of analytical instrumentation is essential to the production of quality data. Strict calibration procedures are followed for each method. These procedures are designed to determine and document the method detection limits, the working range of the analytical instrumentation and any fluctuations that may occur from day to day.

Sufficient raw data records are retained to allow an outside party to reconstruct all facets of the initial calibration. Records contain, but are not limited to, the following: calibration date, method, instrument, analyst(s) initials or signatures, analysis date, analytes, concentration, response, type of calibration (Avg RF, curve, or other calculations that may be used to reduce instrument responses to concentration.)

Sample results must be quantitated from the initial calibration and may not be quantitated from any continuing instrument calibration verification unless otherwise required by regulation, method or program.

If the initial calibration results are outside of the acceptance criteria, corrective action is performed and any affected samples are reanalyzed if possible. If the reanalysis is not possible, any data associated with an unacceptable initial calibration will be reported with appropriate data qualifiers (refer to Section 12).

**Note:** Instruments are calibrated initially and as needed after that and at least annually.

# 20.4.1 CALIBRATION STANDARDS

Calibration standards are prepared using the procedures indicated in the Reagents and Standards section of the determinative method SOP.

Standards for instrument calibration are obtained from a variety of sources. All standards are traceable to national or international standards of measurement, or to national or international standard reference materials.

The lowest concentration calibration standard that is analyzed during an initial calibration must be at or below the stated reporting limit for the method based on the final volume of extract (or sample).

The other concentrations define the working range of the instrument/method or correspond to the expected range of concentrations found in actual samples that are also within the working range of the instrument/method. Results of samples not bracketed by initial instrument calibration standards (within calibration range to 3 significant figures) must be reported as having less certainty, e.g., defined qualifiers or flags (additional information may be included in the case narrative). The exception to these rules is ICP methods or other methods where the referenced method does not specify two or more standards.

All initial calibrations are verified with a standard obtained from a second source and traceable to a national standard, when available (or vendor certified different lot if a second source is not available). For unique situations, such as air analysis where no other source or lot is available, a standard made by a different analyst at a different time or a different preparation would be considered a second source. This verification occurs immediately after the calibration curve has been analyzed, and before the analysis of any samples.

# 20.4.1.1 <u>Calibration Verification</u>

The calibration relationship established during the initial calibration must be verified initially and at least daily as specified in the laboratory method SOPs in accordance with the referenced

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analytical methods and NELAC (2003) standard, Section 5.5.5.10. The process of calibration verification applies to both external standard and internal standard calibration techniques, as well as to linear and non-linear calibration models. Initial calibration verification performed with a standard source secondary to the calibration standards (i.e second source standard), but continuing calibration verifications may use the same source standards as the calibration curve.

**Note:** The process of calibration verification referred to here is fundamentally different from the approach called "calibration" in some methods. As described in those methods, the calibration factors or response factors calculated during calibration are used to update the calibration factors or response factors used for sample quantitation. This approach, while employed in other EPA programs, amounts to a daily single-point calibration

All target analytes and surrogates, including those reported as non-detects, must be included in periodic calibration verifications for purposes of retention time confirmation and to demonstrate that calibration verification criteria are being met, i. e., RPD, per NELAC (2003) Standard, Section 5.5.5.10.

All samples must be bracketed by periodic analyses of standards that meet the QC acceptance criteria (e.g., calibration and retention time). The frequency is found in the determinative methods or SOPs.

**Note:** If an internal standard calibration is being used for GCMS then bracketing standards are not required, only daily verifications are needed. The results from these verification standards must meet the calibration verification criteria and the retention time criteria (if applicable).

Generally, the initial calibrations must be verified at the beginning of each 12-hour analytical shift during which samples are analyzed. (Some methods may specify more or less frequent verifications). The 12-hour analytical shift begins with the injection of the calibration verification standard (or the MS tuning standard in MS methods). The shift ends after the completion of the analysis of the last sample, QC, or standard that can be injected within 12 hours of the beginning of the shift.

A continuing instrument calibration verification (CCV) must be repeated at the beginning and, for methods that have quantitation by external calibration models, at the end of each analytical batch. Some methods have more frequent CCV requirements see specific SOPs. Most inorganic methods require the CCV to be analyzed after ever 10 samples or injections, including matrix or batch QC samples.

## 20.4.1.2 Verification of Linear and Non-Linear Calibrations

Calibration verification for calibrations involves the calculation of the percent drift or the percent difference of the instrument response between the initial calibration and each subsequent analysis of the verification standard. (These calculations are available in the laboratory method SOPs. Verification standards are evaluated based on the % Difference from the average CF or RF of the initial calibration or based on % Drift or % Recovery if a linear or quadratic curve is used.

Regardless of whether a linear or non-linear calibration model is used, if initial verification criterion is not met, then no sample analyses may take place until the calibration has been verified or a new initial calibration is performed that meets the specifications listed in the method SOPs. If the calibration cannot be verified after the analysis of a single verification standard, then adjust the instrument operating conditions and/or perform instrument maintenance, and analyze another aliquot of the verification standard. If the calibration cannot be verified with the second standard, then a new initial calibration is performed.

- When the acceptance criteria for the 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. Otherwise, the samples affected by the unacceptable calibration verification shall be reanalyzed after a new calibration curve has been established, evaluated and accepted.
- When the acceptance criteria for the calibration verification are exceeded low, i.e., low bias, those sample results may be reported if they exceed a maximum regulatory limit/decision level. Otherwise, the samples affected by the unacceptable verification shall be reanalyzed after a new calibration curve has been established, evaluated and accepted. Alternatively, a reporting limit standard may be analyzed to demonstrate that the laboratory can still support non-detects at their reporting limit.

#### 20.5 <u>TENTATIVELY IDENTIFIED COMPOUNDS (TICS) – GC/MS ANALYSIS</u>

For samples containing components not associated with the calibration standards, a library search may be made for the purpose of tentative identification. The necessity to perform this type of identification will be determined by the purpose of the analyses being conducted. Data system library search routines should not use normalization routines that would misrepresent the library or unknown spectra when compared to each other.

**Note:** If the TIC compound is not part of the client target analyte list but is calibrated by the laboratory and is both qualitatively and/or quantitatively identifiable, it should not be reported as a TIC. If the compound is reported on the same form as true TICs, it should be qualified and/or narrated that the reported compound is qualitatively and quantitatively (if verification in control) reported compared to a known standard that is in control (where applicable).

For example, the RCRA permit or waste delisting requirements may require the reporting of non-target analytes. Only after visual comparison of sample spectra with the nearest library searches may the analyst assign a tentative identification.

## 20.6 <u>GC/MS TUNING</u>

Prior to any GCMS analytical sequence, including calibration, the instrument parameters for the tune and subsequent sample analyses within that sequence must be set.

Prior to tuning/auto-tuning the mass spec, the parameters may be adjusted within the specifications set by the manufacturer or the analytical method. These generally don't need any adjustment but it may be required based on the current instrument performance. If the tune verification does not pass it may be necessary to clean the source or perform additional maintenance. Any maintenance is documented in the maintenance log.

# Table 20-1. Example: Instrumentation List

Department	Item	Manufacturer	Model	Serial Number	Installation Date
BTEX	Gas Chromatograph (FID/PID)	Hewlett Packard	5890 Series II	S/N3133A37156	1992
BTEX	Gas Chromatograph (FID/PID)	Hewlett Packard	5890 Series II	S/N3033A33301	1998
BTEX	Gas Chromatograph (FID/PID)	Hewlett Packard	5890 Series II	S/N3336A60066	1997
BTEX	Gas Chromatograph (FID/PID)	Hewlett Packard	5890 Series II	S/N3336A60064	1993
BTEX	Gas Chromatograph (FID/PID)	Hewlett Packard	5890 Series II	S/N3223A2733	1993
BTEX	Gas Chromatograph (FID/PID)	Hewlett Packard	5890 Series II	S/N3121A35567	1993
BTEX	Gas Chromatograph (FID/PID)	Hewlett Packard	5890A	S/N2750A15898	1997
BTEX	Gas Chromatograph (FID/PID)	Hewlett Packard	5890 Series II	S/N3203A41169	1993
BTEX	Gas Chromatograph (FID/PID)	Hewlett Packard	5890 Series II	S/N3203A40477	1993
BTEX	Gas Chromatograph (FID/PID/ELCD)	Hewlett Packard	5890 Series II	S/N3203A40699	1993
Extractions	Accelerated Solvent Extractor	Dionex	ASE 200	00120362	2001
Extractions	Accelerated Solvent Extractor	Dionex	ASE 200	99120782	2002
Extractions	Accelerated Solvent Extractor	Dionex	ASE 200	96090216	2001
Extractions	Accelerated Solvent Extractor	Dionex	ASE 200	97240463	2001
Extractions	Accelerated Solvent Extractor	Dionex	ASE 200E	07090746	2007
Extractions	Accelerated Solvent Extractor	Dionex	ASE 200	07090745	2007
Extractions	Flashpoint Tester	Koehler	K-162	10A/Y-2	1992
Extractions	Microwave	CEM	MARS5	MD3165	2010
Extractions	SPE-Controller	Horizon Technology	SPE-DEX	020357	2003

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Department	Item	Manufacturer	Model	Serial Number	Installation Date
GC SV Drinking Water	Gas Chromatograph (Dual ECD)	Agilent	6890N	US10244151	2010
GCMS SV Drinking Water	Gas Chromatograph/Mass Spectrometer	Agilent	6890/G1530N	US10243060	2010
GCMS SV Drinking Water	Gas Chromatograph/Mass Spectrometer	Agilent	6890/G1530N	US10226108	2010
GCMS SV Drinking Water	Gas Chromatograph/Mass Spectrometer	Agilent	6890N/5973N	US10232062/US21863660	2009
GCMS SV Drinking Water	Gas Chromatograph/Mass Spectrometer	Hewlett Packard	5890/5971A	3133A37717/2950A00539	2009
GCMS Vol. Drinking Water	Gas Chromatograph/Mass Spectrometer	Agilent	6890N / 5973	US00002015 / US10440578	2009
GCMS Vol. Drinking Water	Gas Chromatograph/Mass Spectrometer	Agilent	6890N / 5973	CN10503040 / US10461983	2009
GCMS Vol. Drinking Water	Gas Chromatograph/Mass Spectrometer	Agilent	6890N / 5973	CN10521030 / US40620627	2009
GCMS-Semi	Gas Chromatograph/Mass Spectrometer	Agilent	6890N/5975B/G 3171A	CN10636107/US62724086	2006
GCMS-Semi	Gas Chromatograph/Mass Spectrometer	Agilent	6890/5973/G257 9A	CN10427051/US41720775	2007
GCMS-Semi	Gas Chromatograph/Mass Spectrometer	Hewlett Packard	5890Ser.II/5971	3033A30488/3133A37717	1993
GCMS-Semi	Gas Chromatograph/Mass Spectrometer	Agilent	6890/5973/G258 9A	US10130035/US10480674	2003
GCMS-Semi	Gas Chromatograph/Mass Spectrometer	Hewlett Packard	5890Ser.II/5972	3235A46723	1995
GCMS-Semi	Gas Chromatograph/Mass Spectrometer	Hewlett Packard	5890Ser.II/5971	3140A39653	1993
GCMS-Semi	Gas Chromatograph/Mass Spectrometer	Hewlett Packard	5890Ser.II	3033A32428	1987
GCMS-Semi	Gas Chromatograph/Mass Spectrometer	Hewlett Packard	5890IIB/5971A	2921A24077/3188A02848	1992
GCMS-Semi	Gas Chromatograph/Mass Spectrometer	Agilent	7890/5975	CN10824037/US83140433	2010
GCMS-Semi	Gas Chromatograph/Mass Spectrometer	Agilent	7890/5975	CN10752039/US80148288	2010
GCMS-Semi	Gas Chromatograph/Mass Spectrometer	Agilent	6890N/5973/G25 78A	US10341048/US33210028	2005
GCMS-Semi	Gas Chromatograph/Mass Spectrometer	Agilent	6890/5973	US10226108/US21843299	2010
GCMS-Semi	Gas Chromatograph/Mass Spectrometer	Hewlett Packard	6890Plus (G1530A)/5973 (G1098A)	US00032006/US93122851	2008

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Department	Item	Manufacturer	Model	Serial Number	Installation Date
GCMS-Semi	Gas Chromatograph/Mass Spectrometer	Agilent	6890N/5973 Inert	CN10349032/US33220240	2008
GCMS- Volatiles	Gas Chromatograph/Mass Spectrometer	Hewlett Packard	6890/5973A	US00022931/US82311546	2000
GCMS- Volatiles	Gas Chromatograph/Mass Spectrometer	Agilent	6850/5973N	US00001207/US01140222	2001
GCMS- Volatiles	Gas Chromatograph/Mass Spectrometer	Agilent	6890N/5973	CN0523048/US43146864	2006
GCMS- Volatiles	Gas Chromatograph/Mass Spectrometer	Hewlett Packard	6890/5973A	US00007750/US70810354	2000
GCMS- Volatiles	Gas Chromatograph/Mass Spectrometer	Agilent	6890N / 5973 Inert	CN10345035 / US33220184	2009
GCMS- Volatiles	Gas Chromatograph/Mass Spectrometer	Agilent	6850/5973N	US0001947/US10340261	2002
GCMS- Volatiles	Gas Chromatograph/Mass Spectrometer	Hewlett Packard	5890II/5971A	3235A46434/3040A01409	2000
GCMS- Volatiles	Gas Chromatograph/Mass Spectrometer	Agilent	6850/5973N	US00002140/US10440793	2002
GCMS- Volatiles	Gas Chromatograph/Mass Spectrometer	Agilent	6850/5973N	US00002860/US21843317	2003
GCMS- Volatiles	Gas Chromatograph/Mass Spectrometer	Agilent	6890/5973	US00034262/US01112246	2004
GCMS- Volatiles	Gas Chromatograph/Mass Spectrometer	Agilent	6850/5973	US00001206/US01140215	2001
GCMS- Volatiles	Gas Chromatograph/Mass Spectrometer	Agilent	6890N/5973	US00001682/US92522712	2001
GCMS- Volatiles	Gas Chromatograph/Mass Spectrometer	Hewlett Packard	6890/5973A	US00020097/US72810389	1999
GCMS- Volatiles	Gas Chromatograph/Mass Spectrometer	Agilent	6890N/5973	US10206070/US10462145	2006
GCMS- Volatiles	Gas Chromatograph/Mass Spectrometer	Agilent	6890N/5973 inert	CN10339005/US35120285	2007
GCMS- Volatiles	Gas Chromatograph/Mass Spectrometer	Agilent	6890N/5973N	US10222064/US10462085	2006
GCMS- Volatiles	Gas Chromatograph/Mass Spectrometer	Hewlett Packard	589011/5972	3336A60514/3524A02884	1997
GCMS- Volatiles	Gas Chromatograph/Mass Spectrometer	Agilent	6890N/5973	CN10318007/US30945517	2004
GCMS- Volatiles	Gas Chromatograph/Mass Spectrometer	Agilent	6890N/5973	CN01521014/US44647184	2005
GCMS- Volatiles	Gas Chromatograph/Mass Spectrometer	Agilent	6890N/5973	CN10318006/US30945515	2004
GC-Semi	Gas Chromatograph	Agilent	6890N/1530N	CN10551059	2007

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Department	Item	Manufacturer	Model	Serial Number	Installation Date
GC-Semi	Gas Chromatograph (Dual ECD)	Agilent	6890N/G1540N	CN10551052	Not available
GC-Semi	Gas Chromatograph (Dual ECD)	Agilent	6890N	US10215019	2002
GC-Semi	Gas Chromatograph (Dual ECD)	Agilent	6890N/G1530N	US10322076	2007
GC-Semi	Gas Chromatograph (Dual ECD)	Agilent	7890A/G3440A	CN10741034	2007
GC-Semi	Gas Chromatograph (Dual ECD)	Agilent	6890N/G1540N	US10423014	Not available
GC-Semi	Gas Chromatograph (Dual ECD)	Agilent	6890N/G1540N	US10423015	Not available
GC-Semi	Gas Chromatograph (Dual ECD)	Agilent	6890N/G1530N	US10250081	Not available
GC-Semi	Gas Chromatograph (Dual ECD)	Hewlett Packard	5890 Series II	336A51142	Not available
GC-Semi	Gas Chromatograph (Dual ECD)	Hewlett Packard	5890 Series II	3336A56851	2010
GC-Semi	Gas Chromatograph (Dual ECD)	Hewlett Packard	5890 Series II	3223A43015	Not available
GC-Semi	Gas Chromatograph (Dual FID)	Agilent	6890N/G1540N	US10546010	2007
GC-Semi	Gas Chromatograph (Dual FID)	Hewlett Packard	5890 Series II	3126A36534	Not available
GC-Semi	Gas Chromatograph (Dual FID)	Agilent	6890N/G1540N	US10546009	2007
GC-Semi	Gas Chromatograph (FID/PID)	Agilent	5890 Series II	S/N3133A37568	2008
GC-SV Drinking Water	Gas Chromatograph (Dual ECD)	Agilent	6890N	US10402034	2009
GC-SV Drinking Water	Gas Chromatograph (Dual ECD)	Agilent	6890N	US10244152	2009
GC-SV Drinking Water	Gas Chromatograph (Dual ECD)	Agilent	6890N	US10212094	2009
GC-SV Drinking Water	Gas Chromatograph (Dual ECD)	Agilent	6890N	CN10631072	2010
HPLC	HPLC (DAD)	Hewlet Packard	G1316A	US54000547	2009
HPLC	HPLC (DAD)	Agilent	1100	DE14914766	2009
HPLC	HPLC (FLD)	Agilent	1100	DE14903629	2009
HPLC	HPLC (FLD)	Agilent	1100	DE14903835	2009
HPLC	HPLC (MWD)	Hewlett Packard	Series 1050	2807G00138	2008
Inorganic Prep	pH Meter	Mettler Toledo	SevenEasy	1227116127	Not available
Metals	GFAA	Perkin Elmer	SIMAA 6000	5016	1993
Metals	Hg FIAS Mercury Analyzer	Perkin Elmer	FIMS 400	4167	1995
Metals	Hg FIAS Mercury Analyzer	Perkin Elmer	FIMS 400	401510021001	2010
Metals	Inductively Coupled Plasma Spectrophotometer	Perkin Elmer	Optima 4300 DV	077N1100901	2002

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Department	ltem	Manufacturer	Model	Serial Number	Installation Date
Metals	Inductively Coupled Plasma Spectrophotometer	Perkin Elmer	Optima 5300DV	077N5112802	2006
Metals	Inductively Coupled Plasma Spectrophotometer/MS	Agilent	7700 series G3281A	JP09480189	2010
Metals	Inductively Coupled Plasma Spectrophotometer/MS	Perkin Elmer	ELAN 6100E	1650004	2001
Metals	Inductively Coupled Plasma Spectrophotometer/MS	Perkin Elmer	ELAN 6100E	G1970008	2004
Metals	Mercury Analyzer	Leeman	Hydra AF Gold+	AFG+ 3010	2010
Metals	Microwave Digestion	CEM	MARS XPRESS	MD8441	2010
Microbiology	Compound Microscope (10x100)	VWR	BB-P/TB-P	V167531	2009
Microbiology (Irvine)	Incubator for Micro	Not available	Not available	Not available	2009
Microbiology (Irvine)	Incubator for Micro (35C)	VWR	1915	800902	2009
Microbiology (Irvine)	Incubator for Micro (35C)	VWR	1915	1102003	2009
Microbiology (Irvine)	Incubator for Micro (55C)	Fisher Scientific	516D	502N0034	2009
Microbiology (Irvine)	Quanti Tray Sealer	ldexx	89-10894-04	6345	2009
Microbiology (Irvine)	Stereo Microscope with Fluorescence source	VWR	HF-745	V167693	2009
Microbiology (Irvine)	UV Lamp (big)	UVP	C-65	95025701	2009
Microbiology (Irvine)	UV Lamp (small)	UVP	CC-10	95007201	2009
Microbiology (Irvine)	Water Bath, circulating (44.5C)	Precision	2862	200035	2009
Microbiology (Irvine)	Water Bath, circulating (44.5C)	Precision	2866	202462-195	2009
Microbiology (Ontario)	Incubator for Micro (35C)	Fisher Scientific	Not available	Not available	Not available
Microbiology (Ontario)	Water Bath, circulating (44.5C)	Fisher Scientific	2866	202462-195	3/15/2007
Microbiology (Ontario)	Water Bath, circulating (44.5C)	Fisher Scientific	Not available	Not available	Not available
Microbiology (Ontario)	ph meter	Orion	ea940	tz22a	Not available
Microbiology (Ontario)	Autoclave # 2	Sanyo	mls-3786	3y0521	Sep-05
Microbiology (Ontario)	QT Sealer	Idexx	89-10894-02	4025	Not available
Microbiology (Ontario)	Rotator shaker	Thermolyne	m49235		Not available
Microbiology (Ontario)	Hot plate	VWR	58849-001	50317009	2002
Mobile Lab	Fixed Wavelength Infrared Spectrophotometer	Foxboro	Miran1FF	2733	Not available
Mobile Lab	Gas Chromatograph/Mass Spectrometer	Hewlett Packard/O.I.	6890/5973	US00029799	Not available

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Department	Item	Manufacturer	Model	Serial Number	Installation Date
Wetchem	Ammonia Probe	Orion	96-12		Not available
Wetchem	BOD auto-analyzer	Mantek	Tetra Rinse	MS-004-189	Not available
Wetchem	BOD probe	Jenco			Not available
Wetchem	Conductivity Meter	VWR	21800-012	Q022545	2009
Wetchem	Conductivity/Dissolved Oxygen Probe	Corning	M90	001253	Not available
Wetchem	Digestion Unit	Gerhardt	Kjeldatherm KB	4062216	2007
Wetchem	Drying Oven	Fisher	Isotemp Standard OB702F	2153100457536	2010
Wetchem	Drying Oven	Fisher	Isotemp Standard OB602G	2032100355237	2010
Wetchem	Drying Oven	Fisher	630G	801N0001	Not available
Wetchem	Drying Oven	Scientific Products	DX-61	194002	Not available
Wetchem	Drying Oven	Lab Line			Not available
Wetchem	Fluoride Probe	Orion	96-09	9609BN	Not available
Wetchem	Incubator for BOD	VWR	2020	6003205	2002
Wetchem	Incubator for BOD	Fisher	307C	00037-090-00	2002
Wetchem	Ion Chromatograph	Metrohm	761	NA	2010
Wetchem	Ion Chromatograph	Metrohm	881	1881000007119	2010
Wetchem	Ion Chromatograph	Dionex	LC 25	02050420	2005
Wetchem	Ion Chromatograph	Metrohm	861/838	1861004003159/1838001009124	2010
Wetchem	Ion Chromatograph	Dionex	AD 25	01070608	2007
Wetchem	Ion Chromatograph	Dionex	LC 30	97040546	2002
Wetchem	Ion Chromatograph	Dionex	LC20	94010215	2007
Wetchem	Ion Chromatograph	Dionex	CD25/IP25	04060626/04060363	2008
Wetchem	Ion Chromatograph	Dionex	DX-100	94120366	1997
Wetchem	Ion Chromatograph	Dionex	CD 25	01090576	2002
Wetchem	Ion Chromatograph	Dionex	ICS-1000	03110585	2002
Wetchem	Ion Chromatograph	Dionex	CD 20	98060923	1996
Wetchem	Ion Chromatograph	Dionex	CD25A/AS 40	03070269/96060542	2007
Wetchem	lon Chromatograph (with UV/VIS)	Dionex	AD 20	98020642	2000
Wetchem	Ion Chromatograph/Mass Spectrometer	Metrohm (IC) / Agilent (MS)	LC30- 1/LC110/IC800	1820023004102/US34800214	2005
Wetchem	pH Meter	Beckman	Phi - 32		Not available
Wetchem	pH Meter	Beckman	Phi - 40		Not available
Wetchem	pH Meter	Beckman	Phi - 40		Not available
Wetchem	pH Probe	Orion	91-56	9156000	Not available
Wetchem	TOC Analyzer	O.I. Analytical	Solids	C905776109	2009
Wetchem	TOC Analyzer	Tekmar- Dohrmann	Phoenix 8000	US02106006	2002
Wetchem	TOC Analyzer	Shimadzu	5000A	33N01036A	1998
Wetchem	UV/VS Spectrometer	Thermo Spectronic	Genesys20	3SGG06B0117	2002

Instrument	Procedure	Frequency
Graphite Furnace	Inspect graphite tube	Daily
(GFAA)	Inspect contact rings	Daily
	Clean windows	Daily
	Align lamp	Daily
Mercury Analyzer	Check tubing for wear	Daily
	Fill rinse tank with 10% HCI	Daily
	Fill reductant bottle with 10% Stannous Chloride	Daily
ICP	Check/replace pump tubing	Daily/as needed
	Check liquid argon supply Check fluid level in waste container	Daily Daily
	Check/clean/replace filters	Daily/as needed
	Check torch	Daily
	Clean torch and nebulizer	As needed
ICP MS	Check/replace pump tubing	Daily/as needed
	Inspect torch and injector cones	Daily
	Clean/replace ion lens	As needed
	Replace torch o-rings	As needed
	Check/replace gas filters	As needed
	Change rough pump oil	As needed
	Check chiller water level	Weekly
UV-Vis	Clean sample holder	As required
Spectrophotometer	Precision check/alignment of flow cell Wavelength verification check	As required Semi-annually
0		•
Gas Chromatograph/Mass	Bake trap (VOC only) Clean source	Daily As needed
Spectometer (GCMS)	Check/change vacuum pump oil	As needed Annually, as needed
	Clean injectors; replace liners (SVOC only)	Daily
	Replace column	As needed
	Clean cooling fan grills	Semiannually
Gas Chromatograph	Change septum	As needed
(GC)	Check gases	Daily
	Replace or clip column	As needed
	Clean injectors; replace liners	As needed
	Clean cooling fan grills	Semiannually
Electron Capture	Detector wipe test (Ni-63)	Semi-annually
Detector (ECD)	Detector cleaning	Sent out, as needed
Flame Ionization Detector (FID)	Detector cleaning	As required
Flame Photoionization Detector (FPD)	Clean and/or Replace Lamp	As required
Photoionization	Change O-rings	As required
Detector (PID)	Clean lamp window	As required

### Table 20-2. Example: Schedule of Routine Maintenance

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Instrument	Procedure	Frequency
lon Chromatograph (IC)	Replace column disks Change guard columns Check pump seals Replace tubing Replace suppressor Check fluid level in waste container Clean cooling fan grills	As required As required As required As required As required Daily Semiannually
Balances	Class "S" traceable weight check Clean pan and check if level Outside calibration service	Daily, when used Daily At least Annually
Conductivity Meter	0.01 M KCI calibration Conductivity cell cleaning	Daily As required
Turbidimeter	Check light bulb Clean sample holder	Daily, when used Daily, when used
Deionized/Distilled Water	Daily conductivity check Check deionizer light Monitor for VOA's System cleaning Replace cartridge & large mixed bed resins	Daily Daily As required As required As required
Drying Ovens	Temperature monitoring Temperature adjustments	When used As required
Refrigerators/ Freezers	Temperature monitoring Temperature adjustment Defrosting/cleaning	Daily As required As required
pH/Specific Ion Meter	Calibration/check slope Clean electrode	Daily As required
BOD Incubator	Temperature monitoring Incubator cleaning	Daily As required
Centrifuge	Check brushes and bearings	As needed
Water baths	Temperature monitoring Water replaced	Daily Monthly or as needed
Automated Solvent Extraction units (ASE)	Check solvent reservoirs Check tubing	Daily Daily
TurboVaps	Check gas lines Check water level Calibrate temperature	Daily Daily Annually
Total Organic Carbon Analyzer	Check gas flow Check reagent reservoir levels Replace o-rings Check autosampler needle Replace scrubbers Replace catalyst	Daily Daily As needed Daily Annually As needed
Automated Analyzer	Clean sampler Check all tubing Clean detector Clean optics and cells	Daily Daily Daily Daily

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Instrument	Procedure	Frequency	
Infrared Spectrophotometer (IR)	Clean lens/optimize	As needed	
Flashpoint Apparatus	Check gas line for leaks	Daily	
	Check stirrer speed	Annually	
Rotators	Verify rotation speed	Annually	
UNCONTROLLED			

### SECTION 21. MEASUREMENT TRACEABILITY (NELAC 5.5.6)

# 21.1 <u>OVERVIEW</u>

Traceability of measurements shall be assured using a system of documentation, calibration, and analysis of reference standards. Laboratory equipment that are peripheral to analysis and whose calibration is not necessarily documented in a test method analysis or by analysis of a reference standard shall be subject to ongoing certifications of accuracy. At a minimum, these must include procedures for checking specifications of ancillary equipment: balances, thermometers, temperature, Deionized (DI) and Reverse Osmosis (RO) water systems, automatic pipettes and other volumetric measuring devices. (Refer to Section 20.3). With the exception of Class A Glassware. (Microsyringes are verified at least semi-annually or disposed of after 6 months of use.) Wherever possible, subsidiary or peripheral equipment is checked against standard equipment or standards that are traceable to national or international standards. Class A glassware should be routinely inspected for chips, acid etching or deformity. If the Class A glassware is suspect, the accuracy of the glassware will be assessed prior to use.

### 21.2 <u>NIST-TRACEABLE WEIGHTS AND THERMOMETERS</u>

Reference standards of measurement shall be used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated.

For NIST-traceable weights and thermometers, the laboratory requires that all calibrations be conducted by a calibration laboratory accredited by A2LA, NVLAP (National Voluntary Laboratory Accreditation Program), APLAC (Asia-Pacific Laboratory Accreditation Cooperation), or EA (European Cooperation for Accreditation). A certificate and scope of accreditation is kept on file at the laboratory.

### 21.3 **REFERENCE STANDARDS / MATERIALS**

Reference standards/materials, where commercially available, are traceable to certified reference materials. Commercially prepared standard materials are purchased from vendors accredited by A2LA, and/or NVLAP, with an accompanying Certificate of Analysis that documents the standard purity. If a standard cannot be purchased from a vendor that supplies a Certificate of Analysis, the purity of the standard is documented by analysis. The receipt of all reference standards must be documented. Reference standards are labeled with a unique Standard Identification Number and expiration date. All documentation received with the reference standard is retained as a QC record and references the Standard Identification Number.

All reference, primary and working standards/materials, whether commercially purchased or laboratory prepared, must be checked regularly to ensure that the variability of the standard or material from the 'true' value does not exceed method requirements. The accuracy of calibration standards is checked by comparison with a standard from a second source. In cases where a second standard manufacturer is not available, a vendor certified different lot is acceptable for use as a second source. For unique situations, such as air analysis where no other source or

lot is available, a standard made by a different analyst would be considered a second source. The appropriate Quality Control (QC) criteria for specific standards are defined in laboratory SOPs. In most cases, the analysis of an Initial Calibration Verification (ICV) or LCS (where there is no sample preparation) is used as the second source confirmation. These checks are generally performed as an integral part of the analysis method (e.g. calibration checks, laboratory control samples).

All standards and materials must be stored and handled according to method or manufacturer's requirements in order to prevent contamination or deterioration. Refer to the Corporate Environmental Health & Safety Manual or laboratory SOPs. For safety requirements, please refer to method SOPs and the laboratory Environmental Health and Safety Manual.

# 21.4 <u>DOCUMENTATION AND LABELING OF STANDARDS, REAGENTS, AND</u> <u>REFERENCE MATERIALS</u>

Reagents must be at a minimum the purity required in the test method. The date of reagent receipt and the expiration date are documented. The lots for most of the common solvents and acids are tested for acceptability prior to company wide purchase. [Refer to TestAmerica's Corporate SOP (CA-Q-S-001), Solvent and Acid Lot Testing and Approval.]

All manufacturer or vendor supplied Certificate of Analysis or Purity must be retained, stored appropriately, and readily available for use and inspection. These records are maintained in organized files within each department. Records must be kept of the date of receipt and date of expiration of standards, reagents and reference materials. In addition, records of preparation of laboratory standards, reagents, and reference materials must be retained, stored appropriately, and be readily available for use and inspection. For detailed information on documentation and labeling, please refer to the laboratory SOP No., IR-QA-STDCNTRL, *Reagent and Standard Preparation, Control, and Documentation*.

Commercial materials purchased for preparation of calibration solutions, spike solutions, etc.., are usually accompanied with an assay certificate or the purity is noted on the label. If the assay purity is 96% or better, the weight provided by the vendor may be used without correction. If the assay purity is less than 96% a correction will be made to concentrations applied to solutions prepared from the stock commercial material.

**21.4.1** All standards, reagents, and reference materials must be labeled in an unambiguous manner. Standards are logged into the laboratory's LIMS system, and are assigned a unique identification number. The following information is typically recorded in the electronic database within the LIMS.

- Standard ID
- Description of Standard
- Department
- Preparer's name
- Final volume and number of vials prepared
- Solvent type and lot number
- Preparation Date

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- Expiration Date
- Standard source type (stock or daughter)
- Standard type (spike, surrogate, other)
- Parent standard ID (if applicable)
- Parent Standard Analyte Concentration (if applicable)
- Parent Standard Amount used (if applicable) ROLLED
- Component Analytes
- Final concentration of each analyte
- Comment box (text field)

Records are maintained electronically for standard and reference material preparation. These records show the traceability to purchased stocks or neat compounds. These records also include method of preparation, date of preparation, expiration date and preparer's name or initials. Preparation procedures are provided in the Method SOPs.

21.4.2 All standards, reagents, and reference materials must be clearly labeled with a minimum of the following information:

- Expiration Date (include prep date for reagents)
- Standard ID from LIMS
- Special Health/Safety warnings if applicable

21.4.3 In addition, the following information may be helpful:

- Date of receipt for commercially purchased items or date of preparation for laboratory prepared items
- Date opened (for multi-use containers, if applicable)
- Description of standard (if different from manufacturer's label or if standard was prepared in the laboratory)
- Concentration (if applicable)
- Initials of analyst preparing standard or opening container

All containers of prepared reagents must include a preparation date, expiration date and an ID number to trace back to preparation.

Procedures for preparation of reagents can be found in the Method SOPs.

Standard ID numbers must be traceable through associated logbooks, worksheets and raw data.

All reagents and standards must be stored in accordance to the following priority: 1) with the manufacturer's recommendations; 2) with requirements in the specific analytical methods as specified in the laboratory SOP.

### SECTION 22. SAMPLING (NELAC 5.5.7)

### 22.1 <u>OVERVIEW</u>

The laboratory provides sampling services. Sampling procedures are described in the SOPs IR-SC-FIELD, *Field Sampling*.

### 22.2 SAMPLING CONTAINERS

The laboratory offers clean sampling containers for use by clients. These containers are obtained from reputable container manufacturers and meet EPA specifications as required. Any certificates of cleanliness that are provided by the supplier are maintained at the laboratory.

# 22.2.1 <u>Preservatives</u>

Upon request, preservatives are provided to the client in pre-cleaned sampling containers. In some cases containers may be purchased pre-preserved from the container supplier. Whether prepared by the laboratory or bought pre-preserved, the grades of the preservatives are at a minimum:

- Hydrochloric Acid Reagent ACS (Certified VOA Free) or equivalent
- Methanol Purge and Trap grade
- Nitric Acid Instra-Analyzed or equivalent
- Sodium Bisulfate ACS Grade or equivalent
- Sodium Hydroxide Instra-Analyzed or equivalent
- Sulfuric Acid Instra-Analyzed or equivalent
- Sodium Thiosulfate ACS Grade or equivalent

# 22.3 DEFINITION OF HOLDING TIME

The date and time of sampling documented on the COC form establishes the day and time zero. As a general rule, when the maximum allowable holding time is expressed in "days" (e.g., 14 days, 28 days), the holding time is based on calendar day measured. Holding times expressed in "hours" (e.g., 6 hours, 24 hours, etc.) are measured from date and time zero. The first day of holding time ends twenty-four hours after sampling. Holding times for analysis include any necessary reanalysis.

### 22.4 SAMPLING CONTAINERS, PRESERVATION REQUIREMENTS, HOLDING TIMES

The preservation and holding time criteria specified in the laboratory SOPs are derived from the source documents for the methods. If method required holding times or preservation requirements are not met, the reports will be qualified using a flag, footnote or case narrative. As soon as possible or "ASAP" is an EPA designation for tests for which rapid analysis is advised, but for which neither EPA nor the laboratory have a basis for a holding time.

### 22.5 SAMPLE ALIQUOTS / SUBSAMPLING

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Taking a representative sub-sample from a container is necessary to ensure that the analytical results are representative of the sample collected in the field. The size of the sample container, the quantity of sample fitted within the container, and the homogeneity of the sample need consideration when sub-sampling for sample preparation. It is the laboratory's responsibility to take a representative subsample or aliquot of the sample provided for analysis.

Analysts should handle each sample as if it is potentially dangerous. At a minimum, safety glasses, gloves, and lab coats must be worn when preparing aliquots for analysis.

Guidelines on taking sample aliquots & subsampling are located in the laboratory SOP, No. IR-QA-SUBSAMP, Subsampling.

# SECTION 23. HANDLING OF SAMPLES (NELAC 5.5.8)

Sample management procedures at the laboratory ensure that sample integrity and custody are maintained and documented from sampling/receipt through disposal.

# 23.1 CHAIN OF CUSTODY (COC)

The COC form is the written documented history of any sample and is initiated when bottles are sent to the field, or at the time of sampling. This form is completed by the sampling personnel and accompanies the samples to the laboratory where it is received and stored under the laboratory's custody. The purpose of the COC form is to provide a legal written record of the handling of samples from the time of collection until they are received at the laboratory. It also serves as the primary written request for analyses from the client to the laboratory. The COC form acts as a purchase order for analytical services when no other contractual agreement is in effect. An example of a COC form may be found in Figure 23-1.

# 23.1.1 Field Documentation

The information the sampler needs to provide at the time of sampling on the container label is:

- Sample identification
- Date and time
- Preservative

During the sampling process, the COC form is completed and must be legible (see Figure 23-1). This form includes information such as:

- Client name, address, phone number and fax number (if available)
- Project name and/or number
- The sample identification
- Date, time and location of sampling
- Sample collectors name
- The matrix description
- The container description
- The total number of each type of container
- Preservatives used
- Analysis requested
- Requested turnaround time (TAT)
- Any special instructions
- Purchase Order number or billing information (e.g. quote number) if available
- The date and time that each person received or relinquished the sample(s), including their signed name.

The samples are stored in a cooler with ice, as applicable, and remain solely in the possession of the client's field technician until the samples are delivered to the laboratory. The sample collector must assure that each container is in his/her physical possession or in his/her view at

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all times, or stored in such a place and manner to preclude tampering. The field technician relinquishes the samples in writing on the COC form to the sample control personnel at the laboratory or to a TestAmerica courier. Samples are only considered to be received by lab when personnel at the laboratory have physical contact with the samples.

**Note:** Independent couriers are not required to sign the COC form. The COC is usually kept in the sealed sample cooler. The receipt from the courier is stored in log-in by date; it lists all receipts each date.

# 23.1.2 Legal / Evidentiary Chain-of-Custody

If samples are identified for legal/evidentiary purposes on the COC, login will complete the custody seal retain the shipping record with the COC, and initiate an internal COC for laboratory use by analysts and a sample disposal record.

# 23.2 SAMPLE RECEIPT

Samples are received at the laboratory by designated sample receiving personnel and a unique laboratory project identification number is assigned. Each sample container shall be assigned a unique sample identification number that is cross-referenced to the client identification number such that traceability of test samples is unambiguous and documented. Each sample container is affixed with a durable sample identification label. Sample acceptance, receipt, tracking and storage procedures are summarized in the following sections.

# 23.2.1 Laboratory Receipt

When samples arrive at the laboratory, sample receiving personnel inspect the coolers and samples. The integrity of each sample must be determined by comparing sample labels or tags with the COC and by visual checks of the container for possible damage. This inspection is documented by using a Project Receipt Checklist (PRC) See figure 23-3. Any non-conformance, irregularity, or compromised sample receipt must be documented on a Notification of Discrepancy form (NOD) and brought to the immediate attention of the client via the PM. The COC, shipping documents, documentation of any non-conformance, irregularity, or compromised sample receipt instructions become part of the project record. See laboratory SOP IR-SC-LOGIN for more details.

# 23.2.1.1 Unique Sample Identification

All samples that are processed through the laboratory receive a unique sample identification to ensure that there can be no confusion regarding the identity of such samples at anytime. This system includes identification for all sample containers received at the laboratory.

The laboratory assigns a unique identification (e.g., Sample ID) code made up of the following information (consisting of 6 components):

- laboratory location code (single letter)
- calendar year code (single letter)
- calendar month code (single letter)
- login ID number (4-digit number consecutive for the month)
- sample number (2-digit number based on sequence in COC)

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• specific sample container (one or two letter, A-Z, AA-AZ, etc)

### Example: IUA0214-01A

The above example states that the sample is

- From TestAmerica Irvine Laboratory (Location I).
- Logged in the year 2011 (U=2011, where A = 1991)
- Logged in the month of January (A=January, B=February, etc)
- Login number 0214 (214th workorder logged at Irvine for January)
- Sample number 01
- Container A (where A refers to a specific single container for sample 01

# 23.3 SAMPLE ACCEPTANCE POLICY

The laboratory has a written sample acceptance policy (Figure 23-2) that clearly outlines the circumstances under which samples shall be accepted or rejected. These include:

- a COC filled out completely;
- samples must be properly labeled;
- proper sample containers with adequate volume for the analysis (Sampling Guide) and necessary QC;
- samples must be preserved according to the requirements of the requested analytical method (Sampling Guide);
- sample holding times must be adhered to (Sampling Guide);
- the project manager will be notified if any sample is received in damaged condition.

Data from samples which do not meet these criteria are flagged and the nature of the variation from policy is defined. A copy of the sample acceptance policy is provided to each client prior to shipment of samples.

- **23.3.1** After inspecting the samples, the sample receiving personnel sign and date the COC form, make any necessary notes of the samples' conditions and store them in appropriate refrigerators or storage locations.
- **23.3.2** Any deviations from these checks that question the suitability of the sample for analysis, or incomplete documentation as to the tests required will be resolved by consultation with the client. If the sample acceptance policy criteria are not met, the laboratory shall either:
  - Retain all correspondence and/or records of communications with the client regarding the disposition of rejected samples, or
  - Fully document any decision to proceed with sample analysis that does not meet sample acceptance criteria.

Once sample acceptance is verified, the samples are logged into the LIMS according SOP No. IR-SC-LOGIN.

# 23.4 SAMPLE STORAGE

In order to avoid deterioration, contamination or damage to a sample during storage and handling, from the time of receipt until all analyses are complete, samples that are stored in an organized manner in refrigerators or freezers (for analyses requiring thermal preservation) or secure shelving in the sample receiving area for acid-preserved water containers requiring only metals analysis. In addition, samples to be analyzed for volatile organic parameters are stored in separate refrigerators designated for volatile organic parameters only. Samples are never to be stored with reagents, standards or materials that may create contamination.

To ensure the integrity of the samples during storage, refrigerator blanks are maintained in the volatile sample refrigerators and analyzed every two weeks. See laboratory SOP No. IR-QA-REFBLANK, *Refrigerator Storage Blank*, for full details.

Analysts and technicians retrieve the sample container allocated to their analysis from the designated refrigerator and place them on carts, analyze the sample, and return the remaining sample or empty container to the refrigerator from which it originally came. All unused portions of samples, including empty sample containers, are returned to the secure sample control area. All samples are kept in the refrigerators for two to four weeks after analysis, which meets or exceeds most sample holding times. After two to four weeks the samples are moved to dry room temperature, sample archive area where they are stored for an additional two to four weeks before they are disposed of. This four to eight week holding period allows samples to be checked if a discrepancy or question arises. Special arrangements may be made to store samples for longer periods of time. This extended holding period allows additional metal analyses to be performed on the archived sample and assists clients in dealing with legal matters or regulatory issues.

Access to the laboratory is controlled such that sample storage need not be locked at all times unless a project specifically demands it. Samples are accessible to laboratory personnel only. Visitors to the laboratory are prohibited from entering the refrigerator and laboratory areas unless accompanied by an employee of TestAmerica.

# 23.5 HAZARDOUS SAMPLES AND FOREIGN SOILS

To minimize exposure to personnel and to avoid potential accidents, hazardous and foreign soil samples are stored in an isolated area designated for hazardous waste only. For any sample that is known to be hazardous at the time of receipt or, if after completion of analysis the result exceeds the acceptable regulatory levels, a Hazardous Sample Notice must be completed by the analyst. This form may be completed by Sample Control, Project Managers, or analysts and must be attached to the report. The sample itself is clearly marked with a red stamp, stamped on the sample label reading "HAZARDOUS" or "FOREIGN SOIL" and placed in a colored and/or marked bag to easily identify the sample. The date, log number, lab sample number, and the result or brief description of the hazard are all written on the Hazardous & Foreign Soil Sample Notice. A copy of the form must be included with the original COC and Work Order and the original must be given to the Sample Control Custodian. Analysts will notify Sample Control of any sample determined to be hazardous after completion of analysis by completing a

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Hazardous Sample Notice. All hazardous samples are either returned to the client or disposed of appropriately through a hazardous waste disposal firm that lab-packs all hazardous samples and removes them from the laboratory. Foreign soil samples are sent out for incineration by a USDA-approved waste disposal facility.

# 23.6 SAMPLE SHIPPING

In the event that the laboratory needs to ship samples, the samples are placed in a cooler with enough ice to ensure the samples remain just above freezing and at or below 6.0°C during transit. The samples are carefully surrounded by packing material to avoid breakage (yet maintain appropriate temperature). A trip blank is enclosed for those samples requiring water/solid volatile organic analyses (see Note). The chain-of-custody form is signed by the sample control technician and attached to the shipping paperwork. Samples are generally shipped overnight express or hand-delivered by a TestAmerica courier to maintain sample integrity. All personnel involved with shipping and receiving samples must be trained to maintain the proper chain-of-custody documentation and to keep the samples intact and on ice. The Environmental, Health and Safety Manual contains additional shipping requirements.

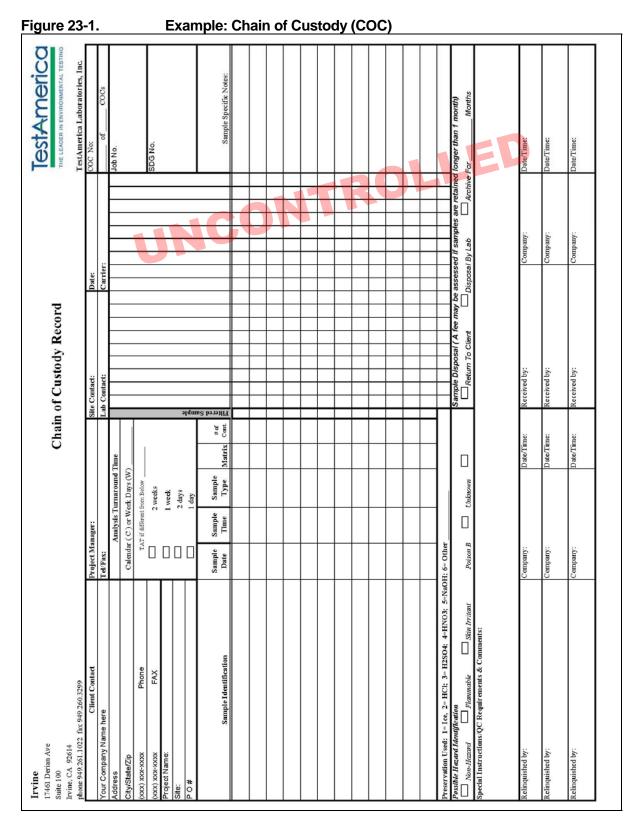
Note: If a client does not request trip blank analysis on the COC or other paperwork, the laboratory will not analyze the trip blanks that were supplied. However, in the interest of good client service, the laboratory will advise the client at the time of sample receipt that it was noted that they did not request analysis of the trip blank; and that the laboratory is providing the notification to verify that they are not inadvertently omitting a key part of regulatory compliance testing.

# 23.7 SAMPLE DISPOSAL

Samples should be retained for a minimum of 30 days after the project report is sent, however, provisions may be made for earlier disposal of samples once the holding time is exceeded. Some samples are required to be held for longer periods based on regulatory or client requirements (e.g., 60 days after project report is sent). The laboratory must follow the longer sample retention requirements where required by regulation or client agreement. Several possibilities for sample disposal exist: the sample may be consumed completely during analysis, the sample may be returned to the customer or location of sampling for disposal, or the sample may be disposed of in accordance with the laboratory's waste disposal procedures (Laboraoty SOP No. IR-EHS-WASTE, *Hazardous Waste Disposal*. All procedures in the laboratory Environmental, Health and Safety Manual are followed during disposal. Samples are normally maintained in the laboratory no longer than two months from receipt unless otherwise requested. Unused portions of samples found or suspected to be hazardous according to state or federal guidelines may be returned to the client upon completion of the analytical work.

If a sample is part of a known litigation, the affected legal authority, sample data user, and/or submitter of the sample must participate in the decision about the sample's disposal. All documentation and correspondence concerning the disposal decision process must be kept on file. Pertinent information includes the date of disposal, nature of disposal (such as sample depletion, hazardous waste facility disposal, return to client), names of individuals who conducted the arrangements and physically completed the task. The laboratory will remove or deface sample labels prior to disposal unless this is accomplished through the disposal method (e.g., samples are incinerated). A Waste Disposal Record should be completed.

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# Figure 23-2a. Example: Sample Acceptance Policy (page 1 of 2)

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U	estAmerica
TH	IE LEADER IN ENVIRONMENTAL TESTING
	TestAmerica Sample Acceptance Policy
A 11	
an; de	incoming work will be evaluated against the criteria listed below. Where applicable, data from y samples that do not meet the criteria listed below will be noted on the laboratory report fining the nature and substance of the variation. In addition the client will be notified either by ephone, fax or e-mail ASAP after the receipt of the samples.
1)	Samples must arrive with labels intact with a Chain of Custody filled out completely. The following information must be recorded.
	<ul> <li>Client name, address, phone number and fax number (if available)</li> <li>Design the series and (assume here)</li> </ul>
	Project name and/or number     The completion identification
	The sample identification
	Date, time and location of sampling
	The collectors name     The matrix description
	The matrix description     The contained description
	The container description The total number of each type of container
	The total number of each type of container      Breecen stirles used
	Preservatives used     Analysis requested
	<ul> <li>Analysis requested</li> <li>Requested turnaround time (TAT)</li> </ul>
	<ul> <li>Any special instructions</li> </ul>
	<ul> <li>Purchase Order number or billing information (e.g. quote number) if available</li> <li>The date and time that each person received or relinguished the sample(s), including</li> </ul>
	their signed name.
	The date and time of receipt must be recorded between the last person to relinquish the samples and the person who receives the samples in the lab, and they must be exactly the same.
	<ul> <li>Information must be legible</li> </ul>
2)	Samples must be preparty labeled
2)	Samples must be properly labeled. <ul> <li>Use durable labels (labels provided by TestAmerica are preferred)</li> </ul>
	Include a unique identification number
	Include sampling date and time & sampler ID
	<ul> <li>Include preservative used.</li> <li>Use indelible ink</li> </ul>
	<ul> <li>Information must be legible</li> </ul>
3)	Proper sample containers with adequate ∨olume for the analysis and necessary QC are required for each analysis requested. See TA Sample Container Guide.
4)	Samples must be preserved according to the requirements of the requested analytical method (See TA Sample Container Guide). Most analytical methods require chilling samples to 4° C (other than water samples for metals analysis). For these methods, the criteria are met if the samples are chilled to below 6° C and above freezing (0°C). For methods with other temperature criteria (e.g. some bacteriological methods require $\leq 10$ °C), the samples must arrive within $\pm 2°$ C of the required temperature or within the method specified range. <b>Note:</b> Samples that are hand delivered to the laboratory immediately after collection may not have had time to cool sufficiently. In this case the samples will be considered acceptable as long as there is evidence that the chilling process has begun (arrival on ice).
	Continued on other side.
	17461 Derian Ave., Suite 100, Irvine, CA 92606 (949) 261-1022 FAX (949) 261-1228

Figure 23-2b.	Example: Sample Acceptance Policy (page 2 of 2)
	Chemical preservation (pH) will be verified prior to analysis and the project manager will be notified immediately if there is a discrepancy. If analyses will still be performed, all affected results will be flagged to indicate improper preservation.
5)	<ul> <li>Sample Holding Times</li> <li>TestAmerica will make every effort to analyze samples within the regulatory holding time. Samples must be received in the laboratory with enough time to perform the sample analysis. Except for short holding time samples (&lt; 48hr HT) sample must be received with at least 48 hrs (working days) remaining on the holding time for us to ensure analysis.</li> </ul>
	Analyses that are designated as "field" analyses (Odor, pH, Dissolved Oxygen, Disinfectant Residual; a.k.a. Residual Chlorine, and Redox Potential) should be analyzed ASAP by the field sampler prior to delivering to the lab. However, if the analyses are to be performed in the laboratory, TestAmerica will make every effort to analyze the samples within 24 hours from receipt of the samples in the testing laboratory. Samples for "field" analyses received after 4:00 pm on Friday or on the weekend will be analyzed no later than the next business day after receipt (Monday unless a holiday). Samples will remain refrigerated and sealed until the time of analysis. The actual times of all "field" sample analyses are noted on the "Short Hold Time Detail Report" in the final report. Only samples analyzed outside of these criteria will be qualified on the final report with an 'H' to indicate holding time exceedance.
6)	All samples submitted for Volatile Organic analyses must have a Trip Blank submitted at the same time. TestAmerica will supply a blank with the bottle order.
7)	The project manager will be notified if any sample is received in damaged condition TestAmerica will request that a sample be resubmitted for analysis.
8)	Recommendations for packing samples for shipment.
	Pack samples in Ice rather than "Blue" ice packs.
	Soil samples should be placed in plastic zip-lock bags. The containers often have dirt around the top and do not seal very well and are prone to intrusion from the water from melted ice.
	Water samples would be best if wrapped with bubble-wrap or paper (newspaper, or paper towels work) and then placed in plastic zip-lock bags.
	<ul> <li>Fill extra cooler space with bubble wrap.</li> </ul>
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Figure	23-3.

Example: Project Receipt Checklist

	PROJECT RECEIPT CHECKLI	Irvine Facility ST
Client: Element ID :		ILLED
	Courier DHL Fed Ex UPS	
	tact Broken None	••••••••••••••••••••••••••••••••••••••
Custody Seal Status Samples: 🗌 In	tact Broken None	
COC present Yes No		
All signatures present on COC	No []N/A Yes []No []N/A	
IR ID No	a but received on ice: Yes N	
Short hold present? 🗌 Yes 🗌 No		
	a □rush–24hr □rush–48hr ar □normal	
Anomalies: No Yes	– See NOD	
Number of containers in cooler(s):_ Number of containers on chain of c	ıstody(s)	
Did Chain of custody(s) agree with	sample labels ID's: Yes No-s	See NOD
[ sheled		

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### SECTION 24. ASSURING THE QUALITY OF TEST RESULTS (NELAC 5.5.9)

### 24.1 <u>OVERVIEW</u>

In order to assure our clients of the validity of their data, the laboratory continuously evaluates the quality of the analytical process. The analytical process is controlled not only by instrument calibration as discussed in Section 20, but also by routine process quality control measurements (e.g. Blanks, Laboratory Control Samples (LCS), Matrix Spikes (MS), duplicates (DUP), surrogates, Internal Standards (IS)). These quality control checks are performed as required by the method or regulations to assess precision and accuracy. In addition to the routine process quality control samples, Proficiency Testing (PT) Samples (concentrations unknown to laboratory) are analyzed to help ensure laboratory performance.

# 24.2 <u>CONTROLS</u>

Sample preparation or pre-treatment is commonly required before analysis. Typical preparation steps include homogenization, grinding, solvent extraction, sonication, acid digestion, distillation, reflux, evaporation, drying and ashing. During these pre-treatment steps, samples are arranged into discreet manageable groups referred to as preparation (prep) batches. Prep batches provide a means to control variability in sample treatment. Control samples are added to each prep batch to monitor method performance and are processed through the entire analytical procedure with investigative/field samples.

# 24.3 NEGATIVE CONTROLS

Control Type	Details
Method Blank (MB)	are used to assess preparation and analysis for possible contamination during the preparation and processing steps.
	The specific frequency of use for method blanks during the analytical sequence is defined in the specific standard operating procedure for each analysis. Generally it is 1 for each batch of samples; not to exceed 20 environmental samples.
	The method blank is prepared from a clean matrix similar to that of the associated samples that is free from target analytes (e.g., Reagent water, Ottawa sand, glass beads, etc.) and is processed along with and under the same conditions as the associated samples.
	The method blank goes through all of the steps of the process (including as necessary: filtration, clean-ups, etc.).
Calibration Blanks	are prepared and analyzed along with calibration standards where applicable. They are prepared using the same reagents that are used to prepare the standards. In some analyses the calibration blank may be included in the calibration curve.
Instrument Blanks	are blank reagents or reagent water that may be processed during an analytical sequence in order to assess contamination in the analytical system. In general, instrument blanks are used to differentiate between contamination caused by the analytical system and that caused by the sample handling or sample prep process. Instrument blanks may also be inserted throughout the analytical sequence to minimize the effect of carryover from samples with high analyte content.

#### Table 24-1. Example – Negative Controls

Control Type	Details	
Trip Blank <sup>1</sup>	are required to be submitted by the client with each shipment of samples requiring aqueous and solid volatiles analyses. Additionally, trip blanks may be prepared and analyzed for volatile analysis of air samples, when required by the client. A trip blank may be purchased (certified clean) or is prepared by the laboratory by filling a clean container with pure deionized water that has been purged to remove any volatile compounds. Appropriate preservatives are also added to the container. The trip blank is sent with the bottle order and is intended to reflect the environment that the containers are subjected to throughout shipping and handling and help identify possible sources if contamination is found. The field sampler returns the trip blank in the cooler with the field samples.	
Field Blanks <sup>1</sup>	are sometimes used for specific projects by the field samplers. A field blank prepared in the field by filling a clean container with pure reagent water and appropriate preservative, if any, for the specific sampling activity being undertaken. (EPA OSWER)	
Equipment Blanks <sup>1</sup>	are also sometimes created in the field for specific projects. An equipment blank is a sample of analyte-free media which has been used to rinse common sampling equipment to check effectiveness of decontamination procedures. (NELAC)	
Holding Blanks	also referred to as refrigerator or freezer blanks, are used to monitor the sample storage ur volatile organic compounds during the storage of VOA samples in the laboratory	

<sup>1</sup> When known, these field QC samples should not be selected for matrix QC as it does not provide information on the behavior of the target compounds in the field samples. Usually, the client sample ID will provide information to identify the field blanks with labels such as "FB", "EB", or "TB."

Evaluation criteria and corrective action for these controls are defined in the specific standard operating procedure for each analysis.

**24.3.1** <u>Negative Controls for Microbiological Methods</u> – Microbiological Methods utilize a variety of negative controls throughout the process to ensure that false positive results are not obtained. These controls are critical to the validity of the microbiological analyses. Some of these negative controls are:

Control Type	Details
	are analyzed for each lot of pre-prepared media, ready-to-use media and for each batch of medium prepared by the laboratory.
	blanks are run at the beginning and end for each sterilized filtration unit used in a filtration series. For pre-sterilized single use funnels a sterility check is performed on at least one funnel per lot.
(Sample Containers)	are performed on at least one container per lot of purchased, pre-sterilized containers. If containers are prepared and sterilized by the laboratory, one container per sterilization batch is checked. Container sterility checks are performed using non-selective growth media.
	are performed on each batch of dilution water prepared by the laboratory and on each batch of pre-prepared dilution water. All checks are performed using non-selective growth media.

#### Table 24-2. Negative Controls for Microbiology

Negative culture controls demonstrate that a media does not support the growth of non-target organisms and ensures that there is not an atypical positive reaction from the target organisms. Prior to the first use of the media, each lot of pre-prepared selective media or batch of laboratory prepared selective media is analyzed with at least one known negative culture control as appropriate to the method.

# 24.4 POSITIVE CONTROLS

Control samples (e.g., QC indicators) are analyzed with each batch of samples to evaluate data based upon (1) Method Performance (Laboratory Control Sample (LCS) or Blank Spike (BS)), which entails both the preparation and measurement steps; and (2) Matrix Effects (Matrix Spike (MS) (Matrix spikes are not applicable to air) or Sample Duplicate (MD, DUP), which evaluates field sampling accuracy, precision, representativeness, interferences, and the effect of the matrix on the method performed. Each regulatory program and each method within those programs specify the control samples that are prepared and/or analyzed with a specific batch

Note that frequency of control samples vary with specific regulatory, methodology and project specific criteria. Complete details on method control samples are as listed in each analytical SOP.

# 24.4.1 <u>Method Performance Control - Laboratory Control Sample (LCS)</u>

The LCS measures the accuracy of the method in a blank matrix and assesses method performance independent of potential field sample matrix affects in a laboratory batch.

The LCS is prepared from a clean matrix similar to that of the associated samples that is free from target analytes (for example: Reagent water, Ottawa sand, glass beads, etc.) and is processed along with and under the same conditions as the associated samples. The LCS is spiked with verified known amounts of analytes or is made of a material containing known and verified amounts of analytes, taken through all preparation and analysis steps along with the field samples. Where there is no preparation taken for an analysis (such as in aqueous volatiles), or when all samples and standards undergo the same preparation and analysis process (such as Phosphorus), a calibration verification standard is reported as the LCS. In some instances where there is no practical clean solid matrix available, aqueous LCS's may be processed for solid matrices; final results may be calculated as mg/kg or ug/kg, assuming 100% solids and a weight equivalent to the aliquot used for the corresponding field samples, to facilitate comparison with the field samples.

Certified pre-made reference material purchased from a NIST/A2LA accredited vendor may also be used for the LCS when the material represents the sample matrix or the analyte is not easily spiked (e.g. solid matrix LCS for metals, TDS, etc.).

The specific frequency of use for LCS during the analytical sequence is defined in the specific standard operating procedure for each analysis. It is generally 1 for each batch of samples; not to exceed 20 environmental samples.

If the mandated or requested test method, or project requirements, do not specify the spiking components, the laboratory shall spike all reportable components to be reported in the Laboratory Control Sample (and Matrix Spike) where applicable (e.g. no spike of pH). However, in cases where the components interfere with accurate assessment (such as simultaneously spiking chlordane, toxaphene and PCBs in Method 608), the test method has an extremely long list of components or components are incompatible, at a minimum, a representative number of the listed components (see below) shall be used to control the test method. The selected components of each spiking mix shall represent all chemistries, elution patterns and masses,

permit specified analytes and other client requested components. However, the laboratory shall ensure that all reported components are used in the spike mixture within a two-year time period.

- For methods that have 1-10 target analytes, spike all components.
- For methods that include 11-20 target analytes, spike at least 10 or 80%, whichever is greater.
- For methods with more than 20 target analytes, spike at least 16 components.
- Exception: Due to analyte incompatibility in pesticides, Toxaphene and Chlordane are only spiked at client request based on specific project needs.
- Exception: Due to analyte incompatibility between the various PCB aroclors, aroclors 1016 and 1260 are used for spiking as they cover the range of all of the aroclors. Specific aroclors may be used by request on a project specific basis.

### 24.4.2 Positive Controls for Microbiological Methods

- Each lot of pre-prepared media (including chromofluorogenic reagent) and each batch of laboratory prepared media is tested with a pure culture of known positive reaction.
- In addition, every analytical batch also contains a pure culture of known positive reaction.
- A pure culture of known negative reaction is also tested with each analytical batch to ensure specificity of the procedure.

### 24.5 SAMPLE MATRIX CONTROLS

Control Type	Details		
Matrix Spikes (MS)	Use	used to assess the effect sample matrix of the spiked sample has on the precision and accuracy of the results generated by the method used;	
	Typical Frequency <sup>1</sup>	At a minimum, with each matrix-specific batch of samples processed, an MS is carried through the complete analytical procedure. Unless specified by the client, samples used for spiking are randomly selected and rotated between different client projects. If the mandated or requested test method does not specify the spiking components, the laboratory shall spike all reportable components to be reported in the Laboratory Control Sample and Matrix Spike. Refer to the method SOP for complete details	
	Description	essentially a sample fortified with a known amount of the test analyte(s).	
Surrogate	Use	Measures method performance to sample matrix (organics only).	
	Typical Frequency <sup>1</sup>	Are added to all samples, standards, and blanks, for all organic chromatography methods except when the matrix precludes its use or when a surrogate is not available. The recovery of the surrogates is compared to the acceptance limits for the specific method. Poor surrogate recovery may indicate a problem with sample composition and shall be reported, with data qualifiers, to the client whose sample produced poor recovery.	
	Description	Are similar to matrix spikes except the analytes are compounds with properties that mimic the analyte of interest and are unlikely to be found in environment samples.	
Duplicates <sup>2</sup>	Use	For a measure of analytical precision, with each matrix-specific batch of samples processed, a matrix duplicate (MD or DUP) sample, matrix spike duplicate (MSD), or LCS duplicate (LCSD) is carried through the complete analytical procedure.	

 Table 24-3.
 Sample Matrix Control

### **Company Confidential & Proprietary**

Details		
Typical Frequency <sup>1</sup>	Duplicate samples are usually analyzed with methods that do not require matrix spike analysis.	
Description	Performed by analyzing two aliquots of the same field sample independently or an additional LCS.	
Use	Are spiked into all environmental and quality control samples (including the initial calibration standards) to monitor the qualitative aspect of organic and some inorganic analytical measurements.	
Typical Frequency <sup>1</sup>	All organic and ICP methods as required by the analytical method.	
Description	Used to correct for matrix effects and to help troubleshoot variability in analytical response and are assessed after data acquisition. Possible sources of poor internal standard response are sample matrix, poor analytical technique or instrument performance.	
	Frequency <sup>1</sup> Description Use Typical Frequency <sup>1</sup>	

### Table 24-3. Sample Matrix Control

<sup>1</sup> See the specific analytical SOP for type and frequency of sample matrix control samples.

<sup>2</sup> LCSD's are normally not performed except when regulatory agencies or client specifications require them. The recoveries for the spiked duplicate samples must meet the same laboratory established recovery limits as the accuracy QC samples. If an LCSD is analyzed both the LCS and LCSD must meet the same recovery criteria and be included in the final report. The precision measurement is reported as "Relative Percent Difference" (RPD). Poor precision between duplicates (except LCS/LCSD) may indicate non-homogeneous matrix or sampling.

# 24.6 ACCEPTANCE CRITERIA (CONTROL LIMITS)

As mandated by the test method and regulation, each individual analyte in the LCS, MS, or Surrogate Spike is evaluated against the control limits published in the test method. Where there are no established acceptance criteria, the laboratory calculates in-house control limits with the use of control charts or, in some cases, utilizes client project specific control limits. When this occurs, the regulatory or project limits will supersede the laboratory's in-house limits.

**Note:** For methods, analytes and matrices with very limited data (e.g., unusual matrices not analyzed often), interim limits are established using available data or by analogy to similar methods or matrices.

Once control limits have been established, they are verified, reviewed, and updated if necessary on an annual basis unless the method requires more frequent updating. Control limits are established per method (as opposed to per instrument) regardless of the number of instruments utilized.

Laboratory generated % Recovery acceptance (control) limits are generally established by taking  $\pm$  3 Standard Deviations (99% confidence level) from the average recovery of a minimum of 20-30 data points (more points are preferred).

- Regardless of the calculated limit, the limit should be no tighter than the Calibration Verification (ICV/CCV). (Unless the analytical method specifies a tighter limit).
- In-house limits cannot be any wider than those mandated in a regulated analytical method. Client or contract required control limits are evaluated against the laboratory's statistically derived control limits to determine if the data quality objectives (DQOs) can be achieved. If laboratory control limits are not consistent with DQOs, then alternatives must be considered, such as method improvements or use of an alternate analytical method.

- The lowest acceptable recovery limit will be 10% (the analyte must be detectable and identifiable). Exception: The lowest acceptable recovery limit for Benzidine will be 5% and the analyte must be detectable and identifiable.
- The maximum acceptable recovery limit will be 150%.
- The maximum acceptable RPD limit will be 35% for waters and 40% for soils. The minimum RPD limit is 10%.
- If either the high or low end of the control limit changes by ≤ 5% from previous, the control chart is visually inspected and, using professional judgment, they may be left unchanged if there is no affect on laboratory ability to meet the existing limits.

**24.6.1** The lab maintains a current listing of control limits and tracks when the updates are performed. In addition, the laboratory retains data that can be used to recreate historical control limits. Refer to laboratory SOP NO. IR-QA-CNTRLLIM for full details.

**24.6.2** A LCS that is within the acceptance criteria establishes that the analytical system is in control and is used to validate the process. Samples that are analyzed with an LCS with recoveries outside of the acceptance limits may be determined as out of control and should be reanalyzed if possible. If reanalysis is not possible, then the results for all affected analytes for samples within the same batch must be qualified when reported. The internal corrective action process (see Section 12) is also initiated if an LCS exceeds the acceptance limits. Sample results may be qualified and reported without reanalysis if:

- The analyte results are below the reporting limit and the LCS is above the upper control limit.
- If the analytical results are above the relevant regulatory limit and the LCS is below the lower control limit.
- NELAC work, there are an allowable number of Marginal Exceedances (ME):

<11 analytes	0 marginal exceedances are allowed.
11 – 30 Analytes	1 marginal exceedance is allowed
31-50 Analytes	2 marginal exceedances are allowed
51-70 Analytes	3 marginal exceedances are allowed
71-90 Analytes	4 marginal exceedances are allowed
> 90 Analytes	5 marginal exceedances are allowed

- Marginal exceedances are recovery exceedances between 3 SD and 4 SD from the mean recovery limit (NELAC).
- Marginal exceedances must be random. If the same analyte exceeds the LCS control limit repeatedly, it is an indication of a systematic problem. The source of the error must be located and corrective action taken. The laboratory has a system to monitor marginal exceedances to ensure that they are random.

Though marginal exceedences may be allowed, the data must still be qualified to indicate it is outside of the normal limits.

**24.6.3** If the MS/MSDs do not meet acceptance limits, the MS/MSD and the associated spiked sample is reported with a qualifier for those analytes that do not meet limits. If obvious preparation errors are suspected, or if requested by the client, unacceptable MS/MSDs are reprocessed and reanalyzed to prove matrix interference. A more detailed discussion of acceptance criteria and corrective action can be found in the lab's method SOPs and in Section 12.

**24.6.4** If a surrogate standard falls outside the acceptance limits, if there is not obvious chromatographic matrix interference, reanalyze the sample to confirm a possible matrix effect. If the recoveries confirm or there was obvious chromatographic interference, results are reported from the original analysis and a qualifier is added. If the reanalysis meets surrogate recovery criteria, the second run is reported (or both are reported if requested by the client). Under certain circumstances, where all of the samples are from the same location and share similar chromatography, the reanalysis may be performed on a single sample rather than all of the samples and if the surrogate meets the recovery criteria in the reanalysis, all of the affected samples would require reanalysis.

# 24.7 ADDITIONAL PROCEDURES TO ASSURE QUALITY CONTROL

The laboratory has written and approved method SOPs to assure the accuracy of the test method including calibration (see Section 20), use of certified reference materials (see Section 21) and use of PT samples (see Section 15).

A discussion regarding MDLs, Limit of Detection (LOD) and Limit of Quantitation (LOQ) can be found in Section 19.

- Use of formulae to reduce data is discussed in the method SOPs and in Section 20.
- Selection of appropriate reagents and standards is included in Section 9 and 21.
- A discussion on selectivity of the test is included in Section 5.
- Constant and consistent test conditions are discussed in Section 18.
- The laboratories sample acceptance policy is included in Section 23.

# SECTION 25. REPORTING RESULTS (NELAC 5.5.10)

### 25.1 <u>OVERVIEW</u>

The results of each test are reported accurately, clearly, unambiguously, and objectively in accordance with State and Federal regulations as well as client requirements. Analytical results are issued in a format that is intended to satisfy customer and laboratory accreditation requirements as well as provide the end user with the information needed to properly evaluate the results. Where there is conflict between client requests and laboratory ethics or regulatory requirements, the laboratory's ethical and legal requirements are paramount, and the laboratory will work with the client during project set up to develop an acceptable solution. Refer to Section 7.

A variety of report formats are available to meet specific needs.

In cases where a client asks for simplified reports, there must be a written request from the client (and kept with all other project information). There still must be enough information that would show any analyses that were out of conformance (QC out of limits) and there should be a reference to a full report that is made available to the client. Review of reported data is included in Section 19.

### 25.2 <u>TEST REPORTS</u>

Analytical results are reported in a format that is satisfactory to the client and meets all requirements of applicable accrediting authorities and agencies. A variety of report formats are available to meet specific needs. The report is printed on laboratory letterhead, reviewed, and signed by the appropriate project manager. At a minimum, the standard laboratory report shall contain the following information:

**25.2.1** A report title (e.g. Analytical Report For Samples) with a "sample results" column header.

**25.2.2** Each report cover page printed on company letterhead, which includes the laboratory name, address and telephone number.

**25.2.3** A unique identification of the report (e.g. work order number) and on each page an identification in order to ensure the page is recognized as part of the report and a clear identification of the end.

**Note:** Page numbers of report are represented as page # of ##. Where the first number is the page number and the second is the total number of pages.

**25.2.4** A copy of the chain of custody (COC).

- Any COCs involved with Subcontracting are included.
- In most cases, the applicable COC is not paginated but is an integral part of the report. If the COC is not a paginated portion of the report then there will be a statement on the front of the report to effect of "The Chain of Custody, X page(s), is included and is an integral part of

this report.". The number of pages of the CoC (X) is entered into Element so that it is correct for each report.

• Any additional addenda to the report must be treated in a similar fashion so it is a recognizable part of the report and cannot accidentally get separated from the report (e.g., Sampling information).

**25.2.5** The name and address of client and a project name/number, if applicable.

25.2.6 Client project manager or other contact

**25.2.7** Description and unambiguous identification of the tested sample(s) including the client identification code.

**25.2.8** Date of receipt of sample, date and time of collection, and date(s) of test preparation and performance, and time of preparation or analysis if the required holding time for either activity is less than or equal to 72 hours.

**25.2.9** Date reported or date of revision, if applicable.

**25.2.10** Method of analysis including method code (EPA, Standard Methods, etc).

- **25.2.11** Reporting Limits.
- **25.2.12** Method detection limits (if requested)

**25.2.13** Definition of Data qualifiers and reporting acronyms (e.g. MDL).

**25.2.14** Sample results.

**25.2.15** QC data consisting of method blank, surrogate, LCS, and MS/MSD recoveries and control limits.

**25.2.16** Condition of samples at receipt including temperature. This may be accomplished in a narrative or by attaching sample login sheets (Refer to Sec. 25.2.4 – Item 3 regarding additional addenda).

**25.2.17** A statement expressing the validity of the results, that the source methodology was followed and all results were reviewed for error.

**25.2.18** A statement to the effect that the results relate only to the items tested and the sample as received by the laboratory.

**25.2.19** A statement that the report shall not be reproduced except in full, without prior express written approval by the laboratory coordinator.

**25.2.20** A signature and title of the person(s) accepting responsibility for the content of the report and date of issue. Signatories are appointed by the Lab Director.

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**25.2.21** When NELAC accreditation is required, the lab shall certify that the test results meet all requirements of NELAC or provide reasons and/or justification if they do not.

**25.2.22** Where applicable, a narrative to the report (or a listing of data qualifiers) that explains the issue(s) and corrective action(s) taken in the event that a specific accreditation or certification requirement was not met.

**25.2.23** When soil samples are analyzed, a specific identification as to whether soils are reported on a "wet weight" or "dry weight" basis.

**25.2.24** Appropriate laboratory certification number for the state of origin of the sample, if applicable.

**25.2.25** If only part of the report is provided to the client (client requests some results before all of it is complete), it must be clearly indicated on the report (e.g., "partial"). A complete report must be sent once all of the work has been completed.

**25.2.26** Any non-TestAmerica subcontracted analysis results are provided as a separate report on the official letterhead of the subcontractor unless specified otherwise by the client (documentation with regards to this request should be kept in the project file). All TestAmerica subcontracting is clearly identified on the report as to which laboratory performed a specific analysis.

Note: Refer to the Corporate SOP on Electronic Reporting and Signature Policy (No. CA-I-P-002) for details on internally applying electronic signatures of approval.

# 25.3 **REPORTING LEVEL OR REPORT TYPE**

The laboratory offers four levels of quality control reporting. Each level, in addition to its own specific requirements, contains all the information provided in the preceding level. The packages provide the following information in addition to the information described above:

- Level I is a report with the features described in Section 25.2 above.
- Level II is a Level I report plus summary information, including results for the method blank reported to the laboratory MDL, percent recovery for laboratory control samples and matrix spike samples, and the RPD values for all MSD and sample duplicate analyses.
- Level III contains all the information supplied in Level II, plus all sample raw data but not raw data for tunes, calibrations, etc.
- Level IV is the same as Level III with the addition of all tune and calibration data.
- CLP-like forms may also be provided with level III or level IV packages if requested.

In addition to the various levels of QC packaging, the laboratory also provides reports in CD deliverable form. Initial reports may be provided to clients by facsimile. All faxed reports are followed by hardcopy. Procedures used to ensure client confidentiality are outlined in Section 25.6.

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#### 25.3.1 Electronic Data Deliverables (EDDs)

EDDs are routinely offered as part of TestAmerica's services. Irvine offers a variety of EDD formats including:

- ERPRIMS (Environmental Restoration Information Management System)
- NAS (New Agency Standard) •
- EQUIS •
- Format A ٠
- Microsoft Excel
- Microsoft Access •
- FoxPro •
- GISKEY ٠
- Text File

ICONTROLLED EDD specifications are submitted to the IT department by the PM for review and undergo the contract review process. Once the facility has committed to providing data in a specific electronic format, the coding of the format may need to be performed. This coding is documented and validated. The validation of the code is retained by the IT staff coding the EDD.

EDDs shall be subject to a review to ensure their accuracy and completeness. If EDD generation is automated, review may be reduced to periodic screening if the laboratory can demonstrate that it can routinely generate that EDD without errors. Any revisions to the EDD format must be reviewed until it is demonstrated that it can routinely be generated without errors. If the EDD can be reproduced accurately and if all subsequent EDDs can be produced error-free, each EDD does not necessarily require a review.

#### 25.4 SUPPLEMENTAL INFORMATION FOR TEST

The lab identifies any unacceptable QC analyses or any other unusual circumstances or observations such as environmental conditions and any non-standard conditions that may have affected the quality of a result. This is typically in the form of a footnote or a qualifier and/or a narrative explaining the discrepancy in the front of the report.

Numeric results with values outside of the calibration range, either high or low are gualified as 'estimated'.

Where quality system requirements are not met, a statement of compliance/non-compliance with requirements and/or specifications is required, including identification of test results derived from any sample that did not meet NELAC sample acceptance requirements such as improper container, holding time, or temperature.

Where applicable, a statement on the estimated uncertainty of measurements; information on uncertainty is needed when a client's instructions so require.

Opinions and Interpretations - The test report contains objective information, and generally does not contain subjective information such as opinions and interpretations. If such information is required by the client, the Laboratory Director will determine if a response can be prepared. If so, the Laboratory Director will designate the appropriate member of the management team to

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prepare a response. The response will be fully documented, and reviewed by the Laboratory Director, before release to the client. There may be additional fees charged to the client at this time, as this is a non-routine function of the laboratory.

**Note:** Review of data deliverable packages for submittal to regulatory authorities requires responses to non-conforming data concerning potential impact on data quality. This necessitates a limited scope of interpretation, and this work is performed by the QA Department. This is the only form of "interpretation" of data that is routinely performed by the laboratory.

When opinions or interpretations are included in the report, the laboratory provides an explanation as to the basis upon which the opinions and interpretations have been made. Opinions and interpretations are clearly noted as such and where applicable, a comment should be added suggesting that the client verify the opinion or interpretation with their regulator.

# 25.5 ENVIRONMENTAL TESTING OBTAINED FROM SUBCONTRACTORS

If the laboratory is not able to provide the client the requested analysis, the samples would be subcontracted following the procedures outlined in the Corporate SOP on Subcontracting (SOP # CA-L-S-002).

Data reported from analyses performed by a subcontractor laboratory are clearly identified as such on the analytical report provided to the client. Results from a subcontract laboratory outside of TestAmerica provided as a separate report on the official letterhead of the subcontractor unless specified otherwise by the client (documentation with regards to this request should be kept in the project file).

# 25.6 <u>CLIENT CONFIDENTIALITY</u>

In situations involving the transmission of environmental test results by telephone, facsimile or other electronic means, client confidentiality must be maintained.

TestAmerica will not intentionally divulge to any person (other than the Client or any other person designated by the Client in writing) any information regarding the services provided by TestAmerica or any information disclosed to TestAmerica by the Client. Furthermore, information <u>known</u> to be potentially endangering to national security or an entity's proprietary rights will not be released.

**Note:** This shall not apply to the extent that the information is required to be disclosed by TestAmerica under the compulsion of legal process. TestAmerica will, to the extent feasible, provide reasonable notice to the client before disclosing the information.

**Note:** Authorized representatives of an accrediting authority are permitted to make copies of any analyses or records relevant to the accreditation process, and copies may be removed from the laboratory for purposes of assessment.

**25.6.1** Report deliverable formats are discussed with each new client. If a client requests that reports be faxed or e-mailed, the reports are faxed with a cover sheet or e-mailed with the following note that includes a confidentiality statement similar to the following:

The pages included herein are information from TestAmerica Irvine which is confidential or privileged. The information is intended for the use of the individual or entity named on this cover sheet. If you are not the intended recipient, be aware that any disclosure, copying, distribution, or use of the contents of this information is prohibited. If you have received this document in error, please notify us by telephone immediately so that we can arrange for the retrieval of the original document at no cost to you.

# 25.7 FORMAT OF REPORTS

The format of reports is designed to accommodate each type of environmental test carried out and to minimize the possibility of misunderstanding or misuse.

# 25.8 AMENDMENTS TO TEST REPORTS

Corrections, additions, or deletions to reports are only made when justification arises through supplemental documentation. Justification is documented using the laboratory's corrective action system (refer to Section 12).

The revised report is retained on the Archive data server, as is the original report. The revised report is stored in the Archive data server under the sample number followed by "Rev". The revised report will have the word "revised" or "amended" next to the date rather than the word "reported".

When the report is re-issued, a notation of "report re-issue "is placed on the cover/signature page of the report or at the top of the narrative page with a brief explanation of reason for the re-issue and a reference back to the last final report generated. For Example: Report was revised on 11/3/08 to include toluene in sample NQA1504 per client's request. This final report replaces the final report generated on 10/27/08 at 10:47am.

# 25.9 POLICIES ON CLIENT REQUESTS FOR AMENDMENTS

### 25.9.1 Policy on Data Omissions or Reporting Limit Increases

Fundamentally, our policy is simply to not omit previously reported results (including data qualifiers) or to not raise reporting limits and report sample results as ND. This policy has few exceptions. Exceptions are:

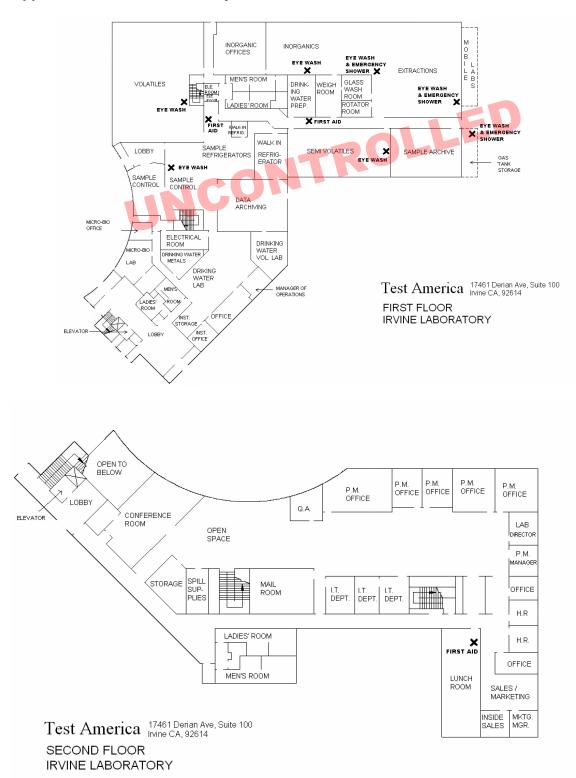
- Laboratory error.
- Sample identification is indeterminate (confusion between COC and sample labels).
- An incorrect analysis (not analyte) was requested (e.g., COC lists 8315 but client wanted 8310). A written request for the change is required.
- Incorrect limits reported based on regulatory requirements.
- The requested change has absolutely <u>no possible</u> impact on the interpretation of the analytical results and there is <u>no possibility</u> of the change being interpreted as misrepresentation by anyone inside or outside of our company.

### 25.9.2 <u>Multiple Reports</u>

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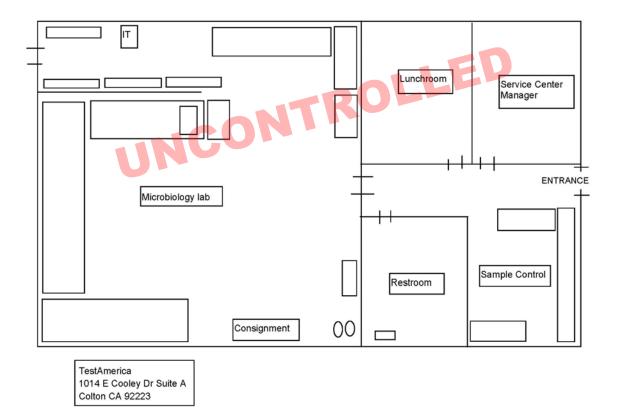
TestAmerica does not issue multiple reports for the same work order where there is different information on each report (this does not refer to copies of the same report) unless required to meet regulatory needs and approved by QA.

UNCONTROLLED



### Appendix 1. Laboratory Floor Plan- Irvine

# Appendix 1. Laboratory Floor Plan- Ontario



## Appendix 2. Glossary/Acronyms

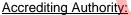
### **Glossary:**

#### Acceptance Criteria:

Specified limits placed on characteristics of an item, process, or service defined in requirement documents. (ASQC)

#### 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. In the context of the National Environmental Laboratory Accreditation Program (NELAP), this process is a voluntary one. (NELAC)



The Territorial, State, or Federal Agency having responsibility and accountability for environmental laboratory accreditation and which grants accreditation (NELAC) [1.5.2.3]

#### Accuracy:

The degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components which are due to sampling and analytical operations; a data quality indicator. (QAMS)

#### 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. (NELAC)

#### Batch:

Environmental samples which are prepared and/or analyzed together with the same process and personnel, using the same lot(s) of reagents. A preparation batch is composed of one to 20 environmental samples of the same matrix, meeting the above mentioned criteria and with a maximum time between the start of processing of the first and last sample in the batch to be 24 hours. An analytical batch is composed of prepared environmental samples (extracts, digestates or concentrates) and /or those samples not requiring preparation, which are analyzed together as a group using the same calibration curve or factor. An analytical batch can include samples originating from various environmental matrices and can exceed 20 samples. (NELAC Quality Systems Committee)

#### Blank:

A sample that has not been exposed to the analyzed sample stream in order to monitor contamination during sampling, transport, storage or analysis. The blank is subjected to the usual analytical and measurement process to establish a zero baseline or background value and is sometimes used to adjust or correct routine analytical results. (ASQC)

## Blind Sample:

A sample for analysis with a composition known to the submitter. The analyst/laboratory may know the identity of the sample but not its composition. It is used to test the analyst's or laboratory's proficiency in the execution of the measurement process.

#### Calibration:

To determine, by measurement or comparison with a standard, the correct value of each scale reading on a meter, instrument, or other device. The levels of the applied calibration standard should bracket the range of planned or expected sample measurements. (NELAC)

#### Calibration Curve:

The graphical relationship between the known values, such as concentrations, of a series of calibration standards and their instrument response. (NELAC)

#### Calibration Method:

A defined technical procedure for performing a calibration. (NELAC)

#### Calibration Standard:

A substance or reference material used to calibrate an instrument (QAMS)

#### Certified Reference Material (CRM):

A reference material one or more of whose property values are certified by a technically valid procedure, accompanied by or traceable to a certificate or other documentation which is issued by a certifying body. (ISO Guide 30–2.2)

## Chain of Custody:

An unbroken trail of accountability that ensures the physical security of samples and includes the signatures of all who handle the samples. (NELAC) [5.12.4]

#### Clean Air Act:

The enabling legislation in 42 U>S>C> 7401 et seq., Public Law 91-604, 84 Stat. 1676 Pub. L. 95-95, 91 Stat., 685 and Pub. L. 95-190, 91 Stat., 1399, as amended, empowering EPA to promulgate air quality standards, monitor and enforce them. (NELAC)

Comprehensive Environmental Response, Compensation and Liability Act (CERCLA/SUPERFUND):

The enabling legislation in 42 U.S.C. 9601-9675 et seq., as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA), 42 U.S.C. 9601 et seq., to eliminate the health and environmental threats posed by hazardous waste sites. (NELAC)

## Compromised Samples:

Those samples which are improperly sampled, insufficiently documented (chain of custody and other sample records and/or labels), improperly preserved, collected in improper containers, or exceeding holding times when delivered to a laboratory. Under normal conditions, compromised samples are not analyzed. If emergency situation require analysis, the results must be appropriately gualified. (NELAC)

#### Confidential Business Information (CBI):

Information that an organization designates as having the potential of providing a competitor with inappropriate insight into its management, operation or products. NELAC and its representatives agree to safeguarding identified CBI and to maintain all information identified as such in full confidentiality.

### Confirmation:

Verification of the identity of a component through the use of an approach with a different scientific principle from the original method. These may include, but are not limited to:

Second column confirmation Alternate wavelength Derivatization Mass spectral interpretation Alternative detectors or Additional Cleanup procedures

#### (NELAC)

#### Conformance:

An affirmative indication or judgment that a product or service has met the requirements of the relevant specifications, contract, or regulation; also the state of meeting the requirements. (ANSI/ASQC E4-1994)

<u>Correction</u>: Actions necessary to correct or repair analysis specific non-conformances. The acceptance criteria for method specific QC and protocols as well as the associated corrective actions. The analyst will most frequently be the one to identify the need for this action as a result of calibration checks and QC sample analysis. No significant action is taken to change behavior, process or procedure.

#### Corrective Action:

The action taken to eliminate the causes of an existing nonconformity, defect or other undesirable situation in order to prevent recurrence. (ISO 8402)

#### Data Audit:

A qualitative and quantitative evaluation of the documentation and procedures associated with environmental measurements to verify that the resulting data re of acceptable quality (i.e., that they meet specified acceptance criteria). (NELAC)

#### Data Reduction:

The process of transforming raw data by arithmetic or statistical calculations, standard curves, concentration factors, etc., and collation into a more useable form. (EPA-QAD)

#### Deficiency:

An unauthorized deviation from acceptable procedures or practices, or a defect in an item. (ASQC)

#### **Detection Limit:**

The lowest concentration or amount of the target analyte that can be identified, measured, and reported with confidence that the analyte concentration is not a false positive value. See Method Detection Limit. (NELAC)

### Document Control:

The act of ensuring that documents (and revisions thereto) are proposed, reviewed for accuracy, approved for release by authorized personnel, distributed properly, and controlled to ensure use of the correct version at the location where the prescribed activity if performed. (ASQC)

#### Duplicate Analyses:

The analyses or measurements of the variable of interest performed identically on two subsamples of the same sample. The results from duplicate analyses are used to evaluate analytical or measurement precision but not the precision of sampling, preservation or storage internal to the laboratory. (EPA-QAD)

#### Environmental Detection Limit (EDL):

The smallest level at which a radionuclide in an environmental medium can be unambiguously distinguished for a given confidence interval using a particular combination of sampling and measurement procedures, sample size, analytical detection limit, and processing procedure. The EDL shall be specified for the 0.95 or greater confidence interval. The EDL shall be established initially and verified annually for each test method and sample matrix. (NELAC Radioanalysis Subcommittee)

#### Equipment Blank:

Sample of analyte-free media which has been used to rinse common sampling equipment to check effectiveness of decontamination procedures. (NELAC)

#### External Standard Calibration:

Calibrations for methods that do not utilize internal standards to compensate for changes in instrument conditions.

#### Federal Water Pollution Control Act (Clean Water Act, CWA):

The enabling legislation under 33 U.S.C. 1251 et seq., Public Law 92-50086 Stat 816, that empowers EPA to set discharge limitations, write discharge permits, monitor, and bring enforcement action for non-compliance. (NELAC)

#### Field Blank:

Blank prepared in the field by filing a clean container with pure de-ionized water and appropriate preservative, if any, for the specific sampling activity being undertaken (EPA OSWER)

#### Field of Testing:

NELAC's approach to accrediting laboratories by program, method and analyte. Laboratories requesting accreditation for a program-method-analyte combination or for an up-dated/improved method are required to submit to only that portion of the accreditation process not previously addressed (see NELAC, section 1.9ff). (NELAC)

#### Holding Times (Maximum Allowable Holding Times):

The maximum times that samples may be held prior to analyses and still be considered valid or not compromised. (40 CFR Part 136)

#### Internal Standard:

A known amount of standard added to a test portion of a sample and carried through the entire measurement process as a reference for evaluating and controlling the precision and bias of the applied analytical test method. (NELAC)

#### Internal Standard Calibration:

Calibrations for methods that utilize internal standards to compensate for changes in instrument conditions.

#### Instrument Blank:

A clean sample (e.g., distilled water) processed through the instrumental steps of the measurement process; used to determine instrument contamination. (EPA-QAD)

Laboratory Control Sample (however named, such as laboratory fortified blank, spiked blank, or QC check sample):

A sample matrix, free from the analytes of interest, spiked with verified known amounts of analytes or a material containing known and verified amounts of analytes, taken through all preparation and analysis steps. Where there is no preparation taken for an analysis (such as in aqueous volatiles), or when all samples and standards undergo the same preparation and analysis process (such as Phosphorus), there is no LCS. It is generally used to establish intra-laboratory or analyst specific precision and bias or to assess the performance of all or a portion of the measurement system.

An LCS shall be prepared at a minimum of 1 per batch of 20 or less samples per matrix type per sample extraction or preparation method except for analytes for which spiking solutions are not available such as total suspended solids, total dissolved solids, total volatile solids, total solids, pH, color, odor, temperature, dissolved oxygen or turbidity. The results of these samples shall be used to determine batch acceptance.

Note: NELAC standards allow a matrix spike to be used in place of this control as long as the acceptance criteria are as stringent as for the LCS. (NELAC)

#### Laboratory Duplicate:

Aliquots of a sample taken from the same container under laboratory conditions and processed and analyzed independently. (NELAC)

# Least Squares Regression (1<sup>st</sup> Order Curve):

The least squares regression is a mathematical calculation of a straight line over two axes. The y axis represents the instrument response (or Response ratio) of a standard or sample and the x axis represents the concentration. The regression calculation will generate a correlation coefficient (r) that is a measure of the "goodness of fit" of the regression line to the data. A value of 1.00 indicates a perfect fit.

In order to be used for quantitative purposes, r must be greater than or equal to 0.99 for organics and 0.995 for inorganics.

## Limit of Detection (LOD):

An estimate of the minimum amount of a substance that an analytical process can reliably detect. An LOD is analyte- and matrix-specific and may be laboratory dependent. (Analytical Chemistry, 55, p.2217, December 1983, modified) See also Method Detection Limit.

#### Matrix:

The component or substrate that contains the analyte of interest. For purposes of batch and QC requirement determinations, the following matrix distinctions shall be used:

Aqueous: Any aqueous sample excluded from the definition of Drinking Water matrix or Saline/Estuarine source. Includes surface water, groundwater, effluents, and TCLP or other extracts.

Drinking Water: any aqueous sample that has been designated as a potable or potential potable water source.

Saline/Estuarine: any aqueous sample from an ocean or estuary, or other salt water source such as the Great Salt Lake.

Non-aqueous Liquid: any organic liquid with <15% settleable solids.

Biological Tissue: any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origin.

Solids: includes soils, sediments, sludges, and other matrices with >15% settleable solids.

Chemical Waste: a product or by-product of an industrial process that results in a matrix not previously defined.

Air: whole gas or vapor samples including those contained in flexible or rigid wall containers and the extracted concentrated analytes of interest from a gas or vapor that are collected with a sorbant tube, impinger solution, filter, or other device. (NELAC)

#### Matrix Spike (spiked sample or fortified sample):

Prepared by adding a known mass of target analyte to a specified amount of matrix sample for which an independent estimate of target analyte concentration is available. Matrix spikes are used, for example, to determine the effect of the matrix on a method's recovery efficiency.

Matrix spikes shall be performed at a frequency of one in 20 samples per matrix type per sample extraction or preparation method except for analytes for which spiking solutions are not available such as, total suspended solids, total dissolved solids, total volatile solids, total solids, pH, color, odor, temperature, dissolved oxygen or turbidity. The selected sample(s) shall be rotated among client samples so that various matrix problems may be noted and/or addressed. Poor performance in a matrix spike may indicate a problem with the sample composition and shall be reported to the client whose sample was used for the spike. (QAMS)

#### Matrix Spike Duplicate (spiked sample or fortified sample duplicate):

A second replicate matrix spike is prepared in the laboratory and analyzed to obtain a measure of the precision of the recovery for each analyte.

Matrix spike duplicates or laboratory duplicates shall be analyzed at a minimum of 1 in 20 samples per matrix type per sample extraction or preparation method. The laboratory shall document their procedure

to select the use of an appropriate type of duplicate. The selected sample(s) shall be rotated among client samples so that various matrix problems may be noted and/or addressed. Poor performance in the duplicates may indicate a problem with the sample composition and shall be reported to the client whose sample was used for the duplicate. (QAMS)

#### 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. (NELAC)

#### Method Detection Limit:

The minimum concentration of a substance (an analyte) that can be measured and reported with 99% confidence that the analyte concentration is greater than zero and is determined from analysis of a sample in a given matrix containing the analyte. (40 CFR Part 136, Appendix B)

#### Negative Control:

Measures taken to ensure that a test, its components, or the environment do not cause undesired effects, or produce incorrect test results. (NELAC)

#### Performance Audit:

The routine comparison of independently obtained qualitative and quantitative measurement system data with routinely obtained data in order to evaluate the proficiency of an analyst or laboratory. (NELAC)

#### Performance Based Measurement System (PBMS):

A set of processes wherein the data quality needs, mandates or limitations of a program or project are specified and serve as criteria for selecting appropriate test methods to meet those needs in a cost-effective manner. (NELAC)

#### Positive Control:

Measures taken to ensure that a test and/or its components are working properly and producing correct or expected results from positive test subjects. (NELAC)

#### Precision:

The degree to which a set of observations or measurements of the same property, obtained under similar conditions, conform to themselves; a data quality indicator. Precision is usually expressed as standard deviation, variance or range, in either absolute or relative terms. (NELAC)

#### Preservation:

Refrigeration and/or reagents added at the time of sample collection (or later) to maintain the chemical and/or biological integrity of the sample. (NELAC)

#### Proficiency Testing:

A means of evaluating a laboratory's performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by an external source. (NELAC) [2.1]

## Proficiency Testing Program:

The aggregate of providing rigorously controlled and standardized environmental samples to a laboratory for analysis, reporting of results, statistical evaluation of the results and the collective demographics and results summary of all participating laboratories. (NELAC)

## Proficiency Test Sample (PT):

A sample, the composition of which is unknown to the analyst and is provided to test whether the analyst/laboratory can produce analytical results within specified acceptance criteria. (QAMS)

#### Quality Assurance:

An integrated system of activities involving planning, quality control, quality assessment, reporting and quality improvement to ensure that a product or service meets defined standards of quality with a stated level of confidence. (QAMS)

#### Quality Assurance [Project] Plan (QAPP):

A formal document describing the detailed quality control procedures by which the quality requirements defined for the data and decisions pertaining to a specific project are to be achieved. (EAP-QAD)

### Quality Control:

The overall system of technical activities which purpose is to measure and control the quality of a product or service so that it meets the needs of users. (QAMS)

#### Quality Control Sample:

An uncontaminated sample matrix spiked with known amounts of analytes from a source independent from the calibration standards. It is generally used to establish intra-laboratory or analyst specific precision and bias or to assess the performance of all or a portion of the measurement system. (EPA-QAD)

#### 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. (NELAC)

#### 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 (ANSI/ASQC-E-41994)

#### Quantitation Limits:

The maximum or minimum levels, concentrations, or quantities of a target variable (e.g., target analyte) that can be quantified with the confidence level required by the data user. (NELAC)

#### Range:

The difference between the minimum and the maximum of a set of values. (EPA-QAD)

#### Reagent Blank (method reagent blank):

A sample consisting of reagent(s), without the target analyte or sample matrix, introduced into the analytical procedure at the appropriate point and carried through all subsequent steps to determine the contribution of the reagents and of the involved analytical steps. (QAMS)

#### Reference Material:

A material or substance one or more properties of which are sufficiently well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials. (ISO Guide 30-2.1)

## Reference Standard:

A standard, generally of the highest metrological quality available at a given location, from which measurements made at that location are derived. (VIM-6.0-8)

#### Replicate Analyses:

The measurements of the variable of interest performed identically on two or more sub-samples of the same sample within a short time interval. (NELAC)

#### Report Limit (RL):

The laboratory nominal Quantitation Limit (QL) or the level of sensitivity required by the client but not lower than the LOD.

## Resource Conservation and Recovery Act (RCRA):

The enabling legislation under 42 USC 321 et seq. (1976), that gives EPA the authority to control hazardous waste from the "cradle-to-grave", including its generation, transportation, treatment, storage, and disposal. (NELAC)

## Safe Drinking Water Act (SDWA):

The enabling legislation, 42 USC 300f et seq. (1974), (Public Law 93-523), that requires the EPA to protect the quality of drinking water in the U.S. by setting maximum allowable contaminant levels, monitoring, and enforcing violations. (NELAC)

#### Sample Duplicate:

Two samples taken from and representative of the same population and carried through all steps of the sampling and analytical procedures in an identical manner. Duplicate samples are used to assess variance of the total method including sampling and analysis. (EPA-QAD)

<u>Second Order Polynomial Curve (Quadratic)</u>: The 2<sup>nd</sup> order curves are a mathematical calculation of a slightly curved line over two axis. The y axis represents the instrument response (or Response ratio) of a standard or sample and the x axis represents the concentration. The 2<sup>nd</sup> order regression will generate a coefficient of determination (COD or  $r^2$ ) that is a measure of the "goodness of fit" of the quadratic curvature the data. A value of 1.00 indicates a perfect fit. In order to be used for quantitative purposes,  $r^2$  must be greater than or equal to 0.99.

#### Selectivity:

(Analytical chemistry) the capability of a test method or instrument to respond to a target substance of constituent in the presence of non-target substances. (EPA-QAD)

#### Sensitivity:

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

#### Spike:

A known mass of target analyte added to a blank, sample or sub-sample; used to determine recovery efficiency or for other quality control purposes.

If the mandated or requested test method does not specify the spiking components, the laboratory shall spike all reportable components to be reported in the Laboratory Control Sample and Matrix Spike. However, in cases where the components interfere with accurate assessment (such as simultaneously spiking chlordane, toxaphene and PCBs in Method 608), the test method has an extremely long list of components or components are incompatible, a representative number (at a minimum 10%) of the listed components may be used to control the test method. The selected components of each spiking mix shall represent all chemistries, elution patterns and masses permit specified analytes and other client requested components. However, the laboratory shall ensure that all reported components are used in the spike mixture within a two-year time period.. (NELAC)

#### Standard:

The document describing the elements of laboratory accreditation that has been developed and established within the consensus principles of NELAC and meets the approval requirements of NELAC procedures and policies. (ASQC)

#### Standard Operating Procedures (SOPs):

A written document which details the method of an operation, analysis, or action whose techniques and procedures are thoroughly prescribed and which is accepted as the method for performing certain routine or repetitive tasks. (QAMS)

#### Standardized Reference Material (SRM):

A certified reference material produced by the U.S. National Institute of Standards and Technology or other equivalent organization and characterized for absolute content, independent of analytical method. (EPA-QAD)

#### Surrogate:

A substance with properties that mimic the analyte of interest. It is unlikely to be found in environment samples and is added to them for quality control purposes.

Surrogate compounds must be added to all samples, standards, and blanks, for all organic chromatography methods except when the matrix precludes its use or when a surrogate is not available. Poor surrogate recovery may indicate a problem with sample composition and shall be reported to the client whose sample produced poor recovery. (QAMS)

#### Systems Audit (also Technical Systems Audit):

A thorough, systematic, qualitative on-site assessment of the facilities, equipment, personnel, training, procedures, record keeping, data validation, data management, and reporting aspects of a total measurement system. (EPA-QAD)

#### Toxic Substances Control Act (TSCA):

The enabling legislation in 15 USC 2601 et seq., (1976) that provides for testing, regulating, and screening all chemicals produced or imported into the United States for possible toxic effects prior to commercial manufacture. (NELAC)

#### Traceability:

The property of a result of a measurement whereby it can be related to appropriate standards, generally international or national standards, through an unbroken chain of comparisons. (VIM-6.12)

#### Uncertainty:

A parameter associated with the result of a measurement that characterizes the dispersion of the value that could reasonably be attributed to the measured value.

## Acronyms:

- BS Blank Spike
- BSD Blank Spike Duplicate
- CAR Corrective Action Report
- CCV Continuing Calibration Verification
- CF Calibration Factor
- CFR Code of Federal Regulations
- COC Chain of Custody
- CRS Change Request Form
- DOC Demonstration of Capability
- DQO Data Quality Objectives
- DU Duplicate
- DUP Duplicate
- EHS Environment, Health and Safety
- EPA Environmental Protection Agency
- GC Gas Chromatography
- GC/MS Gas Chromatography/Mass Spectrometry
- HPLC High Performance Liquid Chromatography

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ICP - Inductively Coupled Plasma Atomic Emission Spectroscopy ICV – Initial Calibration Verification IDL - Instrument Detection Limit IH - Industrial Hygiene IS – Internal Standard LCS – Laboratory Control Sample LCSD – Laboratory Control Sample Duplicate LIMS - Laboratory Information Management System JLLED MDL – Method Detection Limit MS – Matrix Spike MSD - Matrix Spike Duplicate MSDS - Material Safety Data Sheet NELAC - National Environmental Laboratory Accreditation Conference NELAP - National Environmental Laboratory Accreditation Program PT – Performance Testing QAM – Quality Assurance Manual QA/QC – Quality Assurance / Quality Control QAPP - Quality Assurance Project Plan RF – Response Factor **RPD** – Relative Percent Difference RSD - Relative Standard Deviation SD – Standard Deviation SOP: Standard Operating Procedure TAT – Turn-Around-Time VOA - Volatiles VOC - Volatile Organic Compound

# Appendix 3. Laboratory Certifications, Accreditations, Validations

The Irvine and Ontario laboratories maintain certifications, accreditations, certifications, and validations with various state and national entities. Programs vary but may include on-site audits, reciprocal agreements with another entity, performance testing evaluations, review of the QA Manual, Standard Operating Procedures, Method Detection Limits, training records, etc. At the time of this QA Manual revision, the laboratory has accreditation/certification/licensing with the following organizations:

	DOLLED						
	IRVINE FIXED LABORATORY (CA01531)						
State	Agency	Program License Numbe					
CA	CDPH-NELAP	DW, WW, HW	01108CA				
CA	CDPH-ELAP	HW	2706				
AZ	DHS	DW, WW, HW	AZ0671				
NV	DEP	DW, WW, RCRA	CA015312009A				
н	DOH	DW					
CNMI	DEQ	DW	MP002				
GUAM	EPA	DW	10-001r				
NM	DWB	DW					
	CSDLAC	WW	10256				
	USDA	Foreign Soil	P330-09-00080				
	EPA	ERLN/Water Laboratory Alliance (WLA)					

IRVINE MOBILE LABORATORY #3 (CA01473)						
State	State Agency Program License Number					
CA	CDPH-ELAP WW, HW 2678					

	ONTARIO SERVICE CENTER (CA01533)					
State	Agency	Program	License Number			
CA	CDPH-ELAP	DW, WW [micro only]	2696			
		POLL				

The certificates and parameter lists (which may differ) for each organization may be found on the corporate web site, the laboratory's public server, the final report review table, and in the following offices: QA, marketing, and project management.

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# Appendix 4

# Laboratory Capabilities

Program	Analyte Group	Technique	Method	Source	Description
Drinking Water	Bacteriological	Microbiology	9215B	Std. Methods	Heterotrophic bacteria (Pour Plate Method)
Drinking Water	Bacteriological	Microbiology	9221 B	Std. Methods	E. Coli
Drinking Water	Bacteriological	Microbiology	9221 B	Std. Methods	Coliforms, Total by MTF (MPN)
Drinking Water	Bacteriological	Microbiology	9221 D	Std. Methods	Coliforms Fecal (Presence/Absence)
Drinking Water	Bacteriological	Microbiology	9221 E	Std. Methods	Fecal Coliforms by MTF
Drinking Water	Bacteriological	Microbiology	9221A	Std. Methods	Coliforms, Total - Fermentation Technique
Drinking Water	Bacteriological	Microbiology	9221A	Std. Methods	Coliforms, Total - Enumeration
Drinking Water	Bacteriological	Microbiology	9223B	Std. Methods	Total Coliforms
Drinking Water	Bacteriological	Microbiology	9223B	Std. Methods	E. Coli
Drinking Water	Bacteriological	Microbiology	SIMPLATE	IDEXX	Heterotrophic Bacteria
Drinking Water	Diquat/paraquat	HPLC	549.2	EPA	Diquat/paraquat
Drinking Water	EDB/DBCP	GC/ECD	504.1	EPA	DBCP & EDB
Drinking Water	General Chemistry	Turbidimetric	180.1	EPA	Turbidity
Drinking Water	General Chemistry	Ion Chromatography (IC)	300.0	EPA	Anions, by IC (Br, PO4, SO4, NO3, NO2,CI, F)
Drinking Water	General Chemistry	Ion Chromatography (IC)	300.1	EPA	Bromate, Chlorite, Chlorate, Bromide
Drinking Water	General Chemistry	Titrimetric	310.1	EPA	Alkalinity, (Total, bicarb, carb, hydrox)
Drinking Water	General Chemistry	Spectrophotometric	330.5	EPA	Chlorine Residual
Drinking Water	General Chemistry	General Chemistry	2120 B	Std. Methods	Color
Drinking Water	General Chemistry	Turbidimetric	2130 B	Std. Methods	Turbidity
Drinking Water	General Chemistry	General Chemistry	2150 B	Std. Methods	Odor
Drinking Water	General Chemistry	Titrimetric	2320 B	Std. Methods	Alkalinity, Hydroxide
Drinking Water	General Chemistry	Titrimetric	2320 B	Std. Methods	Alkalinity, Total
Drinking Water	General Chemistry	Titrimetric	2320 B	Std. Methods	Alkalinity, Carbonate
Drinking Water	General Chemistry	Titrimetric	2320 B	Std. Methods	Alkalinity, Bicarbonate
Drinking Water	General Chemistry	Calculation	2330A+B	Std. Methods	Corrosivity (Langlier Index)
Drinking Water	General Chemistry	Calculation	2340 B	Std. Methods	Hardness (by calculation)
Drinking Water	General Chemistry	Potentiometric	2510 B	Std. Methods	Conductance, Specific
Drinking Water	General Chemistry	General Chemistry	2550 B	Std. Methods	Temperature
Drinking Water	General Chemistry	Spectrophotometric	4500-CN C E	Std. Methods	Cyanide, Total (includes distillation method)
Drinking Water	General	Spectrophotometric	4500-CN E	Std.	Cyanide, Total (Colorimetric-Spec)

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Program	Analyte Group	Technique	Method	Source	Description
	Chemistry			Methods	
Drinking Water	General Chemistry	Automated, Colorimetric	4500-CN G	Std. Methods	Cyanide, Total (Automaed Color. or Spec)
Drinking Water	General Chemistry	Spectrophotometric	4500-CN G	Std. Methods	Cyanide, Amenable to Chlorination
Drinking Water	General Chemistry	Potentiometric	4500-F C	Std. Methods	Fluoride (probe)
Drinking Water	General Chemistry	Potentiometric	4500-F C	Std. Methods	Fluoride
Drinking Water	General Chemistry	Potentiometric	4500-H+B	Std. Methods	рН
Drinking Water	Glyphosate	HPLC	547	EPA	Glyphosate
Drinking Water	Haloacetic Acids (HAAs)	GC/ECD	552.2	EPA	Haloacetic Acids (HAAs)
Drinking Water	Herbicides	GC/ECD	515.4	EPA	Chlorinated Acids
Drinking Water	Metals	Calculation	200.7	EPA	Hardness (calculation from ICP results)
Drinking Water	Metals	Digestion	200.7	EPA	Digestion, Metals - Total Recoverable for ICP
Drinking Water	Metals	ICP	200.7	EPA	Silica
Drinking Water	Metals	Digestion	200.9	EPA	Digestion, Metals - Total Recoverable for Graphite Furance
Drinking Water	Metals	GFAA	200.9	EPA	Metals, Graphite Furnace
Drinking Water	Metals	CVAA	245.1	EPA	Mercury, CVAA
Drinking Water	Perchlorate	IC/MS	332.0	EPA	Perchlorate
Drinking Water	Pesticides	GC/ECD	508.1	EPA	Pesticides
Drinking Water	Pesticides	HPLC	531.1	EPA	Carbamates
Drinking Water	Pesticides	GC/MS	548.1	EPA	Endothall
Drinking Water	Pesticides / PCBs	GC/ECD	505	EPA	Pesticides / PCBs
Drinking Water	Semivolatile Organics	GC/MS	525.2	EPA	Semivolatiles
Drinking Water	Volatile Organics	GC/Microextraction	504.1	EPA	EDB/DBCP/TCP
Drinking Water	Volatile Organics	GC/MS	524.2	EPA	Volatiles, Drinking Water
Drinking Water	Volatile Organics	GC/MS	524.2	EPA	Tentatively Identified Compounds (TICs)
Drinking Water	Volatile Organics	GC/MS	CA SRL 524M-TCP	California DHS	1,2,3-Trichloropropane
Solid & Hazardous Waste	BTEX	GC/FID	8021B	SW-846	BTEX
Solid & Hazardous Waste	Extractable Organics	Extraction	3510C	SW-846	Extraction, Separatory Funnel Liquid-Liquid
Solid & Hazardous Waste	Extractable Organics	Extraction	3520C	SW-846	Extraction, Continuous Liquid- Liquid
Solid & Hazardous Waste	Extractable Organics	Extraction	3550B	SW-846	Extraction, Ultrasonic
Solid & Hazardous Waste	Extractable Organics	Extraction	3580A	SW-846	Extraction, Waste Dilution
Solid & Hazardous Waste	Extractable Organics	Clean-Up	3620B	SW-846	Florisil Cleanup
Solid & Hazardous Waste	Extractable Organics	Clean-Up	3650B	SW-846	Acid-Base Partition Cleanup
Solid & Hazardous Waste	Extractable Organics	Clean-Up	3660B	SW-846	Sulfur Cleanup
Solid & Hazardous Waste	Extractable Organics	Clean-Up	3665A	SW-846	Sulfuric Acid/Permanganate Cleanup

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Program	Analyte Group	Technique	Method	Source	Description
Solid & Hazardous Waste	General Chemistry	Spectrophotometric	9014	SW-846	Cyanide, Total
Solid & Hazardous Waste	General Chemistry	Spectrophotometric	9014	SW-846	Cyanide, Amenable to Chlorination
Solid & Hazardous Waste	General Chemistry	Titrimetric	9034	SW-846	Sulfide, Acid Soluble & Insoluble Forms
Solid & Hazardous Waste	General Chemistry	Ion Chromatography (IC)	9056	SW-846	Anions, by IC (Br, PO4, SO4, NO3, NO2,CI, F)
Solid & Hazardous Waste	General Chemistry	IR	9060	SW-846	Total Organic Carbon (TOC)
Solid & Hazardous Waste	General Chemistry	Spectrophotometric	9065	SW-846	Phenols, Total
Solid & Hazardous Waste	General Chemistry	Potentiometric	9214	SW-846	Fluoride (distillation probe)
Solid & Hazardous Waste	General Chemistry	Pensky Martens Closed Cup	1010 A	SW-846	Ignitability
Solid & Hazardous Waste	General Chemistry	Digestion	3060 A	SW-846	Digestion, Alkaline for Hexavalent Chromium
Solid & Hazardous Waste	General Chemistry	Spectrophotometric	9010 B	SW-846	Cyanide, Total (prep only)
Solid & Hazardous Waste	General Chemistry	Spectrophotometric	9012 B	SW-846	Cyanide, Total
Solid & Hazardous Waste	General Chemistry	Distillation	9030B	SW-846	Sulfide (Distillation)
Solid & Hazardous Waste	General Chemistry	Potentiometric	9040B	SW-846	Corrosivity, as pH
Solid & Hazardous Waste	General Chemistry	Potentiometric	9045C	SW-846	pH, Solid & Waste
Solid & Hazardous Waste	General Chemistry	Potentiometric	9050A	SW-846	Specific Conductance
Solid & Hazardous Waste	General Chemistry	General Chemistry	9095A	SW-846	Paint Filter Test
Solid & Hazardous Waste	General Chemistry	Ion Chromatography (IC)	314.0	EPA	Perchlorate
Solid & Hazardous Waste	Hydrocarbons	Gravimetric	1664 A	EPA	Oil & Grease & Petroleum Hydrocarbons
Solid & Hazardous Waste	Hydrocarbons	GC/FID	8015AZ R.1	Arizona DHS	C10 - C32 Hydrocarbons
Solid & Hazardous Waste	Hydrocarbons	GC/FID	8015B_DRO	SW-846	Diesel Range Organics (DRO)
Solid & Hazardous Waste	Hydrocarbons	GC/FID	8015B_GRO	SW-846	Gasoline Range Organics (GRO)
Solid & Hazardous Waste	Hydrocarbons	GC/FID	8015D_DRO	SW-846	Diesel Range Organics (DRO)
Solid & Hazardous Waste	Hydrocarbons	GC/FID	8015D_GRO	SW-846	Gasoline Range Organics (GRO)
Solid & Hazardous Waste	Hydrocarbons	Gravimetric	9071B	SW-846	Oil & Grease (Gravimetric)
Solid & Hazardous Waste	Hydrocarbons	GC/FID	CA LUFT	CA LUFT	Diesel Range Organics (DRO) CA LUFT
Solid & Hazardous Waste	Leach	TCLP	1311	SW-846	TCLP, Toxicity Characteristic Leachate Procedure
Solid & Hazardous Waste	Leach	SPLP	1312	SW-846	Synthetic Precipitate Leachate Procedure
Solid & Hazardous Waste	Metals	ICP/MS	6020	SW-846	Metals, ICP-MS Analysis
Solid & Hazardous Waste	Metals	Ion Chromatography (IC)	7199	SW-846	Chromium, Hexavalent
Solid & Hazardous Waste	Metals	ICP	9081	SW-846	Cation Exchange Capacity (Sodium Acetate)

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Program	Analyte Group	Technique	Method	Source	Description
Solid & Hazardous Waste	Metals	Digestion	3005 A	SW-846	Digestion, Metals - Waters/Dissolved/Total Rec. for FLAA & ICP
Solid & Hazardous Waste	Metals	Digestion	3010 A	SW-846	Digestion, Metals - Aqueous Samples & Extracts
Solid & Hazardous Waste	Metals	Digestion	3020 A	SW-846	Digestion, Metals for Graphite Furance
Solid & Hazardous Waste	Metals	Digestion	3050 B	SW-846	Digestion, Metals - Sediments, Sludges & Soils
Solid & Hazardous Waste	Metals	General Chemistry	6010B	SW-846	Silica
Solid & Hazardous Waste	Metals	ICP	6010B	SW-846	Metals
Solid & Hazardous Waste	Metals	Spectrophotometric	7196A	SW-846	Chromium, Hexavalent
Solid & Hazardous Waste	Metals	CVAA	7470A	SW-846	Mercury in Liquid Waste
Solid & Hazardous Waste	Metals	CVAA	7471A	SW-846	Mercury in Solid or Semisolid Waste
Solid & Hazardous Waste	Metals	GFAA	HML-939-M	CA DTSC	Organo Lead
Solid & Hazardous Waste	PCBs	GC/ECD	8082	SW-846	PCBs
Solid & Hazardous Waste	Pesticides	GC/ECD	8081A	SW-846	Organochlorine Pesticides
Solid & Hazardous Waste	Semivolatile Organics	Extraction	3545	SW-846	Extraction, Pressurized Fluid
Solid & Hazardous Waste	Semivolatile Organics	GC/MS	8270C	SW-846	Semivolatiles
Solid & Hazardous Waste	Semivolatile Organics	GC/MS	8270C	SW-846	PAHs GC/MS Scan Low Level
Solid & Hazardous Waste	Semivolatile Organics	GC/MS	8270C SIM	SW-846	PAHs GC/MS SIM Low Level
Solid & Hazardous Waste	Volatile Organics	Purge and Trap	5035	SW-846	Closed System Purge and Trap for Soils and Waste
Solid & Hazardous Waste	Volatile Organics	Purge and Trap	5030B	SW-846	Purge and Trap for Aqueous Samples
Solid & Hazardous Waste	Volatile Organics	GC/FID	8015B_DAI	SW-846	Alcohols
Solid & Hazardous Waste	Volatile Organics	GC/FID	8021B	SW-846	BTEX and GRO (Plus MTBE)
Solid & Hazardous Waste	Volatile Organics	GC/MS	8260B	SW-846	Volatiles
Solid & Hazardous Waste	Volatile Organics	GC/MS	8260B SIM	SW-846	Volatiles, SIM Low-Level GC/MS
Solid & Hazardous Waste	Waste Characterization	Waste Characterization	1010	SW-846	Flashpoint, Pensky-Martens
Solid & Hazardous Waste	Waste Characterization	Waste Characterization	1010	SW-846	Ignitability, Pensky-Martens
Solid & Hazardous Waste	Waste Characterization	Waste Characterization	SW 7.1.2	SW-846	Ignitability, Solids/Wastes
Wastewater	Bacteriological	Microbiology	9215B	Std. Methods	Heterotrophic Bacteria (Pour Plate Method)
Wastewater	Bacteriological	Microbiology	9221 B	Std. Methods	Coliforms, Total by MTF (MPN)
Wastewater	Bacteriological	Microbiology	9221 E	Std. Methods	Fecal Coliforms by MTF
Wastewater	Bacteriological	Microbiology	9221 F	Std. Methods	E. Coli
Wastewater	Bacteriological	Microbiology	9221C	Std.	Coliforms, Fecal

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Program	Analyte Group	Technique	Method	Source	Description
			_	Methods	
Wastewater	Bacteriological	Microbiology	9223B	Std. Methods	E. Coli
Wastewater	Bacteriological	Microbiology	9230B	Std. Methods	Enterococci
Wastewater	Bacteriological	Microbiology	9230B	Std. Methods	Enterococci
Wastewater	Bacteriological	Microbiology	9230B	Std. Methods	Fecal Streptococci
Wastewater	Bacteriological	Microbiology	9230B	Std. Methods	Fecal Streptococci
Wastewater	BTEX	GC/FID	8021B	SW-846	BTEX
Wastewater	General Chemistry	Spectrophotometric	110.1	EPA	Color
Wastewater	General Chemistry	Potentiometric	120.1	EPA	Conductance, Specific
Wastewater	General Chemistry	Titrimetric	130.2	EPA	Hardness (EDTA Total as CaCO3)
Wastewater	General Chemistry	General Chemistry	140.1	EPA	Odor
Wastewater	General Chemistry	Potentiometric	150.1	EPA	рН
Wastewater	General Chemistry	Gravimetric	160.1	EPA	Solids, Total Dissolved (180 C)
Wastewater	General Chemistry	Gravimetric	160.2	EPA	Solids, Total Suspended (103 - 105 C)
Wastewater	General Chemistry	Gravimetric	160.3	EPA	Solids, Total (103 - 105 C)
Wastewater	General Chemistry	Gravimetric	160.3	EPA	Moisture, Percent (%)
Wastewater	General Chemistry	Gravimetric	160.4	EPA	Solids, Total Volatile
Wastewater	General Chemistry	Gravimetric	160.4	EPA	Solids, Volatile Suspended
Wastewater	General Chemistry	Gravimetric	160.5	EPA	Solids, Settleable
Wastewater	General Chemistry	Gravimetric	160.5	EPA	Solids, Settleable
Wastewater	General Chemistry	General Chemistry	170.1	EPA	Temperature
Wastewater	General Chemistry	Turbidimetric	180.1	EPA	Turbidity
Wastewater	General Chemistry	Ion Chromatography (IC)	300.0	EPA	Anions, by IC (Br, PO4, SO4, NO3, NO2,CI, F)
Wastewater	General Chemistry	Ion Chromatography (IC)	300.1	EPA	Bromate, Chlorite, Chlorate, Bromide
Wastewater	General Chemistry	Titrimetric	305.1	EPA	Acidity
Wastewater	General Chemistry	Titrimetric	310.1	EPA	Alkalinity, (Total, bicarb, carb, hydrox)
Wastewater	General Chemistry	Ion Chromatography (IC)	314.0	EPA	Perchlorate
Wastewater	General Chemistry	Spectrophotometric	335.1	EPA	Cyanide, Amenable to Chlorination
Wastewater	General Chemistry	Spectrophotometric	335.2	EPA	Cyanide, Free
Wastewater	General Chemistry	Potentiometric	340.2	EPA	Fluoride
Wastewater	General Chemistry	Potentiometric	350.3	EPA	Ammonia

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Program	Analyte Group	Technique	Method	Source	Description
Wastewater	General Chemistry	Spectrophotometric	351.2	EPA	Nitrogen, Total Kjeldahl (TKN)
Wastewater	General Chemistry	Potentiometric	351.4	EPA	Total Kjeldahl Nitrogen (TKN)
Wastewater	General Chemistry	Potentiometric	360.1	EPA	Oxygen, Dissolved
Wastewater	General Chemistry	Spectrophotometric	365.3	EPA	Phosphate (Ortho)
Wastewater	General Chemistry	Spectrophotometric	376.2	EPA	Sulfide (Methylene Blue)
Wastewater	General Chemistry	Potentiometric	405.1	EPA	BOD5
Wastewater	General Chemistry	Spectrophotometric	410.4	EPA	COD, Automated
Wastewater	General Chemistry	Oxidative Combustion	415.1	EPA	Dissolved Organic Carbon
Wastewater	General Chemistry	Spectrophotometric	420.1	EPA	Phenols, Total
Wastewater	General Chemistry	Spectrophotometric	425.1	EPA	MBAS, Surfactants
Wastewater	General Chemistry	Potentiometric	2580	Std. Methods	Oxidation / Redox Potential
Wastewater	General Chemistry	Potentiometric	9040	SW-846	рН
Wastewater	General Chemistry	Potentiometric	9214	SW-846	Fluoride
Wastewater	General Chemistry	Gravimetric	1664 A	EPA	Oil and Grease
Wastewater	General Chemistry	General Chemistry	2120 B	Std. Methods	Color
Wastewater	General Chemistry	Turbidimetric	2130 B	Std. Methods	Turbidity
Wastewater	General Chemistry	General Chemistry	2150 B	Std. Methods	Odor
Wastewater	General Chemistry	Titrimetric	2310 B	Std. Methods	Acidity
Wastewater	General Chemistry	Titrimetric	2320 B	Std. Methods	Alkalinity, Hydroxide
Wastewater	General Chemistry	Titrimetric	2320 B	Std. Methods	Alkalinity, Total
Wastewater	General Chemistry	Titrimetric	2320 B	Std. Methods	Alkalinity, Bicarbonate
Wastewater	General Chemistry	Titrimetric	2320 B	Std. Methods	Alkalinity, Carbonate
Wastewater	General Chemistry	Calculation	2340 B	Std. Methods	Hardness (by calculation)
Wastewater	General Chemistry	Titrimetric	2340 C	Std. Methods	Hardness, EDTA Total as CaCO3
Wastewater	General Chemistry	Potentiometric	2510 B	Std. Methods	Conductance, Specific
Wastewater	General Chemistry	Gravimetric	2540 B	Std. Methods	Solids, Total (103 - 105 C)
Wastewater	General Chemistry	Gravimetric	2540 C	Std. Methods	Solids, Total Dissolved (180 C)
Wastewater	General Chemistry	Gravimetric	2540 D	Std. Methods	Solids, Total Suspended (103 - 105 C)
Wastewater	General Chemistry	Gravimetric	2540 E	Std. Methods	Solids, Volatile Suspended
Wastewater	General Chemistry	Gravimetric	2540 E	Std. Methods	Solids, Total Volatile

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Program	Analyte Group	Technique	Method	Source	Description
Wastewater	General Chemistry	Gravimetric	2540 F	Std. Methods	Solids, Settleable
Wastewater	General Chemistry	Gravimetric	2540 F	Std. Methods	Solids, Settleable
Wastewater	General Chemistry	Gravimetric	2540 G	Std. Methods	Solids, Total Fixed & Volatile
Wastewater	General Chemistry	General Chemistry	2550 B	Std. Methods	Temperature
Wastewater	General Chemistry	Spectrophotometric	3500-Cr D	Std. Methods	Chromium (Hexavalent)
Wastewater	General Chemistry	Spectrophotometric	3500-Fe B	Std. Methods	Ferrous Iron
Wastewater	General Chemistry	Spectrophotometric	4500 S D	Std. Methods	Sulfide
Wastewater	General Chemistry	General Chemistry	4500-CI G	Std. Methods	Chlorine Residual
Wastewater	General Chemistry	Spectrophotometric	4500-CN C E	Std. Methods	Cyanide, Total (includes distillation method)
Wastewater	General Chemistry	Spectrophotometric	4500-CN G	Std. Methods	Cyanide, Amenable to Chlorination
Wastewater	General Chemistry	Spectrophotometric	4500-CN I	Std. Methods	Cyanide, Weak Acid Dissociable
Wastewater	General Chemistry	Spectrophotometric	4500-CN I	Std. Methods	Cyanide, Weak Acid Dissociable
Wastewater	General Chemistry	Potentiometric	4500-F C	Std. Methods	Fluoride
Wastewater	General Chemistry	Potentiometric	4500-H+B	Std. Methods	рН
Wastewater	General Chemistry	Preparation	4500-NH3 B	Std. Methods	Ammonia, Distillation
Wastewater	General Chemistry	Titrimetric	4500-NH3 C	Std. Methods	Ammonia
Wastewater	General Chemistry	Potentiometric	4500-NH3 D	Std. Methods	Ammonia
Wastewater	General Chemistry	Spectrophotometric	4500-Norg C	Std. Methods	Nitrogen, Total Kjeldahl (TKN), macro
Wastewater	General Chemistry	Potentiometric	4500-O G	Std. Methods	Oxygen, Dissolved
Wastewater	General Chemistry	Potentiometric	5210 B	Std. Methods	CBOD5
Wastewater	General Chemistry	Potentiometric	5210 B	Std. Methods	BOD5
Wastewater	General Chemistry	Spectrophotometric	5220 D	Std. Methods	COD, Closed Reflux
Wastewater	General Chemistry	IR	5310 B	Std. Methods	Total Organic Carbon (TOC), Combustion
Wastewater	General Chemistry	UV/Persulfate Oxidation	5310 C	Std. Methods	Total Organic Carbon (TOC)
Wastewater	General Chemistry	Spectrophotometric	5540 C	Std. Methods	Surfactants (MBAS)
Wastewater	Hydrocarbons	Gravimetric	413.1	EPA	Oil & Grease
Wastewater	Hydrocarbons	IR	413.2	EPA	Oil & Grease
Wastewater	Hydrocarbons	Gravimetric	418.1	EPA	Petroleum Hydrocarbons-IR (TPHC)
Wastewater	Hydrocarbons	Gravimetric	1664 A	EPA	Oil & Grease
Wastewater	Hydrocarbons	GC/FID	CA LUFT	CA LUFT	Gasoline Range Organics (GRO)
Wastewater	Hydrocarbons	GC/FID	CALUFT	CALUFT	Diesel Range Organics (DRO) CA
Wastewater	Metals	Calculation	200.7	EPA	Hardness (calculation from ICP

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Program	Analyte Group	Technique	Method	Source	Description
					results)
Wastewater	Metals	ICP	200.7	EPA	Metals, ICP
Wastewater	Metals	ICP/MS	200.8	EPA	Metals, ICP-MS
Wastewater	Metals	Ion Chromatography (IC)	218.6	EPA	Chromium, Hexavalent
Wastewater	Metals	CVAA	245.1	EPA	Mercury, CVAA
Wastewater	Metals	Digestion	3050 B	SW-846	Digestion - Metals, Waters
Wastewater	Metals	Automated, Colorimetric	3500-Fe D	Std. Methods	Ferrous Iron (Konelab)
Wastewater	PCBs	GC/ECD	608_PCB	EPA	PCBs
Wastewater	Pesticides	GC/ECD	608_Pest	EPA	Organochlorine Pesticides
Wastewater	Semivolatile Organics	GC/MS	625	EPA	Semivolatiles
Wastewater	Semivolatile Organics	GC/MS	625	EPA	Polynuclear Aromatic Hydrocarbons (PAHs)
Wastewater	Semivolatile Organics	GC/MS	1625	EPA	Semivolatiles, Isotopic Dilution
Wastewater	Semivolatile Organics	GC/MS	625 mod.	EPA	PAHs GC/MS SIM Low Level
Wastewater	Volatile Organics	GC/MS	624	EPA	Volatiles