



Quality Manual

Prepared by

**David Terz
Quality Assurance Director**

for

Fruit Growers Laboratory

QUALITY MANUAL

TABLE OF CONTENTS

1.0	QUALITY MANUAL IDENTIFICATION AND APPROVALS	1
2.0	COMPANY INTRODUCTION	2
2.1	Company Identification	2
2.2	Company Overview	2
2.3	Company History	2
3.0	QUALITY ASSURANCE POLICY	4
3.1	Quality Assurance Policy Statement	4
3.2	Purpose	4
3.3	Scope	4
3.4	Service and Data Integrity Policy	5
	Figure 3.1 - Service and Data Integrity Policy	6
4.0	MANAGEMENT AND ORGANIZATION	7
4.1	Management Responsibility and Authority	7
4.2	Organizational Charts	9
	Figure 4.1 - Laboratory Network	10
	Figure 4.2 - Corporate Personnel	11
	Figure 4.3 - Santa Paula Laboratory	12
5.0	PERSONNEL	13
5.1	General Requirements for Laboratory Staff	13
5.2	Education, Experience and Training	13
5.3	Records	14
6.0	FACILITIES	15
6.1	Facility descriptions	15
6.2	Working Environment	15
6.3	Work Areas	15
6.4	Security	16
6.5	Facility Floor Plans	16
	Figure 6.1 - Santa Paula Laboratory	17
	Figure 6.2 - Stockton Laboratory	18
7.0	QUALITY SYSTEMS	19
7.1	Audits	19
	7.1.1 Audit Review	20
	7.1.2 Reports to Management	20
7.2	Corrective Actions	20
7.3	Essential Quality Control Procedures	21
7.4	Data Validation	22
	7.4.1 Calculations used in Data Validation	23
	Table 7.1 - Summary list of quality controls used by FGL	24
8.0	EQUIPMENT AND REFERENCE MATERIALS	25
8.1	General Requirements	25
8.2	Equipment Maintenance	25
8.3	Reference Equipment	26
	Table 8.1 - Summary list of equipment	27

9.0	MEASUREMENT TRACEABILITY AND CALIBRATION	29
9.1	General Requirements	29
9.2	Traceability of Calibration	29
9.2.1	Documentation and Labeling of Standards	29
9.3	Calibration	29
9.3.1	General Requirements	29
9.3.2	Reference Equipment Calibrations	30
9.3.3	Support Equipment Calibration Verifications	30
9.3.4	Instrument Calibrations	31
9.3.5	Calibration Verification	31
9.3.5.1	Initial Calibration Verification and Blank	31
9.3.5.2	Continuing Calibration Verification and Blank	31
10.0	TEST METHODS	33
10.1	Test Methods Documentation	33
10.1.1	Published Test Methods	33
10.1.2	Standard Operating Procedures (SOPs)	33
10.2	Method Certification	33
10.2.1	Demonstration of Capability	33
10.3	Agency Certification or Approval	34
11.0	SAMPLE HANDLING	35
11.1	Sample Tracking	35
11.2	Sample Acceptance	35
11.3	Sample Receipt Protocols	35
11.4	Storage Conditions	37
11.5	Sample Disposal	37
11.6	Sample Subcontracting	37
12.0	RECORDS	38
12.1	Record Keeping System and Design	38
12.2	Hardcopy Records Management and Storage	38
12.3	Electronic Records Management and Storage	39
12.4	Sample Handling Records	39
12.5	Laboratory Support Activities	40
13.0	LABORATORY REPORT FORMAT AND CONTENTS	41
14.0	OUTSIDE SUPPORT SERVICES AND SUPPLIES	43
14.1	Subcontracted Analyses	43
14.2	Laboratory Supplies	43
14.3	Laboratory Equipment	43
14.4	Laboratory Water Quality	43
15.0	COMPLAINTS	44
16.0	REFERENCES	45
16.1	General Reference List	45
16.2	DOE 5700.6C / 414.1A QA Criteria Cross Reference	46
17.0	DEFINITIONS	47

1.0 QUALITY MANUAL IDENTIFICATION AND APPROVALS

Document Title: FGL Quality Manual

Quality Manual Approvals:

Approved by:

Name: Mr. Darrell H. Nelson
Title President

Signature: _____

Date: _____

Concurrences:

Name: Mr. Kelly Dunnahoo
Title Vice-President/
Lab Director

Signature: _____

Date: _____

Name: Mr. David E. Terz
Title Quality Assurance Director

Signature: _____

Date: _____

2.0 COMPANY INTRODUCTION

2.1 Company Identification:

Fruit Growers Laboratory, Incorporated (aka FGL Environmental or FGL)

Corporate Headquarters, Laboratory and Field Services:

P.O. Box 272
853 Corporation Street
Santa Paula, CA 93060

Tel: 805-659-0910
Fax: 805-525-4172
Web Site: www.fglinc.com
Quality Assurance email: davidt@fglinc.com
Marketing email: denisb@fglinc.com

Satellite Laboratory and Field Services:

2500 Stagecoach Road
Stockton, California

Tel: 209-942-0181
Fax: 209-942-0423

Field Services

Visalia, California

Tel: 209-734-9473
Fax: 209-734-8435
Pager: 209-627-7476

2.2 Company Overview

Fruit Growers Laboratory, Inc. is a full service agronomic and environmental laboratory. The laboratory will be referred to throughout this plan as FGL.

FGL's organization consists of its primary laboratory and corporate offices in Santa Paula, a satellite laboratory in Stockton and a field service office in Visalia. The corporation employs approximately 60 employees and has annual revenues in excess of \$4,000,000. FGL is classified as a small business for federal projects and a large business for State of California projects. The Standard Industrial Classification (SIC) code is 8734.

2.3 Company History

FGL was established in 1925 as a Cooperative enterprise providing agronomic laboratory services to Sunkist contracted growers in California. Sunkist Growers (a cooperative) is a grower owned agricultural marketing organization.

In 1927 FGL secured its drinking water state certification and since then has provided this service to drinking water purveyors throughout the state. In 1973 Fruit Growers Laboratory was reincorporated as a standard California corporation and continued to expand its services to the environmental and agronomic industries. FGL provides environmental and agricultural analytical support services to a variety of clients out of both our laboratories. These include drinking water

purveyors, wastewater and hazardous waste generators and handlers, farming groups, individuals growers, private companies, prime government contractors, municipalities, state and federal agencies. A substantial proportion of our business is made up of a large number of small clients thus distributing our business over a large base of customers. This helps prevent a small number of larger clients dominating our total business.

The corporation has grown at a conservative rate since its founding. Over the past 23 years it has shown consistent profitability. This has resulted in the corporation's strong financial position and available revenues to further invest in people, equipment and facilities.

3.0 QUALITY ASSURANCE POLICY

3.1 Quality Assurance Policy Statement

FGL Environmental's Quality Assurance Policy

“Management and staff are committed to providing analytical services that are scientifically valid, legally defensible and of known precision and accuracy in order to meet or exceed the definitions and expectations of quality of our clientele.”

3.2 Purpose

The FGL Quality Manual (QM) serves as an operational charter for the company. It defines the purpose, structure and operating principles of the laboratory and presents an overview of the primary factors of the quality assurance system.

This QM has been prepared according to guidelines presented in the USEPA document entitled “Quality Systems,” National Environmental Laboratory Accreditation Conference (NELAC), USEPA, Revision 15, May 25, 2001.

A cross reference for the United States Department of Energy, Order 414.1A and the National Analytical Management Program - Integrated Contract Purchasing Team (NAMP-ICPT), Statement of Work, Revision 0, April 30, 1999 is included in section 16. FGL is currently implementing corrective actions to completely meet these requirements.

The extension for a FGL Standard Operating Procedure (SOP) filename indicates the revision number of the document, i.e. S0QA010.003 indicates revision 3. This quality manual references the most recent version of any document by using a generic extension of .XXX.

3.3 Scope

This QM applies to the services supporting, and generation of, analytical data for all FGL locations. As most environmental client needs are driven by various federal and state regulations, the plan has been designed to meet the requirements of the following services and programs:

- a) Analysis of Drinking Water supplies in support of the Safe Drinking Water Act (SDWA)
- b) Analysis of waste stream samples in accordance with National Pollution Discharge Elimination System/Clean Water Act requirements.
- c) Analysis and characterization of soil, water and waste samples per the Resource Conservation and Recovery Act (RCRA) for compliance or disposal purposes.
- d) Analysis and characterization of soil, water and waste samples for site assessment purposes.

3.4 Service and Data Integrity Policy

FGL recognizes that maintaining a proper ethical standard is an important element of an effective QM. In order to ensure that all personnel understand the importance the company places on maintaining high ethical standards at all times, FGL has established a “Service and Data Integrity Policy” and it is presented as Figure 3.1 on the following page for your information. This policy is used to set the standard within the organization. Each employee is required to sign the policy, signifying agreed compliance with it’s stated purpose. Copies of all signed ethics policy statements are maintained in personnel files.

Figure 3.1 Service and Data Integrity Policy

Service and Data Integrity Policy

Fruit Growers Laboratory Incorporated or FGL Environmental's business is to provide analytical data and support services to its customers. **Each employee of FGL plays a vital role in performing this task.**

Providing a service of superior quality and integrity is impacted by three primary factors:

- 1) FGL management's commitment to, and support of staff in, providing service and data of quality and integrity.
- 2) Each employee's personal commitment to provide a service of quality and integrity.
- 3) Each employee's personal skill and knowledge, gained through education and experience, relating to the job which he/she is performing.

When these three factors are optimized the service being provided will be exceptional.

FGL is pledging its full commitment and support to helping you provide the best possible service to our customers. To uphold this policy, FGL will provide the following:

- 1) the right to "stop the assembly line" when a problem or error is discovered.
- 2) a company wide training program to augment your education and/or experience and to provide you with the skills necessary to perform your job well.
- 3) a management "open door policy" is extended to all employees with a guarantee of no reprisal.

This ensures that each employee has the opportunity and the obligation to be a part of FGL's mission to provide the best possible level of analytical service.

As an employee of FGL, integrity in providing service and data must be the highest priority. Service or data quality problems must be immediately brought to the attention of your manager and/or supervisor for review and to initiate solutions to legitimately satisfy the customers' expectations. Ignoring a problem or the falsification of data or information cannot be tolerated since it could significantly impact the reputation and the long term viability of our customers and FGL Environmental.

In our efforts to provide excellent service and high quality defensible analytical data, FGL strives to employ staff of the highest character and personal integrity. Any staff member that knowingly deviates from this expectation of integrity compromises, not just his or her own position, but that of his/her colleagues and will be subject to immediate discharge.

I have read and understand the above information and agree to abide by this policy. I further understand that nothing contained in this policy alters my at-will employment relationship with FGL Environmental.

Employee Name: _____

Signature: _____ Date: _____

4.0 MANAGEMENT AND ORGANIZATION

This is primarily referenced from section 5.4 of “Quality Systems,” National Environmental Laboratory Accreditation Conference, USEPA, Revision 15, May 25, 2001.

The primary objective of the QM is to ensure that systems are in place such that the Quality Assurance Policy Statement is achieved. The management of FGL is committed to the execution of the QM to enable this objective. The company officers, lab directors and managers are required to comply with the program’s requirements and responsibilities.

4.1 Management Responsibility and Authority

The following provides a listing of responsibilities and authority of key managerial personnel involved in laboratory analysis and oversight of the QM:

a) Laboratory Director

1) Responsibility

- i. Ensure that the lab is organized such that confidence in its independence of judgement and integrity is maintained at all times.
- ii. Establish the scope of this QM and implementing, assessing and continually improving an effective quality system.
- iii. Specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of calibrations and tests.
- iv. Ensure that managers have overall responsibility for the technical operation of the laboratory, comply with the QM and require compliance by all personnel.
- v. Ensure that director and managers have the necessary authority and resources in which to achieve the above.
- vi. Ensure supervision by persons familiar with the calibration or test methods and procedures, the objective of the calibration or test and the assessment of the results. The ratio of supervisory to non-supervisory personnel is such that adherence to laboratory procedures and accepted techniques is maintained.
- vii. Ensure that FGL personnel are free from any commercial and other undue pressures which might adversely affect the quality of their work;
- viii. Ensure that adequate review of new contracts are performed to verify that FGL has the appropriate facilities and resources to commence work.
- ix. Nominate replacements in case directors or managers are absent for a period exceeding 15 days. NELAP will be notified if this absence exceeds 65 consecutive calendar days.

2) Authority

- i. Authority to council and terminate employees for dishonesty, unacceptable work behavior or non-compliance with established QA policies and procedures.
- ii. Authority is granted from the president of FGL.

b) Laboratory/Department Manager(s)

The department managers for technical areas of the lab are considered to be technical directors by NELAC definition and have overall responsibility for technical operations of the laboratory.

1) Responsibility

- i. Ensure that personnel with appropriate educational and/or technical background perform all tests for which the laboratory is accredited.
- ii. Ensure compliance with methods and procedures as written.
- iii. Ensure that analytical procedures are performed in accordance with the requested methods and SOP's.
- iv. Oversee prioritizing of work and perform client contact regarding analyses and data interpretation.
- v. Ensure that adequate review of new contracts are performed to verify that FGL has adequate technical capabilities to commence work.
- vi. Oversee preparation of analytical reports and data review.

2) Authority

- i. Authority to council and terminate employees for dishonesty, unacceptable work behavior or non-compliance with established QA policies and procedures.
- ii. Authority to perform client contact and, where necessary, remediate complaints.
- iii. Authority is granted from the Laboratory Director, to whom they report.

c) Quality Assurance Director

The Quality Assurance Director has direct access to technical directors and to the highest level of management at which decisions are taken on laboratory policy and resources. The Quality Assurance director serves as the focal point for QA/QC in the laboratory and is independent from the laboratory functions and influence.

1) Responsibility

- i. Responsible for the QM and its implementation including recommending pertinent additions to the QM.
- ii. Responsible for monitoring and assessing compliance of the laboratory with the requirements contained in the QM.
- iii. Conduct annual audits and inspections to assess compliance with established methods, policies and procedures (SOP reference: S0QA040.XXX).
- iv. Maintain a document control system, containing current policies and procedures utilized by the company, to ensure that all documents clearly indicate the time period and locations in which the procedure or policy was in force (SOP reference: S0QA075.XXX).
- v. Maintain various analytical certifications for the laboratory.

- vi. Review laboratory performance on performance evaluation studies submitted to FGL by clients and regulatory agencies (SOP reference: S0QA130.XXX).
- vii. Responsible for the oversight and/or review of the quality control data (SOP references: S0QA095.XXX and S0QA105.XXX).
- viii. Investigate all inquiries relative to data quality issues and follow up on corrective actions where necessary (SOP reference: S0QA035.XXX).
- ix. Ensure that adequate review of new contracts are performed to verify that FGL has an adequate Quality Assurance program to commence work.
- x. Prepare and issue reports to management in regard to the responsibilities listed above (SOP reference: S0QA190.XXX).

2) Authority

- i. The quality assurance staff have the authority to stop or change any analytical procedure in order to assure that data quality is maintained.
- ii. Authority is granted from the president of FGL.

4.2 Organizational Charts

The following pages contain general organizational charts for the FGL Laboratory network (Figure 4.1), FGL corporate personnel (Figure 4.2) and the Santa Paula Laboratory (Figure 4.3).

Detailed organizational charts listing all departments and all full time personnel will be provided upon request.

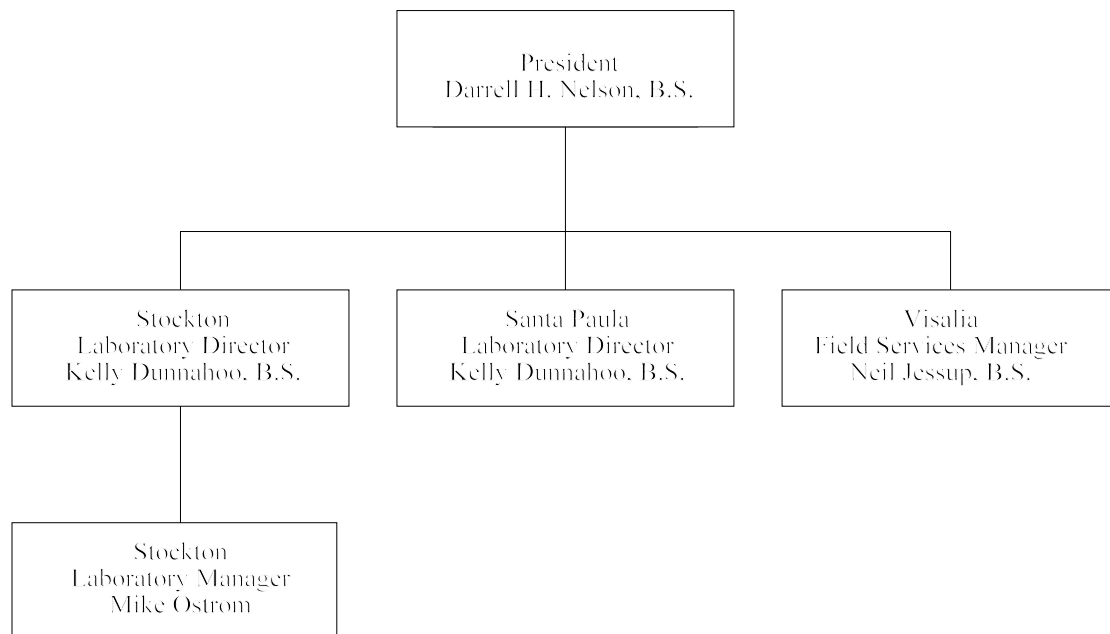


Figure 4.1 Organizational Chart - Laboratory Network

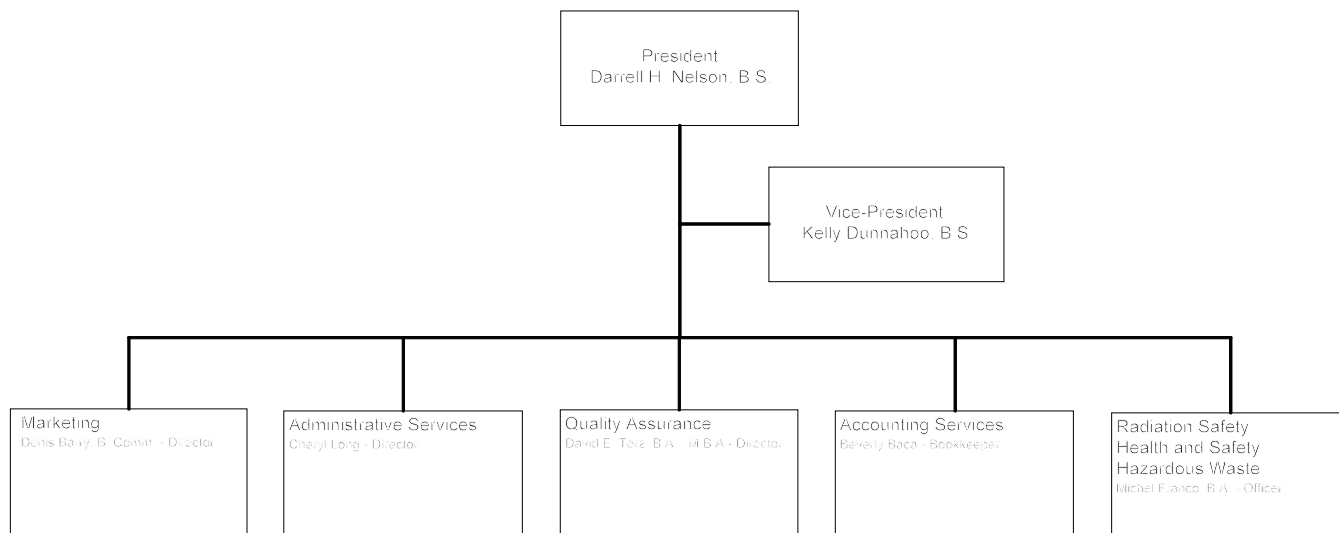


Figure 4.2 Organizational Chart - Corporate Personnel

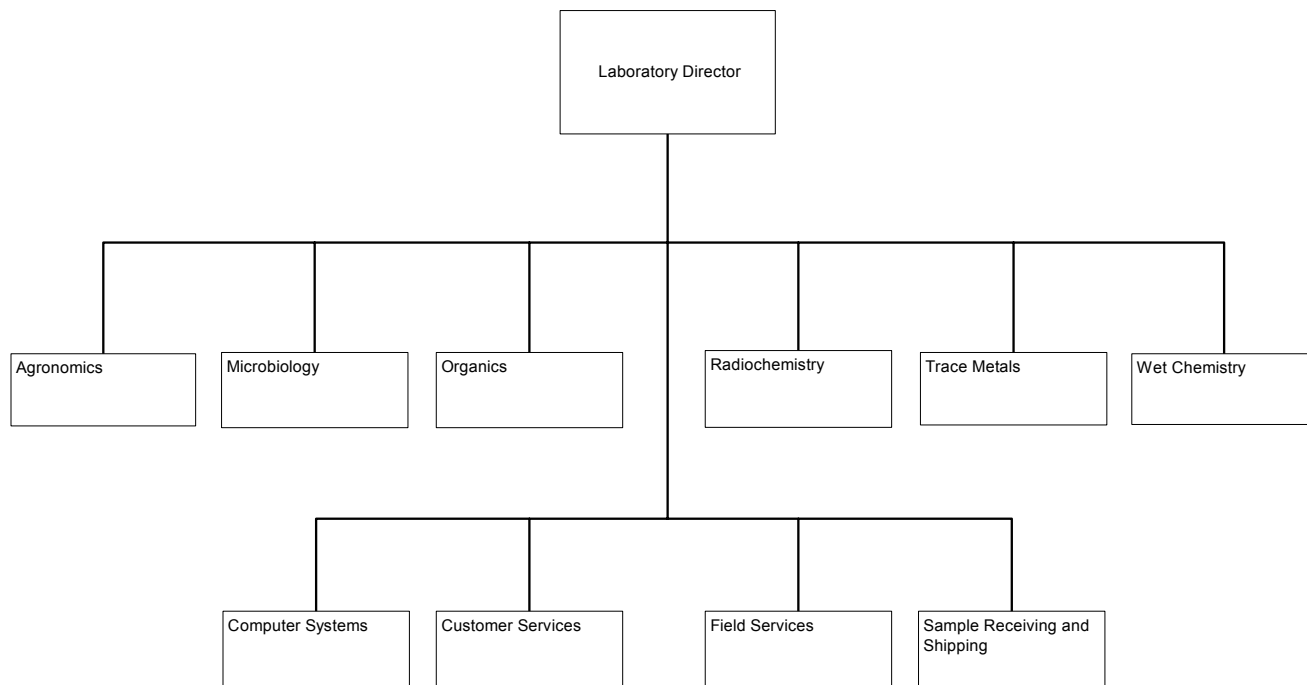


Figure 4.3 Organizational Chart - Santa Paula Laboratory

5.0 PERSONNEL

This is primarily referenced from section 5.6 and Appendix C of "Quality Systems," National Environmental Laboratory Accreditation Conference, USEPA, Revision 15, May 25, 2001.

5.1 General Requirements for Laboratory Staff

a) Responsibility

- 1) To comply with all quality assurance/quality control requirements that pertain to their organizational/technical function.
- 2) Maintain a combination of experience and education to adequately demonstrate a specific knowledge of their particular function and a general knowledge of laboratory operations, analytical test methods, quality assurance/quality control procedures and records management.

b) Authority

- 1) All personnel have the authority to initiate a stop-work order where detrimental ethical, contractual, quality, safety or health conditions exist. The stop-work order must be reported to their manager.
- 2) Authority is granted from the Lab Director and department manager to whom they report.

5.2 Education, Experience and Training

a) Minimal levels of qualification, experience and skills necessary for all positions in the laboratory are specified in the applicable job description.

b) To ensure that all technical staff are knowledgeable in regard to basic laboratory skills, such as using a balance or mechanical pipet, training is provided to each staff member (SOP reference: S0QA145.XXX). Such training will be documented;

c) To ensure initial proficiency, each analyst will be required to perform a demonstration of capability study using the Essential QC for the analysis being trained. An demonstration of capability for a similar test method using the same technology (e.g. GC/MS volatiles by purge and trap for 524.2, 624 or 5035/8260) will also be acceptable and may be applied.

d) To ensure that the training of the each employee is kept up-to-date the following will be performed:

- 1) evidence will be on file that demonstrates that each employee has read, understood, and is using the most recent version of the FGL QM procedures which relate to his/her job responsibilities.
- 2) Training courses or workshops on specific equipment, analytical techniques or laboratory procedures will be documented.
- 3) evidence will be on file that demonstrate that each employee has read, understand and agreed to perform the most recent version of the standard operating procedure.
- 4) Each technical employee will be considered currently proficient by achieving at least one of the following once per year or whenever there is a significant change in instrument type or test method:
 - i. At least four consecutive laboratory control samples which meet all requirements as described in Appendix C, Section C.1.

- ii. At least four consecutive laboratory control samples which meet all requirements as described in Appendix C, Section C.1 on a similar test method using the same technology (e.g., GC/MS volatiles by purge and trap for 524.2, 624 or 5035/8260);
- iii. Method Detection Limit (MDL) studies may also be used for the Demonstration of Capability (DOC) provided that all requirements as described in Appendix C, Section C.1 are met.
- iv. Specific DOC requirements for the test methods are stored in FLG LIMS.

5.3 Records

Records relevant to qualifications, training, skills and experience of the technical personnel will be maintained in a training file for each employee, including records on demonstrated proficiency for each laboratory test method.

6.0 FACILITIES

This is primarily referenced from section 5.7 of "Quality Systems," National Environmental Laboratory Accreditation Conference, USEPA, Revision 15, May 25, 2001.

6.1 Facility descriptions

FGL Santa Paula occupies two buildings totaling 20,000 square feet of space. Approximately 70 percent is dedicated to the analytical laboratory functions. Separate laboratory areas are dedicated to GC/MS volatiles instrumentation, GC/MS semi-volatiles instrumentation, trace metals instrumentation, radiochemistry instrumentation, wet chemistry analysis and trace metals preparation, microbiological preparation and analysis, organic extractions, radiochemistry preparation and analysis (including defined HRAM and LRAM areas).

The GC/MS volatiles analysis area is operated in a positive pressure environment. The GC analysis area and organic extraction area is operated in a negative pressure environment. This coupled with separate HVAC systems for each area provides a contaminant free environment for trace-level volatiles analysis. The laboratory has 22 fume hoods totaling 130 linear feet of hood space. Electrical power for the instrumentation is provided by 110/220 volt circuits.

FGL Stockton occupies one building totaling 3000 square feet of space. Approximately 30 percent is dedicated to the analytical laboratory functions. Separate laboratory areas are dedicated to wet chemistry analysis and microbiology preparation and analysis. The laboratory has 3 fume hoods totaling 18 linear feet of hood space. Electrical power for the instrumentation is provided by 110/220 volt circuits.

6.2 Working Environment

a) Laboratory test areas, energy sources, lighting, heating and ventilation are adequate to facilitate proper performance of tests.

b) The environment in which these activities are undertaken will not invalidate the results or adversely affect the required accuracy of measurement.

c) In instances where monitoring or control of items specified in a test method or by regulation, such as fume hoods and safety showers, the laboratory will meet and document adherence to the laboratory facility requirements.

NOTE - FGL complies with the relevant health and safety requirements. This aspect, however, is outside the scope of this document.

6.3 Work Areas

a) FGL maintains effective separation between neighboring areas when the activities are incompatible including volatile organic analysis and volatile organic chemicals handling areas.

c) Adequate measures are taken to ensure good housekeeping in the laboratory;

d) Work spaces are available to ensure an unencumbered work area. Work areas include:

1) access and entryways to the laboratory;

2) sample receipt area(s);

3) sample storage area(s);

4) sample preparation and testing area(s);

5) data handling and storage area(s).

6) chemical and waste storage area(s);

6.4 Security

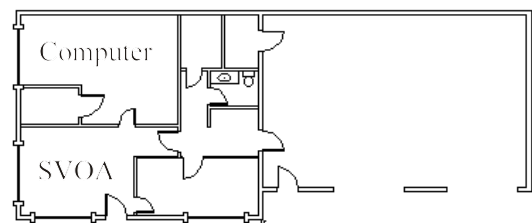
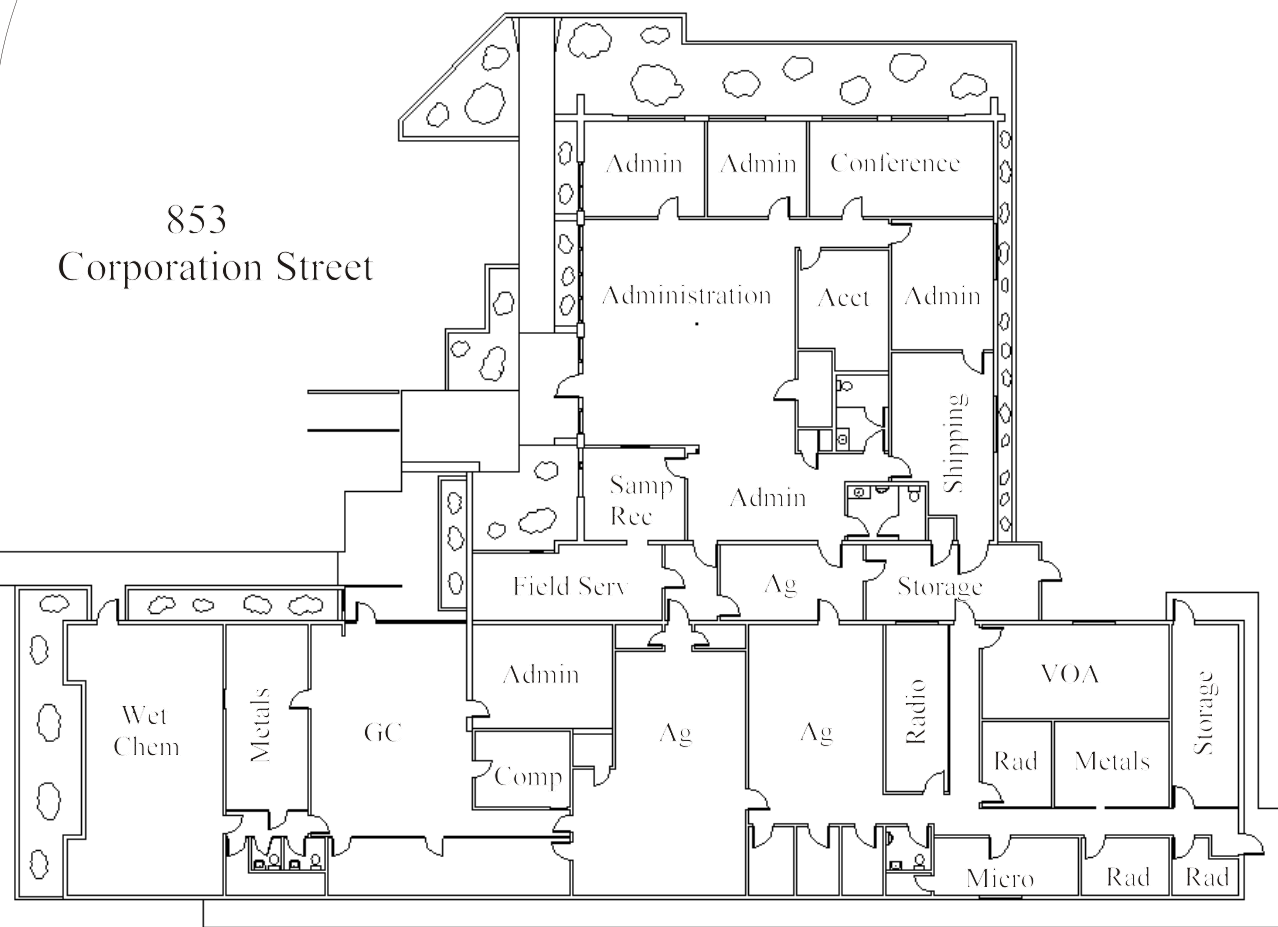
All Laboratory buildings are secured with a keypad access system. Only authorized FGL personnel have access to the facilities.

6.5 Facility Floor Plans

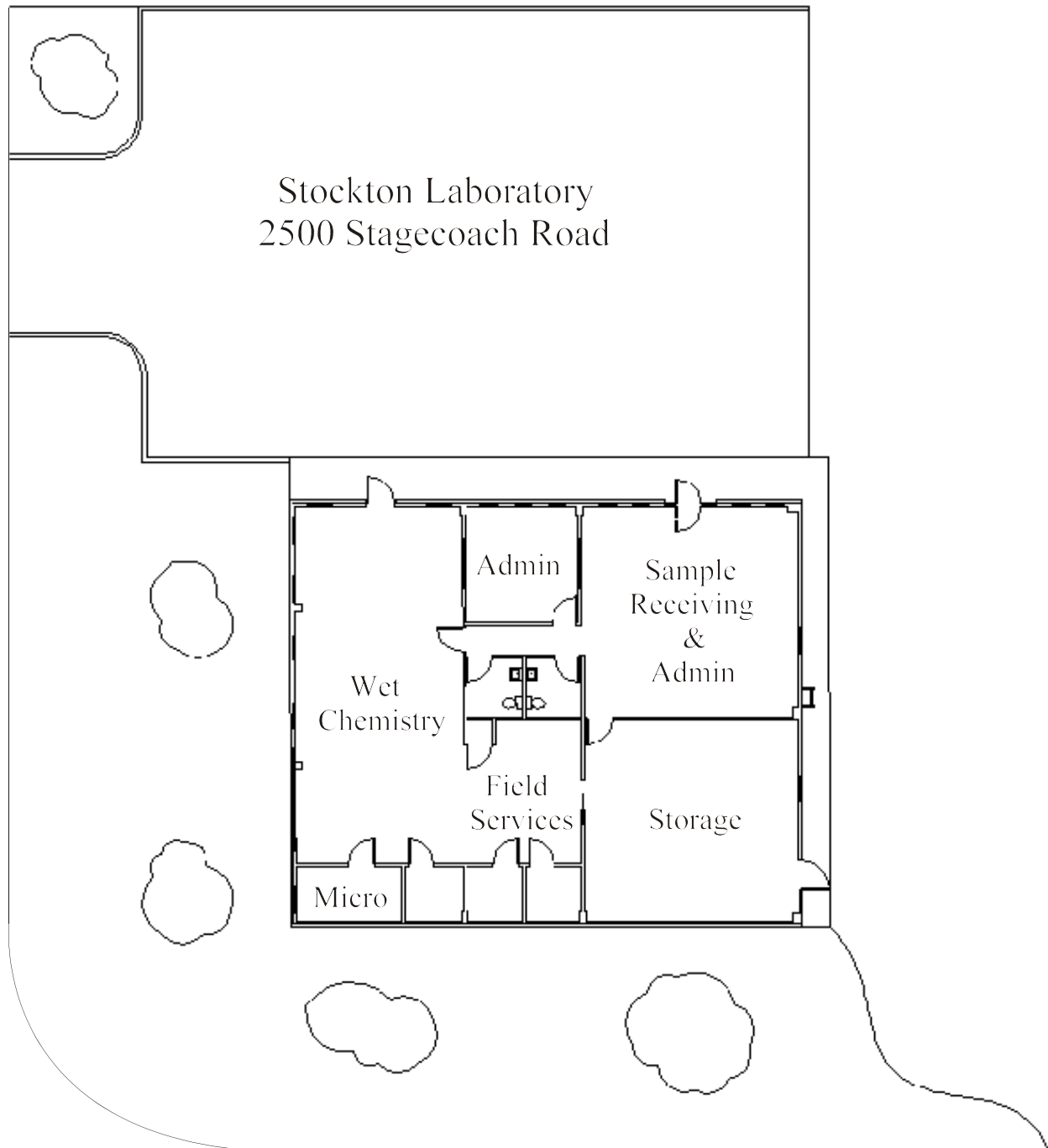
The following pages contain facility floor plans for the FGL Santa Paula Laboratory (figures 6.1) and FGL Stockton Laboratory (figure 6.2).

Santa Paula Laboratory

853
Corporation Street



801
Corporation Street



7.0 QUALITY SYSTEMS

This is primarily referenced from section 5.5 and Appendix D of "Quality Systems," National Environmental Laboratory Accreditation Conference, USEPA, Revision 15, May 25, 2001.

7.1 Audits

a) Internal Audits

The QM can only accomplish its objectives if management and personnel are committed to adherence to the program. In order to assess continued compliance and to identify strong and weak points within the plan, the FGL QA department performs annual internal audits (SOP reference: S0QA040.XXX). Such audits are carried out by the quality assurance director or designee(s) who are trained and who are, wherever possible, independent of the activity to be audited. Where the audit findings cast doubt on the correctness or validity of the laboratory's calibrations or test results, the laboratory will take immediate corrective action and will immediately notify, in writing, any client whose work may have been affected.

To verify that the Quality Assurance department is performing its duties as described by this document, on an annual basis FGL management (outside of quality assurance) will perform a review of the quality system (SOP reference: S0QA205.XXX). Where the review findings show the duties are not complete, the Quality Assurance Director will take corrective action.

b) External Audits

External audits are routinely on a bi-annual basis by regulatory agencies such as California Department of Health Services and Utah Bureau of Laboratory Management to maintain laboratory accreditation.

Client audits are also performed in order to verify compliance with client quality and contractual specifications.

c) Performance Audits

In addition to the audits listed above, FGL ensures the quality of results provided to clients by implementing checks to monitor the quality of the laboratory's analytical activities. Examples of such checks are:

1) internal quality control procedures using regulatory requirements or, whenever possible, statistical techniques (see section 6.3);

2) participation in proficiency testing or other inter-laboratory comparisons. FGL currently participates in the following studies:

I. Water Supply (WS), including Microbiology, twice yearly;

ii. Water Pollution (WP), including Microbiology, twice yearly (includes Discharge Monitoring Report (DMR) study);

iii. Soil/UST, twice yearly;

iv. DOE, Environmental Measurements Laboratory, semi-annual;

v. DOE, Mixed Analyte Performance Evaluation Program (MAPEP), semi-annual;

- 3) when necessary, replicate testings using the same or different test methods;
- 4) when necessary, re-testing of retained samples;
- 5) correlation of results for different parameters of a sample (for example: general mineral balancing or total phosphorus should be greater than or equal to phosphate-phosphorus).

7.1.1 Audit Review

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

7.1.2 Reports to Management

- a) Quarterly activity reports provide the following information to managers:
 - 1) a list of non-conformances for the quarter including an indicator as to whether a corrective action is required;
 - 2) an amended report/invoice summary;
 - 3) temperature monitoring/excursion summary;
 - 4) balance calibration verification summary;
 - 5) water quality monitoring summary;
 - 6) performance evaluation study summaries.
- b) The annual quality assurance report to management summarizes or verifies the following functions:
 - 1) Quality Manual revision;
 - 2) SOP revisions performed;
 - 3) internal quality assurance audit;
 - 4) non-conformance and corrective summaries and status;
 - 5) balance calibration checks;
 - 6) temperature monitoring/excursions;
 - 7) dissolved oxygen probe monthly calibrations;
 - 8) laboratory D.I. and bacteriological water quality checks;
 - 9) container contamination checks;
 - 10) performance evaluations;
 - 11) external quality Assurance audits.

7.2 Corrective Actions

- a) FGL has implemented non-conformance procedures to be followed when departures from

documented policies, procedures and quality control have occurred. This requires the use of a non-conformance report (or similar form such as the report/invoice amendment cover letter) which may require corrective action. This procedure is outlined in the Non-conformance/Corrective Action Program (SOP reference: S0QA035.XXX). These procedures include but are not limited to the following:

- 1) assign a unique non-conformance tracking number to track the non-conformance and, if necessary, the corrective action to final closure;
 - 2) identifying the department in which the non-conformance occurred;
 - 3) identifying the type of non-conformance which occurred, such as calibration failure, standard expiration or reporting;
 - 4) record the pertinent details of the non-conformance, such as analytical method, batch ID, failure and probable cause;
 - 5) quality assurance review to track the non-conformance and determine whether a corrective action will be required.
- b) If a corrective action is deemed necessary the following procedures are performed:
- 1) identify the individual(s) responsible for performing the corrective action;
 - 2) identify the remedial actions (short term) taken to prevent a similar non-conformance from occurring;
 - 3) identify the corrective actions (long term) taken to prevent a similar non-conformance from occurring;
 - 4) quality assurance review to verify the corrective actions taken are adequate;
 - 5) quality assurance closure of the corrective action upon approval.

7.3 Essential Quality Control Procedures

The following essential quality controls, based on NELAC, Chapter 5 (Quality System) section 5.9.4.2 and Appendix D, are utilized, where applicable, for all test methods performed at FGL. The manner in which they are implemented is dependent on the type of test. FGL considers certain quality controls as “critical to data defensibility” and other quality controls as “information only.” Quality controls considered to be “critical to data defensibility” are calibration blanks, calibration verifications, method blanks and LCS’s. In cases where controls “critical to data defensibility” fail, wherever possible, samples will be reprepared and/or analyzed to obtain acceptable data. If this is not possible the client will be notified of the failure and an acceptable resolution determined. In the cases of failing “information only” controls, the information will be provided to the client for their review and evaluation. Table 7.1 contains a comprehensive list of quality control types used by FGL (noted as “critical to data defensibility” and “information only”).

- a) FGL has protocols in place to provide and/or monitor the following quality controls:
- 1) positive and negative controls to monitor sample preparation methods such as Method Blanks and Laboratory Control Samples (LCS), Matrix Spikes (MS), Surrogates (Surr);
 - 2) measures to evaluate analytical variability/reproducibility, such as Matrix Spike Duplicates (MSD’s) or Laboratory Duplicates (Dup’s) (Note: the samples used for these quality controls

are randomly selected by the LIMS. In the case of the LIMS choosing a limited or inappropriate sample the analyst may override the selection);

3) measures to evaluate test method capability, such as Demonstration of Capability (DOC, SOP reference S0QA185.XXX) and Proficiency Testing Samples (PT's, SOP reference S0QA130.XXX);

4) measures to evaluate detection limits, such as method detection limits (MDL, SOP reference: S0QA060.XXX);

5) selection of appropriate formulas to reduce raw data to final results such as regression analysis, comparison to internal/external standard calculations, and statistical analyses;

6) measures to assure the accuracy of the analytical method including Initial and Continuing Calibration Blanks (ICB/CCB), Initial and Continuing Calibration Verifications (ICV/CCV), use of certified reference materials, performance evaluation samples (essential);

7) measures to assure clean glassware and the selection and use of reagents and standards of appropriate quality;

8) use of appropriate techniques to obtain representative subsamples (SOP reference: S0QA165.XXX).

b) The quality control protocols specified by the published test method and/or Standard Operating Procedure will be followed. Where no regulatory quality control protocols are specified FGL will implement those controls which are applicable to the type of sample preparation and analysis being performed (SOP reference: S0QA065.XXX).

c) All quality control measures are assessed and evaluated on an on-going basis. FGL maintains procedures for the development of acceptance/rejection criteria where no method or regulatory criteria exist (SOP reference: S0QA065.XXX);

7.4 Data Validation

In order to determine the validity of data generated the quality controls listed above are reviewed for acceptance. To the extent possible, samples are reported only if all quality control measures are acceptable. If a "critical to data defensibility" quality control measure is found to be out of control, and the data is to be reported, all samples associated with the failed quality control measure are reported with client approval and the appropriate data qualifier(s).

Calculations and data/information entry and transfers are reviewed at the following five specific points:

a) After sample login to verify analyses requested match those analyses which are to be performed. Sampling information such as sample identification, sampling dates and time are also reviewed for transcription accuracy (SOP reference: S0QA100.XXX).

b) After analysis to verify that the quality controls used for analysis and preparation were properly used and valid. Procedures have been defined to properly handle invalid data (SOP reference: S0QA095.XXX). At this time the LIMS performs comprehensive data reviews and reports including:

1) all calibration criteria are acceptable including a summary report;

2) all analytical and preparatory quality controls have been performed in the required frequencies including a summary report;

- 3) all quality control objectives including a summary report for each type of quality control, such as continuing calibration blanks, continuing calibration verifications, internal standards, method blanks, laboratory control samples and matrix spikes. (Note: method blanks will be investigated if blank contamination exceed the established reporting limit for the associated method. Method blank contamination above reporting limits will require immediate corrective action).
 - 4) all standards used are NIST traceable and are within expiration (included in the frequency report);
 - 5) all manual data changes are documented on the data package printouts and a non-conformance is electronically created as an audit trail for review by the quality assurance director;
 - 6) all critical information from the above checks are then presented on a data package summary report which serves as cover sheet and checklist for all data which is to be included in the package.
- c) After data review and printing of data summary reports the analytical data package is reviewed for completeness (SOP reference: S0QA105.XXX) by a second analyst or manager. This review is primarily for failures and data integrity. The LIMS generates a summary indicating what failures occurred and any changes which were made to the data.
- d) Prior to reporting to verify that data is historically reasonable and appropriate cross checks such as general mineral balances and COD is greater than BOD (SOP reference: S0QA110.XXX).
- e) Prior to final signature to verify that the report package is complete in that all analyses requested are being reported and in the proper fashion such as nitrate versus nitrate nitrogen. At this time the invoice is also reviewed to verify that financial agreements are met (SOP reference: S0QA115.XXX).

7.4.1 Calculations used in Data Validation

- a) 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. Accuracy is usually expressed by FGL as percent recovery.
- b) 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 by FGL as percent relative standard deviation or relative percent difference.
- c) Completeness: the degree to which results are deemed to be valid relative to the total number of results reported. Completeness is usually expressed by FGL as the percentage of valid results. FGL does not normally perform this function but can report this calculation if a project requires.
- d) Representativeness: the degree to which results are representative of the site which was sampled. FGL takes steps, such as sample homogenizing and appropriate quantities used for sub-sampling etc., to ensure that the results are relevant and applicable to a specific site/project. However, this is highly dependent on field activities which are out of control of the laboratory. Objectives for representativeness must be determined at the beginning of a project and included in the Field Sampling Plan and Quality Assurance Project Plan.

Table 7.1 Summary list of Quality Controls used by FGL

Quality Control ID	Full Name	
Analysis QC		
Tune	Instrument Tune	Critical to Data Defensibility
InStd	Internal Standard	Critical to Data Defensibility
CALS	Instrument Calibration	Critical to Data Defensibility
InstB	Instrument Blank	Critical to Data Defensibility
ICV	Initial Calibration Verification	Critical to Data Defensibility
ICB	Initial Calibration Blank	Critical to Data Defensibility
HiStd	Calibration Hi Standard	Critical to Data Defensibility
ICSA	Interference Check Sample A	Critical to Data Defensibility
ICSAB	Interference Check Sample AB	Critical to Data Defensibility
CCV	Continuing Calibration Verification	Critical to Data Defensibility
CCB	Continuing Calibration Blank	Critical to Data Defensibility
IDL	Instrument Detection Limit	Critical to Data Defensibility
LDR	Linear Dynamic Range	Critical to Data Defensibility
RTWin	Retention Time Window	Critical to Data Defensibility
Matrix QC		
PDS	Post Digestion Spike (ICP/GFAA)	Information Only
SDil	Serial Dilution (ICP)	Information Only
Preparation QC		
Surr	Surrogate	Information Only
MDL	Method Detection Limit	Critical to Data Defensibility
Blank	Method Blank	Information Only
LCS	Laboratory Control Standard/Sample	Critical to Data Defensibility
MS	Matrix Spike of MS/MSD pair	Information Only
MSD	Matrix Spike Duplicate of MS/MSD pair	Information Only
BS	Blank Spike of BS/BSD pair	Information Only
BSD	Blank Spike Duplicate of BS/BSD pair	Information Only
Dup	Duplicate Sample	Information Only
ExBlk	TCLP/STLC Extraction Blank	Critical to Data Defensibility
ExDup	TCLP/STLC Extraction Duplicate	Critical to Data Defensibility
SRC	Sample Replicate Check	Information Only

8.0 EQUIPMENT AND REFERENCE MATERIALS

This is primarily referenced from section 5.8 of "Quality Systems," National Environmental Laboratory Accreditation Conference, USEPA, Revision 15, May 25, 2001.

8.1 General Requirements

a) The laboratory is furnished with all items of equipment including reference materials, such as certified balance weights and reference thermometers, required for the correct performance of tests for which it is accredited.

b) Each major item of equipment is identified by the serial number, LIMS ID, and inventory control number.

c) Records will be maintained in FGL LIMS of each major item of equipment and all reference materials significant to the tests performed. This list will be made available upon request. The records will include:

- 1) the name of the item of equipment;
- 2) the manufacturer's name, type identification, and serial number or other unique identification;
- 3) date received and date placed in service (if available);
- 4) current location, where appropriate.

d) Table 8.1 contains a summary listing of equipment including which lab the equipment is located in, the division in which it is used, the quantity, and instrument type. A more detailed listing including information such as specific manufacturers, model numbers will be made available upon request.

8.2 Equipment Maintenance

a) All equipment is routinely maintained, inspected and cleaned. Specific routine maintenance procedures are documented in section 15.0 of each analytical SOP.

b) Any item of equipment which has been subjected to overloading or mishandling, or which gives suspect results, or has been shown by verification or otherwise to be defective, will be clearly identified and taken out of service until it has been repaired and shown by calibration, verification or test to perform satisfactorily (SOP reference: S0QA140.XXX). The laboratory will review the effect of this defect on previous analyses.

c) Records will be maintained for all routine and non-routine maintenance performed. These procedures are outlined in the instrument maintenance SOP (SOP reference: S0QA140.XXX). Records of the maintenance will include:

- 1) the manufacturer's name, model number, serial number and instrument identification;
- 2) the date the maintenance was performed and the analyst or service technician who performed the maintenance;
- 3) the symptoms of problems occurring on the instrument;
- 4) the cause of the problems occurring on the instrument;
- 5) the repair/maintenance performed to correct the problem.

8.3 Reference Equipment

- a) Reference equipment of measurement held by the laboratory (such as calibrated weights or thermometers) shall be used for calibration only and for no other purpose. Reference equipment of measurement are calibrated by a body that can provide NIST or other appropriate national standards of measurement traceability.
- b) FGL maintains a program for calibration and verification for reference equipment (SOP reference S0QA140.XXX). Please refer to section 9.3.2 for information regarding use of reference equipment and calibration of the support equipment such as thermometers, balances and mechanical pipets.

Table 8.1 Summary list of equipment

LAB	DIVISION	QUANTITY	INSTRUMENT TYPE
SP	Organic	6	Gas Chromatograph/Mass Spectrometer
SP	Organic	8	Gas Chromatograph
SP	Organic	1	High Performance Liquid Chromatograph
SP	Organic	1	Infra-red Spectrophotometer (Fixed wavelength)
SP	Organic	1	Total Organic Carbon Analyzer
SP	Organic	3	Analytical Balance
SP	Inorganic	2	Inductively Coupled Plasma/Mass Spectrometer
SP	Inorganic	2	Inductively Coupled Plasma Spectrophotometer
SP	Inorganic	1	Graphite Furnace AA with Zeeman background correction and autosampler
SP	Inorganic	2	Automated Mercury Analyzer
SP	Inorganic	3	Ion Chromatograph with autosampler
SP	Inorganic	2	Flow injection autoanalyzer
SP	Inorganic	2	UV/VIS Spectrophotometer
SP	Inorganic	1	Nephelometer
SP	Inorganic	1	Oxygen Meter
SP	Inorganic	1	pH/EC/ISE Meter
SP	Inorganic	1	pH Meter
SP	Inorganic	1	Setaflash
SP	Inorganic	3	Analytical Balance
SP	Radio	1	Gamma Ray Spectroscope
SP	Radio	8	Alpha Spectrometer
SP	Radio	1	Alpha Scintillation
SP	Radio	1	Liquid Scintillation
SP	Radio	13	Alpha Counter
SP	Radio	3	Alpha/Beta Counter
SP	Radio	1	Alpha/Beta Counter, with autosampler
SP	Radio	2	Balance
SP	Agronomics	4	Inductively Coupled Plasma Spectrophotometer
SP	Agronomics	2	UV/VIS Spectrophotometer
SP	Agronomics	1	pH Meter
SP	Agronomics	2	EC Meter
SP	Agronomics	1	Chloridometer
SP	Agronomics	1	Nitrogen Analyzer
SP	Agronomics	2	Carbon/Nitrogen/Sulfur Analyzer
SP	Agronomics	6	Analytical Balance
SP	Bacti	3	Incubators
SP	Bacti	3	Waterbaths

LAB	DIVISION	QUANTITY	INSTRUMENT TYPE
SP	Bacti	2	Autoclaves
SP	Field Service	9	Vehicles
SP	Field Service	10	Isco Autosamplers
SP	Computers	1	1 x 16 fibre optic backbone switch
SP	Computers	9	2 x 24 fibre optic to category 5 switches
SP	Computers	2	DSL/T1 Routers
SP	Computers	2	VMS/PCSA Servers for DOS Instrument Data
SP	Computers	2	UNIX/Samba Servers for Foxpro DOS LIMS ver2.0
SP	Computers	5	Linux/Samba Servers for NT File/Print Services
SP	Computers	2	Linux/Samba Servers for MySQL/VB6 LIMS ver3.0
SP	Computers	85	DOS/WIN95/NT Based Computers
STK	Inorganic	2	UV/VIS Spectrophotometer
STK	Inorganic	1	Conductivity Meter
STK	Inorganic	1	pH Meter
STK	Inorganic	1	Nephelometer
STK	Bacti	2	Incubator
STK	Bacti	2	Waterbaths
STK	Bacti	1	Autoclave
STK	Field Services	3	Vehicles
STK	Field Services	4	Isco Autosamplers
STK	Field Services	1	Isco Pump
STK	Computers	1	1 x 24 category 5 switch
STK	Computers	1	DSL Router
STK	Computers	1	Linux/Samba Servers for NT File/Print Services
STK	Computers	6	WIN9x/NTx based computers

9.0 MEASUREMENT TRACEABILITY AND CALIBRATION

This is primarily referenced from section 5.9 of "Quality Systems," National Environmental Laboratory Accreditation Conference, USEPA, Revision 15, May 25, 2001.

9.1 General Requirements

All measuring operations and testing equipment having an effect on the accuracy or validity of tests are calibrated and/or verified before being put into service and on a continuing basis. FGL maintains a program for the calibration and verification of its measuring and test equipment. This includes balances, thermometers and control standards.

9.2 Traceability of Calibration

The overall program of calibration and/or verification and validation of equipment has been designed and operated so as to ensure that, wherever applicable, measurements made by the laboratory are traceable to NIST or other appropriate national standards of measurement. All standards are documented at the laboratory for future traceability (SOP reference: S0QA030.XXX).

9.2.1 Documentation and Labeling of Standards

Documented procedures are maintained for the purchase, reception and storage of calibration standards used for the technical operations of the laboratory.

a) The laboratory retains records for all standards including the manufacturer/vendor, the manufacturer's Certificate of Analysis or purity (if supplied), the date of receipt, recommended storage conditions, and an expiration date after which the standard will not be used unless it is verified by the laboratory.

b) The original stock standard containers (such as provided by the manufacturer or vendor) are labeled with an expiration date.

c) Detailed records are maintained for standard preparation. These records indicate traceability to purchased stocks or neat compounds, reference to the method of preparation, date of preparation, expiration date and preparer's initials.

d) All containers of stock and prepared standards bear a unique identifier and expiration date and are linked to the documentation listed in 9.2.1 a) above.

9.3 Calibration

9.3.1 General Requirements

a) Each calibration is dated and labeled with the test method, instrument, analysis date, and each analyte name, concentration and response (or response factor).

b) Sufficient information is recorded to permit reconstruction of the calibration.

c) Criteria for the acceptance of a calibration procedure, such as calibration curves and concentration (titer) determinations of titrants, are established. General criteria are listed below. Detailed criteria are listed in section 11.0 of each analytical SOP.

9.3.2 Reference Equipment Calibrations

This equipment includes thermometers, balances, balance weights and radiation survey meters . All reference equipment is:

- a) Maintained in proper working order. The records of all calibrations are retained.
- b) Calibrated using NIST traceable references when available, over the entire range of use. The results of such calibration shall be within the specifications required of the application for which is equipment is used or:
 - 1) The equipment shall be removed from service until repaired; or
 - 2) FGL will prepare a deviation curve and correct all measurements for the deviation. All measurements will be recorded and maintained.
- c) Calibrated according to the following frequencies:
 - 1) The primary NIST traceable reference thermometer is calibrated by an outside source on an annual basis. Secondary thermometers used for verification of ovens, refrigerators, freezers, incubators and water baths shall be calibrated with the primary NIST traceable reference on an annual basis. Thermometers used for microbiological procedures are calibrated with the primary NIST traceable reference on a semi-annual basis. The temperature correction is posted on the thermometer (SOP reference: S0QA125.XXX).
 - 2) Balances and balance verification weights are calibrated with NIST traceable references on an annual basis (SOP reference: S0QA155.XXX).
 - 3) Radiation survey meters are calibrated on an annual basis (SOP reference: S2HWS010.XXX).

9.3.3 Support Equipment Calibration Verifications

This equipment includes balances, volumetric dispensing devices (such as Eppendorf®, or automatic dilutor/dispensing devices), autoclaves and ovens, refrigerators, freezers, incubators, water baths. Calibration verification of volumetric dispensing devices is performed if quantitative results are dependent on their accuracy, as in standard preparation and dispensing or dilution into a specified volume. All support equipment is:

- a) Maintained in proper working order. The records of all activities including service calls are retained.
- b) Verified using NIST traceable references when available. The results of the verification shall be within the specifications required of the application for which is equipment is used or the equipment shall be removed from service until repaired.
- c) Verifications according to the following frequencies:
 - 1) Ovens, refrigerators, freezers, incubators and water baths shall be verified with NIST traceable references prior to use on each working day. Additional monitoring as prescribed by the test method shall be performed for any device that is used in a critical test (such as incubators or water baths). The acceptability for use or continued use shall be according to the needs of the analysis or application for which the equipment is being used (SOP reference: S0QA125.XXX).
 - 2) Balances are verified with NIST traceable references prior to use on each working day (SOP reference: S0QA155.XXX).

- 3) Volumetric dispensing devices (except Class A glassware) are verified for accuracy and precision on a quarterly basis (SOP reference: S0QA160.XXX).
- 4) Autoclave sterilization temperatures and pressures for each run are documented by the use of spore strips.

9.3.4 Instrument Calibrations

- a) Calibration curves are prepared as specified in the published test method. If the published test method does not provide guidance in the preparation of a calibration curve (e.g. number of calibration points and range), FGL will use a minimum of two standards plus a zero reference standard.
- b) The calibration curve is subjected to a calibration linearity test, such as a linear regression or percent RSD of response factors (internal standard calibration) or calibration factors (external standard calibration). For those methods which do not contain specific acceptance criteria FGL applies the following:
 - 1) Organics: if, spanning the range of calibration, the RSD of response factors is less than 15 percent, or the RSD of calibration factors is less than 30 percent, an average relative response factor may be used. If that fails then a linear least squares fit is used with a weighted coefficient of determination no less than 0.99. If that fails then a quadratic least squares fit is used with weighted coefficient of determination no less than 0.99.
 - 2) Inorganics: a linear regression or quadratic may be used with a correlation coefficient R^2 no less than 0.995.
- c) Prior to specific analyte calibrations certain tests may require an instrument calibration such as a GC/MS or ICP/MS tune. Acceptance criteria are normally defined in the published test method and must be met prior to instrument use. These criteria are also listed in the specific SOP for that instrument.

9.3.5 Calibration Verification

9.3.5.1 Initial Calibration Verification (ICV) and Blank (ICB)

- a) When available, all initial calibrations are verified with a matrix matched blank (ICB) and a standard obtained from a second or different source (ICV). The ICB and ICV are analyzed with each initial calibration and must be within acceptance range specified by the published test method or limits statistically derived by FGL.
- b) If the initial calibration verification fails, the analysis procedure will be stopped and evaluated. For example, a second standard may be analyzed and evaluated or a new initial calibration curve may be established and verified. In all cases, the initial calibration verification will be acceptable before analyzing any samples.

9.3.5.2 Continuing Calibration Verification (CCV) and Blank (CCB)

Additional standards are analyzed after the initial calibration curve or the integrity of the initial calibration curve (see 9.3.4.1 above) has been accepted.

- a) These standards are analyzed at a frequency specified by the published test method. If published frequencies are not available a minimum frequency of 5% or every 12 hours whichever is more frequent will be used. The verification may use the standards from the original calibration curve or standards from another source.

b) When an initial calibration curve is not established on the day of analysis, the integrity of the initial calibration curve is verified on each day of use (or 24 hour period) by initially analyzing an CCB and CCV at the method defined concentration or a mid-level concentration if not included in the test method.

c) If a calibration check standard fails, and routine corrective action procedures fail to produce a second consecutive calibration check within acceptance criteria, a new initial calibration curve is performed. When the continuing calibration verification acceptance criteria are exceeded high (i.e., high bias) on an automated analytical run, and there are non-detects for the corresponding analyte in environmental samples associated with the continuing calibration check, then those non-detects may be reported. Positive samples affected by the unacceptable check are reanalyzed after a new calibration curve has been established, evaluated and accepted. Additional automated sample analysis will not occur until a new calibration curve is established and verified. Non-automated analyses are corrected by recalibration at the time of analysis.

10.0 TEST METHODS

This is primarily referenced from section 5.10 of "Quality Systems," National Environmental Laboratory Accreditation Conference, USEPA, Revision 15, May 25, 2001.

10.1 Test Methods Documentation

FGL maintains published test methods and standard operating procedures which provide a reference for and specific instructions on the use and operation of all relevant equipment, handling and preparation of samples, calibration and/or testing and administrative procedures. All instructions, standards, manuals and reference data relevant to the work of the laboratory will be maintained up-to-date and be readily available to the staff. A list of all test methods accredited and/or performed by FGL will be made available upon request.

10.1.1 Published Test Methods

- a) The laboratory maintains a collection of current published test method manuals for each accredited analyte or test method. The list of method references which FGL uses is listed in section 16.0 of this document.
- b) Copies of all published test methods are accessible to all personnel.
- c) A comprehensive list of all methods which FGL is capable of performing is available.

10.1.2 Standard Operating Procedures (SOP)

FGL maintains internally written standard operating procedures that accurately reflect all phases of current laboratory activities such as assessing data integrity, corrective actions, performance evaluation study handling, and all test methods. FGL utilizes two standard SOP formats, analytical/preparation and administrative (SOP references: S0QA010.XXX and S0QA015.XXX respectively). Specific SOP's will be made available upon request.

- a) Copies of all SOPs are accessible to all personnel.
- b) The SOPs are organized by the location (e.g. department or customer) in which they are used. SOP's which are used by many locations are controlled to each applicable location (SOP reference: S0QA075.XXX).
- c) Each SOP clearly indicates the effective date of the document, the revision number and the signature(s) of the approving authorities.

10.2 Method Certification

Prior to being accredited for a test method FGL will perform an initial demonstration of capability. This process is used to verify that the procedure is accurate, precise and meets all published regulatory criteria where applicable. Upon demonstrating acceptable results FGL will maintain the records and provide a report package to the appropriate regulatory agency to obtain certification.

10.2.1 Demonstration of Capability

a) Prior to the use of any test method, each analyst must provide a demonstration of capability. The following demonstration of capability requirements are based on NELAC, Chapter 5 (Quality System) Appendix C:

- 1) A quality control sample will be obtained from an outside source. If not available, the QC

check sample may be prepared by the laboratory using stock standards that are prepared independently from those used in instrument calibration.

2) The concentrate will be diluted in a volume of clean matrix sufficient to prepare four aliquots at the required method volume to a concentration approximately 10 times the method-stated or laboratory-calculated method detection limit.

3) The four aliquots shall be prepared and analyzed according to the test method either concurrently or over a period of days.

4) Using the four results, calculate the average recovery in the appropriate reporting units (such as ug/L) and the standard deviation of the population sample (-1) (in the same units) for each parameter of interest.

5) For each parameter, compare the standard deviation and average to the corresponding acceptance criteria for precision and accuracy in the test method (if applicable) or in laboratory-generated acceptance criteria (if a non-standard method). If the standard deviation and average for all parameters meet the acceptance criteria, the method will be considered acceptable and the certification process may continue. If any one of the parameters exceed the acceptance range, the performance is unacceptable for that parameter.

6) When one or more of the tested parameters fail at least one of the acceptance criteria, the analyst must proceed according to a) or b) below.

I) Locate and correct the source of the problem and repeat the test for all parameters of interest beginning with 3) above.

ii) Beginning with 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 3).

c) Thereafter, continuing demonstration of method performance (such as laboratory control samples) is required.

d) In all cases, the appropriate documentation is completed and retained by the laboratory to be made available upon request. All associated supporting data necessary to reproduce the analytical results is retained by the laboratory.

10.3 Agency Certification or Approval

Prior to performing a test method in a given region, FGL will obtain the necessary agency certification. Below is a list of all agencies for which FGL has been certified or approved for analysis (all certifications are available upon request):

a) FGL Santa Paula maintains certifications or approval for the following agencies:

California - Department of Health Services
Hawaii - Department of Health
Utah - Bureau of Laboratory Improvement
United States - Department of Energy

b) FGL Stockton maintains certifications or approval for the following agency:

California - Department of Health Services

11.0 SAMPLE HANDLING

This is primarily referenced from section 5.11 of "Quality Systems," National Environmental Laboratory Accreditation Conference, USEPA, Revision 15, May 25, 2001.

11.1 Sample Tracking

- a) The laboratory maintains a documented system for uniquely identifying the items to be tested, to ensure that there can be no confusion regarding the identity of such items at any time (SOP Reference: S0REC005.XXX). This system includes identification for all samples, subsamples and carried forward to subsequent extracts and/or digestates. The laboratory assigns a unique identification (ID) code to each sample container received in the laboratory.
- b) This laboratory ID code will maintain an unequivocal link with the unique field ID code assigned each container.
- c) The laboratory ID code is placed on the sample container as a durable label.
- d) The laboratory ID code is entered into the LIMS and is the link that associates the sample with related laboratory activities such as sample preparation or calibration.

11.2 Sample Acceptance

The laboratory maintains a written sample acceptance criteria that clearly outlines the circumstances under which samples will be accepted (SOP reference: S0REC005.XXX). This SOP is available to sample collection personnel and includes, but is not limited to, the following areas of concern:

- a) Proper, full, and complete documentation, which includes sample identification, the location, date and time of collection, collector's name, container type, preservation type, sample type and any special remarks concerning the sample. FGL maintains documented procedures listing proper containers and preservation (form reference: F0SHP005.XXX);
- b) Proper sample labeling to include unique identification and a labeling system for the samples with requirements concerning the durability of the labels (water resistant) and the use of indelible ink;
- d) Adherence to specified holding times;
- e) Adequate sample volume. Sufficient sample volume must be available to perform the necessary tests; and
- f) Procedures to be used when samples which show signs of damage or contamination.

11.3 Sample Receipt Protocols

- a) Upon receipt, the condition of the sample, including any abnormalities or departures from standard condition as prescribed in the relevant test method, are recorded.
 - 1) All samples which require thermal preservation are considered acceptable if the arrival temperature is either within $\pm 2^{\circ}\text{C}$ of the required temperature or the method specified range. For samples with a specified temperature of 4°C , samples with a temperature ranging from just above the freezing temperature of water to 6°C shall be acceptable. Samples that are hand delivered to the laboratory immediately after collection may not meet this criteria. In these cases, the samples will be considered acceptable if there is evidence that the chilling process has begun such as arrival on ice.

- 2) FGL has documented procedures for checking chemical preservation such as pH at the time of sample receipt.
- b) The results of all checks are recorded.
- c) Where there is any doubt as to the item's suitability for testing, where the sample does not conform to the description provided, or where the test required is not fully specified, FGL will consult the client for further instruction before proceeding. If the sample does not meet the sample receipt acceptance criteria FGL will either:
 - 1) Retain correspondence and/or records of conversations concerning the final disposition of rejected samples; or
 - 2) Fully document any decision to proceed with the analysis of samples not meeting acceptance criteria.
 - i. The condition of these samples will be noted on the chain of custody or sample discrepancy form;
 - ii. The analysis data will be appropriately "qualified" on the final report.
- d) FGL utilizes a LIMS electronic database to document receipt of all sample containers.
 - 1) At a minimum, the following is recorded in the LIMS:
 - i. Client Name and Address
 - ii. Project Name
 - iii. Sample description
 - iv. Sample date and time
 - v. Name of sampler and employer
 - vi. Date and time of laboratory receipt
 - vii. Name of person who received the sample
 - viii. Unique laboratory ID code
 - ix. Analytical test methods requested
 - x. Container types and preservation
 - xi. Initials of person making the entries.
- e) All documentation, such as a fax transmittal form, that is transmitted either by FGL or by the sample transmitter will be retained.
- f) A complete chain of custody record is retained.

11.4 Storage Conditions

The laboratory maintains documented procedures and appropriate facilities to avoid deterioration, contamination, or damage to the sample during storage, handling, preparation, and testing; any relevant instructions provided with the sample will be followed (S0REC005.XXX). Where items have to be stored under specific environmental conditions, these conditions will be maintained, monitored and recorded where necessary.

a) Samples are stored according to the conditions specified by preservation protocols:

1) Samples which require thermal preservation shall be stored under refrigeration which is $\pm 2^{\circ}\text{C}$ of the specified preservation temperature unless method specific criteria exist. For samples with a specified storage temperature of 4°C , storage at a temperature above the freezing point of water to 6°C shall be acceptable.

2) Samples, sample fractions, extracts, leachates and other sample preparation products are stored away from all standards, reagents, food and other potentially contaminating sources. Samples shall be stored in such a manner to prevent cross contamination.

11.5 Sample Disposal

The laboratory maintains a Hazardous Waste Management Plan which outlines procedures for the disposal of samples, digestates, leachates and extracts or other sample preparation products. Information is also included in section 16.0 of each analytical SOP.

11.6 Sample Subcontracting

a) FGL will advise the client of its intention to sub-contract any portion of the testing to another party.

b) When work is subcontracted, it is done so under chain of custody, and the proper records are included with the report package. When work is subcontracted to an outside laboratory a separate chain of custody is prepared.

c) When subcontracted work is reported by FGL a cover letter is supplied indicating the laboratory which performed the analysis. All original reports and chain of custodies resulting from the subcontracted work are provided to the client.

d) Subcontractors are reviewed for acceptability based on an evaluation of their Quality Manual and reporting format (SOP reference: S0QA050.XXX). On-site audits may be performed based on project specific requirements.

12.0 RECORDS

FGL maintains a record system to comply with all relevant regulations. The system can produce unequivocal, accurate records which document all laboratory activities. FGL retains on record all original observations, calculations and derived data, calibration records and a copy of the test report. This is primarily referenced from section 5.12 of "Quality Systems," National Environmental Laboratory Accreditation Conference, USEPA, Revision 15, May 25, 2001.

12.1 Record Keeping System and Design

The record keeping system allows historical reconstruction of all laboratory activities that produced the resultant sample analytical data. This includes interlaboratory transfers of samples and/or extracts.

- a) The records include the identity of personnel involved in sampling, preparation, calibration or testing.
- b) The records include all information relating to the laboratory facilities equipment, analytical test methods, and related laboratory activities, such as sample receipt, sample preparation, or data verification.
- c) The record keeping system facilitates, the retrieval of all working files and archived records for inspection and verification purposes.
- d) All documentation entries are signed or initialed by responsible staff. The reason for the signature or initials is clearly indicated in the records such as "sampled by", "prepared by", or "reviewed by").
- e) All generated data except those that are generated by automated data collection systems, are recorded directly, promptly and legibly in permanent ink.
- f) Entries in records are not obliterated by methods such as erasures, overwritten files or markings. All corrections to record-keeping errors shall be made by one line marked through the error. The individual making the correction shall sign (or initial) and date the correction. These criteria also apply to electronically maintained records.

12.2 Hardcopy Records Management and Storage

- a) All records (including those pertaining to calibration and test equipment), certificates and reports are safely stored, held secure and in confidence to the client (SOP reference: S0QA215.XXX).
- b) All client records are held in strict confidence and will not be provided to any other party without consent of the client (SOP reference: S0ADM100.XXX).
- c) All records, including those specified in 12.4, are retained for a minimum of five years. All information necessary for the historical reconstruction of data is maintained by the laboratory. Records which are stored only on electronic media are supported by the hardware and software necessary for their retrieval.
- d) The laboratory has established a record management system for control of laboratory notebooks (SOP reference: S0QA020.XXX). Information which is part of a routine analysis is considered to be a record (such as run schedules). Controlled logbooks are typically used for quality assurance documentation such as daily balance, temperature, conductivity checks and instrument maintenance and personal analyst logbooks.

e) Access to archived information is documented with an access log. These records are protected against fire, theft, loss, environmental deterioration, vermin and, in the case of electronic records, electronic or magnetic sources.

12.3 Electronic Records Management and Storage

Where computers or automated equipment are used for the capture, processing, manipulation, recording, reporting, storage or retrieval of test data, the laboratory ensures that:

- a) computer software is documented and adequate for use;
- b) computer and automated equipment are maintained to ensure proper functioning and provided with the environmental and operating conditions necessary to maintain the integrity of calibration and test data;
- c) Records that are stored or generated by computers or personal computers (PC's) have hard copy or write-protected backup copies.
- d) Records which are stored only on electronic media are supported by the hardware and software necessary for their retrieval.
- e) procedures are established for protecting the integrity of data; these procedures include data entry or capture, data storage, data transmission and data processing, maintenance of security of data includes the prevention of unauthorized access to, and the unauthorized amendment of, computer records.
- f) procedures are established for protecting existing data through backing up the appropriate electronic data storage areas (S0ADM010.XXX)

12.4 Sample Handling Records

A record of all procedures to which a sample is subjected while in the possession of the laboratory are maintained. These include records pertaining to:

- a) Sample preservation including appropriateness of sample container and compliance with holding time requirement;
- b) Sample identification, receipt, acceptance or rejection and log-in;
- c) Sample storage and tracking including shipping receipts, transmittal forms;
- d) Sample preparation including cleanup and separation protocols, ID codes, volumes, weights;
- e) Sample analysis including 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); these records will include the following:
 - 1) Laboratory sample ID code;
 - 2) Date of analysis;
 - 3) Instrumentation identification and instrument operating conditions/parameters (or reference to such data);

- 4) Analysis type;
- 5) All manual calculations; and
- 6) Analyst's or operator's initials
- 7) Reviewers initials
- f) Standard origin, receipt, preparation, and use;
- g) Equipment receipt, use, specification, operating conditions and preventative maintenance;
- h) Calibration criteria, frequency and acceptance criteria;
- i) Data and statistical calculations, review, confirmation, interpretation, assessment and reporting conventions;
- j) Method performance criteria including expected quality control requirements;
- k) Quality control protocols and assessment;
- l) Electronic data security, software documentation and verification, software and hardware audits, backups, and records of any changes to automated data entries;

12.5 Laboratory Support Activities

In addition to documenting all the above-mentioned activities, the following shall be retained:

- a) Copies of final reports;
- b) Archived standard operating procedures;
- c) Correspondence relating to laboratory activities for a specific project;
- d) All corrective action reports, audits and audit responses;
- e) Proficiency test results and raw data; and
- f) Personnel qualifications, experience and training records;
- g) Initial and continuing demonstration of proficiency for each analyst; and
- h) A log of names, initials and signatures for all individuals who are responsible for signing or initialing any laboratory record.

13.0 LABORATORY REPORT FORMAT AND CONTENTS

This is primarily referenced from section 5.13 of “Quality Systems,” National Environmental Laboratory Accreditation Conference, USEPA, Revision 15, May 25, 2001.

The results of each test, or series of tests carried out by FGL are reported accurately, clearly, unambiguously and objectively. The results are provided in a test report and include all the information necessary for the interpretation of the test results and all information required by the method used. Some regulatory reporting requirements or formats such as the California drinking water Write-on format, may not require all items listed below, however, FGL will provide all the required information in the proper format to the client to meet the requirements of such regulatory reports.

a) Unless client or regulatory agencies require otherwise, each report to a client shall include at least the following information:

- 1) A title indicating analytical results;
- 2) FGL laboratory addresses, FGL location where the test was carried out, the laboratory certification number and phone number with name of contact person for questions;
- 3) Laboratory ID number linking the report information to all analytical, custody and field documentation. This includes identification on each page and total number of pages.
- 4) Name and address of client, and project name if applicable;
- 5) Description of the tested sample;
- 6) Date of receipt of sample, date and time of sample collection, date(s) of preparation and analysis performed. Time of preparation or analysis listed for samples which are 48 hours or less in holding time.
- 7) Identification of results derived from samples that did not meet NELAC acceptance requirements such as improper container, holding time or temperature.
- 8) Identification of the test method used;
- 9) If FGL performed the sampling, a reference to the method used;
- 10) Any deviations from the test method including data qualifiers and their meaning;
- 11) Testing results including supporting information such as reporting units or reporting on dry weight basis;
- 12) When appropriate, a statement of the estimated uncertainty of the test result;
- 13) A signature and title, or an equivalent electronic identification of the person(s) accepting responsibility for the content of the report, and date of issue;

b) FGL provides many custom options for laboratory sample data and quality assurance reports. This ranges from sample data only to Full CLP analysis and deliverables. Please contact the laboratory if you have project specific requirements.

c) Where the report package contains results of tests performed by sub-contractors, these results are clearly identified with a cover letter and the original full subcontractor report and supporting

custody records.

d) After issuing the report, it may be necessary to amend the original report. In this regard the appropriate sections of the report being amended will be indicated as such and cover letter indicating what was amended and the reason for amendment (SOP reference: S0ADM015.XXX). If an electronic deliverable was provided the electronic deliverable will be amended, redelivered and the new electronic file name will be indicated on the amendment letter.

e) FGL will notify clients promptly of any event such as the identification of defective measuring or test equipment that casts doubt on the validity of results given in any report package or amendment to a report package.

f) Where clients require transmission of test results by telephone, fax or other electronic or electromagnetic means, staff will follow documented procedures that ensure confidentiality.

14.0 OUTSIDE SUPPORT SERVICES AND SUPPLIES

This is primarily referenced from section 5.15 of "Quality Systems," National Environmental Laboratory Accreditation Conference, USEPA, Revision 15, May 25, 2001.

14.1 Subcontracted Analyses

FGL will subcontract all regulatory testing to NELAP accredited laboratories whenever possible. When this is not possible the analytical subcontractors used by FGL will be evaluated. The evaluation is performed by review of the Quality Assurance Plan and reports applicable to the test being subcontracted (SOP reference: S0QA050.XXX). On-Site audits of subcontractors are performed only if it is a project specific requirement. All subcontractor report packages will be clearly identified with a cover letter and the original full subcontractor report and supporting custody records.

If there are any indications that a subcontractor has knowingly supplied services of substandard quality, this information will be forwarded to all clients impacted.

14.2 Laboratory Supplies

a) Upon receipt of supplies FGL receiving/shipping personnel will verify the content of the supplies against the packing slip (SOP reference: S0SHP015.XXX). If the shipment is complete and the supplies received are in acceptable condition then they are provided to the department which placed the order and the approved packing slip is provided to accounting. If the shipment is incomplete or the supplies are unacceptable then the FGL department and the vendor are notified. Arrangements are then made with the vendor to complete the order or obtain supplies in acceptable condition. The accounting department maintains the packing slip records for all shipments.

b) Containers, chemicals and standards are dated upon receipt.

c) Wherever possible analytical reagent grade chemicals and NIST traceable standards are purchased. These supplies are considered acceptable for use by meeting the positive and negative quality control objectives of the analytical test being performed.

14.3 Laboratory Equipment

FGL will, wherever possible or relevant, ensure that purchased equipment is not used until it has been inspected, calibrated or otherwise verified as complying with any standard specifications relevant to the calibrations or tests concerned.

14.4 Laboratory Water Quality

The laboratories utilize type II water, as specified in Standard Methods for the Examination of Water and Wastewater, 18th Edition, section 1080A, for preparation of reagents and standards. For microbiological analyses the laboratory meets the specifications listed in section 9020B. A description of the water systems and related quality controls for each laboratory are listed below:

a) FGL Santa Paula obtains acceptable water quality through the use of a reverse osmosis (RO) system. A granular activated carbon bed is used prior to the RO to remove organics. A finishing bed of activated resin is used for final polishing.

b) FGL Stockton obtains acceptable water quality through the use of anion and cation deionization resin beds.

c) The water quality is verified by daily conductivity checks and daily/monthly/quarterly bacteriology related checks (SOP reference: S0QA170.XXX).

15.0 COMPLAINTS

This is primarily referenced from section 5.16 of “Quality Systems,” National Environmental Laboratory Accreditation Conference, USEPA, Revision 15, May 25, 2001.

When a complaint, or other circumstance, raises doubt concerning FGL’s compliance with internal policies or procedures, or with external regulatory or client specified requirements, FGL will perform the following steps:

- a) Promptly review or audit those areas of activity and responsibility;
- b) Upon completion of the review, appropriate steps will be taken to correct the complaint and;
- c) Where relevant, the practices which led to the complaint will be corrected.
- d) Records of the complaint and subsequent actions will be maintained though the non-conformance/corrective action program (SOP reference: S0QA035.XXX).

16.0 REFERENCES

16.1 General Reference List

References for this plan include quality assurance, laboratory and field methods published by the U.S. Environmental Protection Agency (EPA) and other agencies mainly through the following sources:

- a) "Standard Methods for the Examination of Water and Wastewater," APHA, 20th Edition, 1998.
- b) "Methods for Chemical Analysis in Waters and Waste," (MCAWW) EPA-600/4-79-020
- c) "Methods for Organic Chemical Analysis of Municipal and Industrial Wastewater," EPA Method Book, EPA 600/4-82-057, July 1982.
- d) "Methods for Evaluating Solid Waste," SW-846, 3rd edition (Electronic format only by ChemSoft, Inc.), and Proposed Revisions;
- e) "Prescribed Procedures for Measurement of Radioactivity in Drinking Water," EPA Method Book, EPA-600/4-80-032, August 1980.
- f) "Handbook for Sampling and Sample Preservation of Water and Wastewater," EPA Method Book, EPA-600/4-82-029, September 1982.
- g) "Eastern Environmental Radiation Facility Radiochemistry Procedures Manual," EPA Method Book, EPA 520/5-84-006, August 1984.
- h) "Environmental Measurements Laboratory Procedures," HASL-300, 28th Edition, February 1997 (online at <http://www.eml.doe.gov/publications/procman/>) .
- i) "Quality Systems," National Environmental Laboratory Accreditation Conference, USEPA, Revision 15, May 25, 2001.

16.2 DOE 5700.6C / 414.1A Cross reference

DOE 5700.6C / 414.1A QA Criteria		FGL QM
Management	Program	2.0, 3.0, 4.0
	Personnel Training and Qualifications	5.0
	Quality Improvement	7.0
	Documents & Records	10.1, 12.0
Performance	Work Processes	8.1, 8.2, 10.0
	Design	10.1.2
	Procurement	14.0
	Inspection and Acceptance Testing	8.0, 9.0
Assessment	Self / Management Assessment	7.1(a)
	Independent Assessment	7.1(b)

17.0 DEFINITIONS

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 program of study or an institution 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)

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. (Glossary of Quality Assurance Terms, QAMS, 8/31/92).

Analytical Detection Limit: the smallest amount of an analyte that can be distinguished in a sample by a given measurement procedure throughout a given (e.g., 0.95) confidence interval. (Applicable only to radiochemistry)

Analytical Reagent (AR) Grade: designation for the high purity of certain chemical reagents and solvents given the American Chemical Society. (Quality Systems)

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) which are analyzed together as a group using the same calibration curve or factor. An analytical batch can include prepared samples originating from various environmental matrices and can exceed 20 samples. (Quality Systems)

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, Definitions of Environmental Quality Assurance Terms, 1996)

Calibrate: to determine, by measurement or comparison with a standard, the correct value of each scale reading on a meter or other device, or the correct value for each setting of a control knob. The levels of the applied calibration standard should bracket the range of planned or expected sample measurements.

Calibration: the set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material measure, and the corresponding known values of a measurand. (VIM - 6.13)

Calibration Curve: the graphical relationship between the known values, such as concentrations, of a series of calibration standards and their analytical response.

Calibration Standard: a solution prepared from the primary dilution standard solution or stock standard solutions and the internal standards and surrogate analytes. The Calibration solutions are used to calibrate the instrument response with respect to analyte concentration. (Glossary of Quality Assurance Terms, QAMS, 8/31/92).

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 documents the physical security of samples, data and records.

Confirmation: verification of the presence of a component through the use of an analytical technique that differs from the original test method. These may include: Second column confirmation, Alternate wavelength, Derivatization, Mass spectral interpretation, Alternative detectors or Additional cleanup procedures.

Corrective Action: 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 are of acceptable quality (i.e., that they meet specified acceptance criteria.

Data Reduction: the process of transforming raw data by arithmetic or statistical calculations, standard curves, concentration factors, etc., and collation into a more useful form.

Detection Limit: the lowest concentration or amount of the target analyte that can be determined to be different from zero by a single measurement at a stated degree of confidence. See Method Detection Limit.

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 is performed. (ASQC, Definitions of Environmental Quality Assurance Terms, 1996)

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.

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. (Radioanalysis Subcommittee)

Holding Times (Maximum Allowable Holding Times): the maximum times that samples may be held prior to analysis and still be considered valid. (40 CFR Part 136).

Initial Demonstration of Capability: procedure to establish the ability of the laboratory to generate acceptable accuracy and precision which is included in many of the EPA's analytical test methods. In general the procedure includes the addition of a specified concentration of each analyte (using a QC check sample) in each of four separate aliquots of laboratory pure water. These are carried through the entire analytical procedure and the percentage recovery and the standard deviation are determined and compared to specified limits. (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.

Laboratory Control Sample (however named, such as laboratory fortified blank or spiked blank): a sample matrix, free from the analytes of interest, spiked with verified known amounts of analytes from a source independent of the calibration standards or a material containing known and verified amounts of analytes. 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. (NELAC).

Laboratory Duplicate: Aliquots of a sample taken from the same container under laboratory conditions and processed and analyzed independently.

Limit of Detection (LOD): the lowest concentration level that can be determined by a single analysis and with a defined level of confidence to be statistically different from a blank. (Analytical Chemistry, 55, p.2217, December 1983, modified) See also Method Detection Limit.

Manager (however named): the individual designated as being responsible for the overall operation, all personnel, and the physical plant of the environmental laboratory. A supervisor may report to the manager. In some cases, the supervisor and the manager may be the same individual.

Matrix: The component or substrate which contains the analyte of interest. For purposes of batch determination, the following major matrix types are used at FGL:

Aqueous: Any aqueous sample excluded from the definition of a drinking water matrix or Saline/Estuarine source. Includes surface water, groundwater and effluents.

Water: Any aqueous sample that has been designated a potable or potential potable water source.

Liquid: Any organic liquid with <15% settleable solids.

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

Matrix Spike (spiked sample, 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. (Glossary of Quality Assurance Terms, QAMS, 8/31/92).

Matrix Spike Duplicate (spiked sample/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. (Glossary of Quality Assurance Terms, QAMS, 8/31/92).

May: permitted, but not required (TRADE)

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 containing an analyte of interest through all steps of the analytical procedures. (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).

Must: denotes a requirement that must be met. (Random House College Dictionary)

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: National Environmental Laboratory Accreditation Conference. A voluntary organization

of state and federal environmental officials and interest groups purposed primarily to establish mutually acceptable standards for accrediting environmental laboratories. A subset of NELAP. (NELAC)

NELAP: the overall National Environmental Laboratory Accreditation Program of which NELAC is a part. (NELAC)

Performance Audit: the routine comparison of independently obtained quantitative measurement system data with routinely obtained data in order to evaluate the proficiency of an analyst or laboratory.

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.

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 to maintain the chemical and or biological integrity of the sample.

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 . (Glossary of Quality Assurance Terms, QAMS, 8/31/92).

Proficiency Testing: Determination of the laboratory calibration or testing performance by means of interlaboratory comparisons. (ISO/IEC Guide 2 - 12.6, amended)

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 in comparison to peer laboratories and the collective demographics and results summary of all participating laboratories.

Protocol: a detailed written procedure for field and/or laboratory operation (e.g., sampling, analysis) which must be strictly followed.

Pure Reagent Water: shall be water in which no target analytes or interferences are present at a concentration which would impact the results when using a particular analytical test method.

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. (Glossary of Quality Assurance Terms, QAMS, 8/31/92).

Quality Control: the overall system of technical activities whose purpose is to measure and control the quality of a product or service so that it meets the needs of users. (Glossary of Quality Assurance Terms, QAMS, 8/31/92).

Quality Manual: A document stating the quality policy, quality system and quality practices of an organization. This may be also called a Quality Assurance Plan or a Quality Plan.

NOTE - The quality manual may call up other documentation relating to the laboratory's quality arrangements.

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 datauser. Quantitation limit, for the purposes of NELAC, is defined as 3.18 times the MDL, by convention.

Range: the difference between the minimum and the maximum of a set of values.

Raw Data: any original factual information from a measurement activity or study recorded in a laboratory notebook, worksheets, records, memoranda, notes, or exact copies thereof that are necessary for the reconstruction and evaluation of the report of the activity or study. Raw data may include photography, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments. If exact copies of raw data have been prepared (e.g., tapes which have been transcribed verbatim, data and verified accurate by signature), the exact copy or exact transcript may be submitted.

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. (Glossary of Quality Assurance Terms, QAMS, 8/31/92).

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 - 6.08)

Requirement: a translation of the needs into a set of individual quantified or descriptive specifications for the characteristics of an entity in order to enable its realization and examination.

Selectivity: (Analytical chemistry) the capability of a test method or instrument to respond to a target substance or constituent in the presence of nontarget substances.

Sensitivity: the capability of a test method or instrument to discriminate between measurement responses representing different levels (e.g., concentrations) of a variable of interest.

Shall: denotes a requirement that is mandatory whenever the criterion for conformance with the specification requires that there be no deviation. This does not prohibit the use of alternative approaches or methods for implementing the specification so long as the requirement is fulfilled. (*Style Manual for Preparation of Proposed American National Standards*, American National Standards Institute, eighth edition, March 1991).

Should: denotes a guideline or recommendation whenever noncompliance with the specification is permissible. (*Style Manual for Preparation of Proposed American National Standards*, American National Standards Institute, eighth edition, March 1991).

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. (Glossary of

Quality Assurance Terms, QAMS, 8/31/92).

Spike: a known mass of target analyte added to a blank sample or subsample; used to determine recovery efficiency or for other quality control purposes.

Standard Reference Material (SRM): a certified reference material produced by the U.S. National Institute of Standards and Technology and characterized for absolute content, independent of analytical test method.

Supervisor (however named): the individual(s) designated as being responsible for a particular area or category of scientific analysis. This responsibility includes direct day-to-day supervision of technical employees, supply and instrument adequacy and upkeep, quality assurance/quality control duties and ascertaining that technical employees have the required balance of education, training and experience to perform the required analyses.

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. (Glossary of Quality Assurance Terms, QAMS, 8/31/92).

Test: a technical operation that consists of the determination of one or more characteristics or performance of a given product, material, equipment, organism, physical phenomenon, process or service according to a specified procedure.

NOTE - The result of a test is normally recorded in a document sometimes called a test report or a test certificate. (ISO/IEC Guide 2 - 12.1, amended)

Test Method: defined technical procedure for performing a test.

Control Chart: A chart in which the plotted quality control data is assessed via a tolerance level (e.g. +/- 10% of a mean) based on the precision level judged acceptable to meet overall quality/data use requirements instead of a statistical acceptance criteria (e.g. +/- 3 sigma).

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)

Verification: confirmation by examination and provision of evidence that specified requirements have been met.

NOTE - In connection with the management of measuring equipment, verification provides a means for checking that the deviations between values indicated by a measuring instrument and corresponding known values of a measured quantity are consistently smaller than the maximum allowable error defined in a standard, regulation or specification peculiar to the management of the measuring equipment. The result of verification leads to a decision either to restore in service, to perform adjustments, or to repair, or to downgrade, or to declare obsolete. In all cases it is required that a written trace of the verification performed shall be kept on the measuring instrument's individual record.

Validation: the process of substantiating specified performance criteria.