

QUALITY ASSURANCE MANUAL

AIR TECHNOLOGY LABORATORIES, INC.

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18501 E. Gale Avenue, Suite 130
City of Industry, CA 91748
(626) 964-4032 Phone
(626) 964-5832 Fax

APPROVAL FOR IMPLEMENTATION:

General Manager Approval:	 _____	Date: <u>7-12-17</u>
Laboratory Director Approval:	Mark Johnson  _____	Date: <u>7-12-17</u>
QA/QC Officer Approval:	Mark Johnson  _____	Date: <u>7/12/17</u>

Val Mallari

TABLE OF CONTENTS

<u>Section</u>	<u>Title</u>	<u>Rev. Date</u>	<u>Page #</u>
i	Title Page	5/1/17	1
ii	Approval Signatures	5/1/11	1
iii	Table of Contents	5/1/17	2
1.	Quality Assurance Organization	5/1/17	5
2.	Facilities and Equipment	5/1/16	13
3.	Sample Handling and COC	5/1/16	17
4.	Document Control	5/1/16	20
5.	Analytical Methodology	5/1/16	28
6.	Calibration Procedures and Frequency	5/1/17	33
7.	Limits of Detection / Limits of Quantitation	5/1/17	36
8.	Internal QA/QC and Documentation	5/1/17	37
9.	Data Collection, Validation, and Reporting	5/1/16	41
10.	Corrective Action	5/1/17	44
11.	Holding Times and Preservation	5/1/11	47
12.	Verification Practices	5/1/16	48
13.	Internal Laboratory Audits and Approvals	5/1/17	50
14.	Quality Assurance Reports to Management	5/1/11	53
15.	Management Reviews	5/1/16	54
16.	References	5/1/11	55
17.	Revisions	5/1/16	60

APPENDICES

Referenced Section

1.0	Appendix A:	ATLI Organizational Chart
1.0	Appendix B:	List of Key Personnel and Responsibilities
2.0	Appendix C:	Laboratory Floor plan
2.0	Appendix D:	List of Instrumentation and Equipment
3.0	Appendix E:	ATLI Chain-of-Custody Form
7.0	Appendix F:	Method Detection Limits
11.0	Appendix G:	Tables of Holding Times & Preservation
13.0	Appendix H:	List of Methods & Certifications
2.2.2	Appendix I:	Subcontractor Information Form
10.2	Appendix J:	Non-Conformance Form
13.3	Appendix K:	Internal Audit Checklist
6.2	Appendix L (DoD only):	QSM 5.1 Appendix B Quality Control Tables
8.0	Appendix M (DoD only):	QSM 5.1 Appendix C LCS criteria
1.0	Appendix N:	Job Descriptions/Requirements

Quality Policy Statement

Air Technology Laboratories, Inc. (ATLI) is committed to good professional practice and to the quality of its environmental testing services to its clients. The QA Manual is a contract to this commitment and documents and describes our commitment to accepted laboratory practices and quality of testing services.

ATLI's standard level of service is defined as adherence to this document, International Standards, The NELAC Institute (TNI) Standard, Volume 1, September 2009, DoD QSM version 5.1 and also to the client's expected level of service as defined by the customer. At a minimum ATLI standard of service must satisfy all requirements of applicable regulatory and auditing authorities, and comply with more stringent standards if required in a mandated test method or regulation.

ATLI Management is committed to continually improving the quality system. Procedures as detailed in the QA Manual will communicate to all staff the importance of meeting customer requirements, operating in accordance with statutory and regulatory requirements, and operating in accordance with the laboratory's documented ethics policy.

ATLI management is authorized to ensure that these policies and objectives are documented in this QA Manual.

All ATLI testing and sample control personnel are required to read the QA Manual and implement the policies and procedures in their daily work.

All ATLI management is bound by this QA Manual and commitment to compliance, and operates in accordance with the laboratory's documented ethics policy.

Authorized by the President of ATLI

1 QUALITY ASSURANCE ORGANIZATION

1.1 OVERVIEW

Air Technology Laboratories, Inc. (ATLI) (a California corporation that is legally responsible for all items in this document) currently provides a broad range of air testing analytical services to support regulating agencies, and consulting and engineering firms. ATLI's goal is to provide its client with analytical data of a known quality to meet project Data Quality Objectives (DQO).

It is the purpose of this document to describe how ATLI's Quality Assurance program will accomplish those goals.

While this Quality Manual provides a broad framework from which the laboratory shall conduct its quality systems, specific method quality control requirements are contained in Standard Operating Procedures (SOP) and other Policy Documents.

Copies of all management system documentation provided to DoD ELAP Accreditation Bodies or to personnel on behalf of DoD are in English.

1.2 QUALITY ASSURANCE POLICY AND OBJECTIVES

The reliability of the data generated by ATLI is measured by faithful adherence to quality control, qualifications and experience of its personnel, and an organizational structure that emphasizes accountability. In order to maintain data integrity, validity, and usability, the following statements describe the quality of the data required to be usable for the client.

1.2.1 DATA QUALITY OBJECTIVES (DQOS)

DQOs are used to assess the minimum data quality of a project needed to draw valid conclusions based on the objectives of the test program. DQOs also support specific decisions and planning relative to remedial and regulatory actions.

The DQO process facilitates the determination of the following:

1.2.1.1 Information and data requirements for the specified project.

1.2.1.2 Where, when, and how to collect samples to allow the most precise measurements as possible.

1.2.1.3 Field and Laboratory Quality Assurance/Quality Control required to defend the data quality.

1.2.1.4 Required number of observations.

1.2.1.5 All of the above are usually specified in the Sampling Plans, Work Plans, Statements of Work, and QA Project Plans.

1.2.2 The DQOs are typically expressed in the following terms:

1.2.2.1 *Precision* measures the reproducibility of measurements under a given set of conditions. It is a quantitative measure of the variability of a group of measurements on the same parameter compared to their average value. It is usually stated in terms of standard deviation but other estimates such as the coefficient of variation (relative standard deviation),

relative percent difference, range (maximum value, minimum value) and relative range can be used.

1.2.2.2 *Accuracy* measures the bias in a measurement system. Accuracy may be assessed through the use of blanks, known quality control (QC) samples, and matrix spikes.

1.2.2.3 *Representativeness* is the degree to which data accurately represent a particular characteristic of a population or environmental parameter. It is a qualitative parameter that is most concerned with the proper design of the sampling program.

1.2.2.4 *Completeness* measures the amount of valid data obtained from a measurement system compared to the expected amount. Usually reported as a percentage.

1.2.2.5 *Comparability* measures the confidence in comparing results in one experiment with the results of the same experiment on different samples. It is also demonstrated through the participation in round-robin performance evaluation studies and the use of standard reference materials that are traceable to the National Institutes of Science and Technology (NIST) and EPA.

1.2.3 QUALITY ASSURANCE/QUALITY CONTROL (QA/QC) PROGRAM

ATLI's QA/QC program ensures that analytical measurement systems are maintained in an acceptable state of stability and reproducibility. Specific sections of this QA/QC plan address various QA/QC procedures that are used to generate valid and defensible data. Some elements of the QA/QC program include:

1.2.3.1 PREVENTIVE ACTION

Preventive action identifies opportunities for improvement rather than reacting to problems or complaints. All analytical instruments and equipment are checked and calibrated by the analyst each time the instrument or equipment is used. In addition, the instrument or equipment is rechecked and recalibrated depending on the usage either on a time basis or sample basis according to the Standard Operating Procedures (SOPs). Besides daily checks, a schedule of preventive action and maintenance is kept to reduce the likelihood of instrument downtime. Instrument calibration and precision statistical records are kept to insure stability and reproducibility. Section 2.2.4 describes preventive action in more detail.

1.2.3.2 QUALITY ASSESSMENT PROCEDURES

A quality assessment procedures involve data validation and corrective action, and monitors the reliability of the analytical data and its processes.

1.2.3.2.1 Data validation is a three-tiered process consisting of bench level review, peer review, and managerial review of data.

1.2.3.2.2 Corrective Action is the process by which any observed data discrepancies are addressed and resolved.

1.2.3.3 ORGANIZATION AND PERSONNEL

[Appendix A](#) displays the organizational structure of the analytical services within Air Technology Laboratories, Inc. [Appendix B](#) presents the resumes of Key Personnel including their assignments, responsibilities, education, and years of applicable experience. Appendix B also names the key personnel and their deputies in case of prolonged absences. Specific QA/QC-related responsibilities of those personnel are summarized below.

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

ATLI management is responsible for defining the minimum qualifications, experience, and skills necessary for all positions in the laboratory. Refer to Appendix N for minimum qualifications.

ATLI management formulates goals with respect to the education, training, and skills of laboratory personnel

1.2.3.3.1 GENERAL MANAGER

The General Manager has the overall responsibility for the general operations of ATLI, including but not limited to Administration, Business Office, Regulatory Affairs, and Technical Operations. QA/QC responsibilities include:

- ▶ Supervising and administering the quality assurance program and providing an environment, in which quality work is produced.
- ▶ Ensuring that all general and client-specific quality assurance requirements are strictly followed.
- ▶ Resolving the approval/rejection of deliverable client sample data package and/or reports.

1.2.3.3.2 LABORATORY MANAGER/TECHNICAL DIRECTOR

The Laboratory Manager is responsible for all day-to-day operations including analytical, quality of data deliverables, support services, production timeliness of reports, sales and marketing. QA/QC responsibilities are the same as the General Manager. Responsibilities also include supervision of testing staff, including trainees. The Lab Manager/Technical Director assures that the staff is familiar with methods and procedures, the purpose of each test, and the assessment of the environmental test.

The Technical Director shall have at a minimum a bachelor's degree in chemical, environmental, biological, or physical sciences or engineering; at least 24 semester hours college credit in chemistry & at least 2 years experience in environmental analysis of representative inorganic & organic analytes for which the laboratory is accredited (Master's degree or doctorate may substitute for 1 year of experience).

Should he be absent from the lab for more than 15 days, the Technical Director shall appoint a substitute, fully-qualified Technical Director to replace him until he returns. Should the Technical Director be absent for more than 35 calendar days, the Primary Accrediting Authority shall be notified.

The Technical Director shall not be the Technical Director of another accredited laboratory unless authorized by the appropriate Accrediting Authority.

The Technical Director shall certify and document that personnel with appropriate educational and/or technical background perform all tests for which the laboratory is accredited, and that all

procedures are in compliance with the QA Manual.

1.2.3.3.3 PROJECT MANAGER (PM)

The Project Manager has the overall responsibility for the technical completeness, cost control, and adherence to project schedules, and also acts as liaison between the Client and the Lab. Specific responsibilities include:

- ▶ Implementing the appropriate quality procedures for project activities in support of the QAPP.
- ▶ Communicating with the Lab Manager and/or QAM relating to QA/QC activities.
- ▶ Maintaining the day to day operations of data handling to ensure that clerical errors are kept to the very minimum, and that all analytical data and QC data are properly collated into the reports.

1.2.3.3.4 QUALITY ASSURANCE MANAGER (QAM)

The QAM reports to and is responsible directly to the General Manager for all matters on laboratory quality assurance. Specific roles include:

- ▶ Being responsible for implementation and monitoring of the laboratory quality assurance program.
- ▶ Ensuring that all data generated is scientifically sound, legally defensible, and of known precision and accuracy.
- ▶ Monitoring the QA plan on a periodic basis to ensure compliance with the QA objectives of the laboratory.
- ▶ Developing and implementing new QA procedures within ATLI to improve data quality and the quality system.
- ▶ Conducting audits and inspections of all division sections on a periodic basis; reporting the results of the audits to the General Manager; and implementation of corrective actions to ensure compliance with the QA plan.
- ▶ Coordinating the analysis of performance evaluation (PE) samples (if applicable) for all analytical divisions on a periodic basis.
- ▶ Evaluating the results; reporting the results to the General Manager and appropriate Supervisors; and applying corrective actions as needed.
- ▶ Establishing and maintaining statistical and data records that accurately reflect the quality assurance performance of all analytical divisions.
- ▶ Maintaining and overseeing the master sources of all SOPs, training logs, and completed/full laboratory notebooks.
- ▶ Serving as the in-house client representative on all projects inquiries involving data quality issues.
- ▶ Using available tools, such as audit and surveillance results, control charts (if applicable), proficiency testing results, data analysis, corrective and preventive actions, customer feedback, and management reviews in efforts to monitor trends and continually improve the quality system.

For proper QA oversight, the QA Manager shall not have primary responsibilities in day-to-day laboratory operations. Due to the small size of the laboratory, occasional participation in lab operations are allowed on a temporary basis, such as to cover for vacationing or sick employees.

The QAM or his/her designee shall have general knowledge of the analytical test methods for which data review is performed.

1.2.3.3.5 SENIOR CHEMISTS

The Senior Chemists are directly involved in the day-to-day operation such as scheduling, staff training, QAPP implementation, etc. of their respective group. The Senior Chemists are responsible for:

- ▶ Enforcing the QA/QC procedures and requirements within their respective activities and areas of specialization.
- ▶ Recommending process improvements and corrective actions.
- ▶ Assisting in staff training in the procedures described in the standard operating procedures (SOPs) as they apply to the assigned responsibilities of the staff.
- ▶ Maintaining an environment that emphasizes an intelligent and responsible approach to producing high data quality and accuracy based on the SOPs carried out.

1.2.3.3.6 SAMPLE CONTROL OFFICER

The primary responsibility is to manage the sample control section. The Sample Control Officer is responsible for overseeing sample login, proper documentation, sample tracking, sample storage, sample disposal/return, and coordination and scheduling of sampling programs. Other responsibilities include client contact, and assisting with contract administration.

1.2.3.3.7 DOCUMENT CONTROL OFFICER

The Document Control Officer is responsible for the filing, retrieval and storage of the reports.

1.2.3.3.8 STAFF (CHEMISTS, TECHNICIANS AND SUPPORT PERSONNEL)

Every ATLI laboratory personnel is responsible for the quality of work that is consistent with the requirements established by the ATLI management. The laboratory personnel play an active role in the ATLI Laboratory quality program and whenever possible, make recommendations regarding the process improvements and corrective actions. Specific job descriptions are available in the Human Resource File.

The ATLI personnel responsibilities include:

- ▶ Providing the management and the QAM with the immediate notifications of the quality problems that are not covered by the corrective action measures within the procedures.
- ▶ Identifying and carrying out the approved corrective actions within their respective activities and specialization.
- ▶ Participating in training, as required.

1.2.3.4 PERSONNEL TRAINING / DEMONSTRATION OF CAPABILITY (DOC)

The ATLI training program is designed to be relevant to the present and anticipated tasks of the lab, and ensure that all personnel are qualified and properly trained to perform all required tasks. A copy of SOP Review Log (Form-33 latest revision) and Demonstration of Capability (Form-40 latest revision) signed by for all personnel are maintained in the Training Record Binder after each personnel has reviewed the latest ATLI QAM and the specific SOPs pertaining to their job functions. The training program also provides that all pertinent health and safety issues are covered. It also provides for periodic evaluation of each staff member's skills by

performance evaluation samples.

1.2.3.4.1 INITIAL DEMONSTRATION OF CAPABILITY is performed for new chemists, new methods, chemists that haven't performed the method in one year, a method that undergoes changes that could potentially affect the precision and bias, sensitivity, selectivity, etc.; or a method that has not been used in one year. If a method has been in use for more than a year prior to initial application for accreditation for that method, an initial DOC is not required but the laboratory must have records on file to demonstrate that an initial DOC is not required (e.g. reports, MDLs, PT samples, etc.)

It includes reading and understanding the method, Standard Operating Procedure (SOP) comprehension, standards preparation, method set-up, accurate reporting, correct and accurate QA/QC and routine instrument maintenance. Trainees are given supervised training by the department supervisor or by designated chemist(s) who have already completed the initial proficiency.

The chemist must also:

1.2.3.4.1.1 prepare and analyze at least four (4) Laboratory Control Samples at a concentration described in the method SOP. The LCS samples can be analyzed either concurrently or over a period of days.

1.2.3.4.1.2 calculate the mean recovery in the appropriate reporting units and the standard deviations of the sample for each parameter of interest using all of the results. They must also compare the results to the corresponding acceptance criteria for precision and accuracy in the method (if applicable), the method SOP, or in laboratory-generated acceptance criteria.

1.2.3.4.1.3 All parameters must meet the acceptance criteria before actual sample analysis can begin. If any parameter does not meet the acceptance criteria, the performance is unacceptable for that parameter. The chemist must locate and correct the source of the problem, perform an acceptable initial DOC for that parameter before it can be reported in results. If repeated failures occur, a general problem exists with the measurement system. The problem must be located and corrected and the initial DOC must be performed again for all parameters.

1.2.3.4.1.4 If an analyte not currently found on the laboratory's list of accredited analytes is added to an existing accredited method, an initial DOC is performed for that analyte.

1.2.3.4.2 ON-GOING DEMONSTRATION OF CAPABILITY (supplemental training) includes development of SOPs, learning the importance of documentation, the understanding of meeting QA/QC criteria and quality. Supplemental training can be obtained from reading different procedures, instrument manuals and related literature. Knowledge regarding methods and instrumentation can also be obtained from external training by agencies and manufacturers. Copies of training completion certifications are kept in the chemist's training file.

The chemist can demonstrate on-going capability by one of the following:

1.2.3.4.2.1 acceptable performance of a blind sample (either acquired from PT sample provider, or prepared by QA Manager or Technical Director)

1.2.3.4.2.2 performing another initial DOC

1.2.3.4.2.3 preparing and analyzing at least four (4) consecutive LCS's with acceptable

levels of precision and accuracy prior to analysis.

1.2.3.4.2.4 a documented process of analyst review using QC samples. QC samples can be reviewed to identify patterns for individuals or groups of analysts and determine if corrective action or retraining is necessary. Since client reports undergo three levels of review, the QC samples associated with those reports can be used to demonstrate on-going capability.

1.2.3.4.2.5 If the above items are not technically feasible, then analysis of real world samples with results within predefined acceptance criteria (as defined by ATLI or method) shall be performed.

1.2.3.4.3 The QA Manager maintains the training records. Initial DOC documents include analysts, matrix, analytes, class of analytes, method, latest revisions of laboratory-specific SOP used for analysis, dates of analysis, and summary of LCS analyses.

All employees' training records are updated on a yearly basis to reflect current training qualifications. The supervision of the training program is performed by the QA Manager, the department supervisors, and by the General Manager.

1.2.3.4.4 Generating quality data also requires all staff members and management to commit to operating in an ethical manner and with integrity. According to ATLI's Employee Handbook, under section "Personal Conduct", "disciplinary action, which may include discharge, will be taken for offenses such as: falsifying data and/or company records, violation of safety rules, breach of security and/or confidentiality, commitment of financial or legal resources without authorization of company officer." When a new employee begins work at ATLI, they are required to read the Employee Handbook and an "Ethics and Data Integrity Agreement". Each document requires the employee to sign an acknowledgement memo stating that they have read and understood each item that was submitted to them.

ATLI ensures that management and personnel are free from any undue internal/external commercial, financial and other pressures and influences that may adversely affect the quality of their work by requiring all personnel to sign the Conflict of Interest Declaration on a yearly basis. The Conflict of Interest Form also helps ATLI and all its personnel avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment, or operational integrity

ATLI ensures protection of customers' confidential information and proprietary rights, including procedures for protecting electronic storage and transmission of results by requiring all personnel to sign the Non-Disclosure Agreement on a yearly basis.

1.2.3.4.5 The chemists must undergo yearly Data Integrity training, which is one component of the data integrity system. The data integrity system is described in SOP ATLI-QA-002 latest revision. The other parts of the data integrity system are: signed data integrity documentation for all laboratory personnel, in-depth periodic monitoring of data integrity, and data integrity procedure documentation.

1.2.3.5 Continuous Improvement: Via the weekly lab meetings and internal audits, Management and staff are routinely reminded of the importance of continuously trying to improve the quality system in the areas of meeting customer requirements, operating in accordance with statutory and regulatory requirements, and operating in accordance with the laboratory's documented ethics policy.

1.2.3.6 Contracted (temporary) and additional technical and key support personnel are closely supervised to ensure that they are competent and that they work in accordance with the laboratory's management system. Contracted technical personnel do not sign reports. Depending on the duration of the contract, they may undergo initial DOC procedures.

2 FACILITIES AND EQUIPMENT

2.1 LABORATORY LAY-OUT

The facility is housed in one suite of approximately 6000 square feet in a commercial business park building. Two front and one rear entrances allow access to the facility. One front entrance is for sample receiving while the other front entrance is for the main office. The rear entrance is primarily for supply receipt, and remains locked unless in supervised use. During business hours entrance to the building is limited to authorized personnel. The front doors are controlled via an electronic lock which is operated from the reception area. All entrances are locked after business hours.

The laboratory area primarily occupies the rear half of the suite, while the front half houses offices, restrooms, sample receiving and the lunchroom. [Appendix C](#) displays the ATLI laboratory lay-out.

The laboratory facilities (including but not limited to energy sources, lighting, and environmental conditions) were designed and customized to operate as an air-testing laboratory to ensure correct performance of analytical tests and optimized efficiency. To ensure that environmental conditions do not invalidate results or adversely affect the required quality of any measurement, the laboratory employs two high performance HVAC systems two and fume hoods. If environmental conditions jeopardize the results of the tests, all tests are halted until the conditions are returned to normal.

Good housekeeping is maintained through the utilization of a weekly janitorial service. Special procedures are prepared where necessary.

Access to the facility is controlled. The facility doors are locked 24/7 and patrolled by security guard provided by the property management company.

2.2 PURCHASING

2.2.1 SUPPLIES MANAGEMENT

To ensure the quality of supplies used for various laboratory analyses, all supplies will be acquired from approved vendors. The procedure (Purchasing SOP ATLI-GP-012 latest revision) for acquiring them is as follows:

2.2.1.1 Materials, reagents, standards, solvent, and gases are carefully selected to meet specifications defined in the method analyses.

2.2.1.2 Primary standards are obtained from a reliable, certifiable source, and of highest purity. Analytical standards used for instrument calibration and QC samples are traceable to EPA standards and/or standard reference materials.

2.2.1.3 Materials with a potential shelf life are dated upon receipt to establish their order of use as "first in, first out basis", and to minimize the possibility of exceeding their shelf-life. Pertinent information such as name of supplier, lot number, expiration date, concentration, date opened, date received, and date expired into the chemical inventory logbook. Chemicals are then labeled with a chemical inventory code, date received, and date expired sticker.

Documentation for reagents and solvents are checked to ensure that the stated purity will meet the intended use and the supporting records of the checks are recorded in the Stock Gas Inventory Logbook.

Purchased standards, reagents and reference materials that affect the quality of tests and/or calibrations are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods.

2.2.1.4 Services such as electricity, air, gas, and vacuum are checked for proper specifications for efficient and reliable performance of the instruments.

2.2.1.5 Distilled water is purchased from a commercial water distributor and tested prior to use, via method blank analysis, for any target analyte contamination.

2.2.2 SUBCONTRACTING OF ENVIRONMENTAL TESTS

If it becomes necessary to employ the use of subcontract laboratories (i.e. instrument issues, insufficient capacity, client specific request, or verification of sample analyses), the client must be notified immediately in writing (i.e. email or fax) for approval. Potential subcontract laboratories are identified by the Technical Director or QA Manager and are required to complete the Subcontractor Information Form-37 (Appendix I) to determine capabilities and level of expertise and experience. If applicable, the subcontract laboratory is required to submit any pertinent certifications, approvals, method detection limits, SOPs – whatever information is needed to provide confidence in the laboratory to provide quality data. A register of approved subcontract laboratories is maintained by the QA Manager and stored on the server in the QA folder.

If the subcontracted work is for tests that are covered by TNI, DoD, or other regulator body, the subcontracted lab must be accredited by those bodies for those specific tests. For non-TNI accredited tests, the subcontractor must meet applicable statutory and regulatory requirements for performing the tests and submitting the results of tests performed.

All data from subcontract laboratories must meet all project requirements. Samples must be re-analyzed if specified project requirements are not met. If re-analysis is not possible the client must be contacted immediately and any shortcomings documented fully. The final report is reviewed for typographical and technical errors.

Although it is the subcontract laboratory that performs the analysis, ATLI is responsible to the client for the subcontract lab's work (unless specifically requested by the client).

The report narrative of the final report to the client will include the declaration that specified samples and methods were sub-contracted to a specified laboratory. The laboratory performing the subcontracted work will be indicated in the final report and a copy of the subcontractors report is available to the client when requested.

2.2.3 EQUIPMENT MANAGEMENT

Instrument performance specifications are obtained prior to purchase and reviewed for appropriateness with the intended application. The availability of the supplier's service to install and test it against specifications as part of purchase price is also considered. When first installed, a calibration of the instrument is performed according to the manufacturer's instructions. Analytical reference standards are analyzed for qualitative and quantitative checks on the instrument performance during the sample run. Preventive action and maintenance of the instruments/or equipment is performed to maintain reliability. [Appendix D](#) lists the various instrumentation and equipment operated by ATLI.

2.2.4 INSTRUMENT MAINTENANCE AND PREVENTIVE ACTION PROCEDURES

2.2.5 The maintenance logbook records all maintenance and trouble-shooting activities on each instrument, and ensures that maintenance activities are documented and effective. The maintenance logbook also records the date the instrument was installed, the condition it was received (e.g. new, used, reconditioned), and its operational status.

2.2.6 Instruments are maintained according to the Standard Operating Procedures in conjunction with using the manufacturer documentation. Repairs are conducted as needed, either by manufacturer representatives or by in-house personnel. Routine maintenance (lamp replacement, etc.) is conducted as needed to maintain instrument integrity.

2.2.7 Critical equipment and instrumentation are maintained on a scheduled basis to minimize the downtime of measurement systems. Maintenance logbooks (hard bound) are kept for each instrument. The analyst records all maintenance activities (routine and unscheduled) in the maintenance logbook. Each entry must contain at the minimum: date, event/problem, corrective action, proof of conformance, and initials.

2.2.8 For GC and GCMS methods the primary routine maintenance involves leak checking of autosampler lines to monitor for leaks, and backflushing of autosampler lines to prevent cross contamination. Other routine maintenance procedures would include changing of septum on instruments that utilize direct injection.

2.2.9 Preventive action is a pro-active process to identify opportunities for needed improvement to maintain systems at optimum levels rather than a reaction to the identification of problems or complaints. Apart from the review of the operational procedures, the preventive action might involve analysis of data, including trend and risk analyses and proficiency-testing results.

Examples of preventive actions are

- screening of samples prior to sample analysis (Screening of volatile organic compounds in air samples, ATLI-SOP-005 latest revision)
- running method blanks and back flushing auto sampler lines after samples with high concentrations
- monitoring fixed gas closure within 5% on CCV
- checking gas cylinder pressures
- checking liquid nitrogen pressure and level before leaving automation running
- leak checking canisters
- having common spare parts on hand
- making new standards when LCS/LCD are in control but showing lower recoveries

Preventive action is also initiated based on symptoms that could lead to non-conforming events. Examples of symptoms: noisy chromatographic baseline, peak tailing, loss of response, etc. Technical SOPs and/or instrument manufacturer operating manuals describe maintenance or troubleshooting activities to respond to most symptoms. In addition to the operational procedures, preventive action also includes data and trend analysis of quality control samples (Section 5.2.6), and evaluation of PE samples (Section 12)..Preventive actions performed are documented in the instrument runlogs, maintenance logbooks or client project folders.

2.2.10 Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside-specified limits, and has not responded to trouble-shooting efforts is taken out of service. It is clearly labeled as being out of service to

prevent its use until it has been repaired and shown by calibration/test to perform correctly. Catastrophic failure of support equipment (e.g., refrigerator, freezers, or thermometers) requires immediate written notification to the client if any samples are affected, followed by root cause analysis of failure and either replacement or repair of the failed equipment.

2.2.11 WASTE DISPOSAL

Due to the solvent-free environment of the air lab, laboratory-generated waste is minimal and consists primarily of methanol rinseate waste, and to a lesser extent, acetone used in some cleaning procedures and 40 ml VOA vial water samples.

Old air samples are disposed of by venting to the fume hood. Tedlar bags are sliced open and put into industrial strength plastic trash bags for disposal in the facility's trash receptacle. Liquid wastes are collected in appropriate containers and disposed of according to all applicable Federal, State, and Local requirements.

2.2.12 LABORATORY RESOURCES

Quality data starts even before the actual samples are collected by working with the client prior to project start to ensure that all QAQC requirements are attainable and reasonable.

When large or new projects are scheduled to arrive at the laboratory, the project manager or lab manager obtains all pertinent project information from the client. This includes number of sample(s), matrix types, QC requirements, turn-around-time, data package requirements and expected sample delivery schedule.

A meeting of all key personnel is called to discuss the project requirements. Allocation of personnel, laboratory resources and materials are distributed for the type of work and the expected turn-around-time.

Any project-related issues or concerns by the laboratory are given to the project manager or lab manager and relayed to the client for clarification.

3 SAMPLE HANDLING AND CHAIN-OF-CUSTODY (COC)

The sample receiving area is a clean, dry, and isolated area that is securely locked from the outside.

3.1 SAMPLE COLLECTION - typically clients, i.e., environmental engineering consultants, and government contractors, do the sampling. ATLI has capabilities to perform minor sampling procedures such as, ambient air collection, or soil vapor extraction well samples.

3.2 SAMPLE PREPARATION – Air Samples require little preparation other than dilutions. Refer to method SOPs for sample dilution techniques. Samples collected in stainless steel canisters may require pressurization. Refer to Sample Receipt, Log-in, and Equipment Returns SOP (ATLI-GP-001 latest revision) for proper procedure. Air samples by their nature are homogeneous and do not require special techniques to obtain a representative subsample. Samples that require non-routine or additional sample preparation require that management be notified.

3.3 SAMPLE TRACKING - Samples received at ATLI are considered physical evidence and are handled according to the procedural safeguards established by EPA. The Sample Receipt, Log-in, and Equipment Returns SOP (ATLI-GP-001 latest revision) describes in detail how samples are received, the step-by-step sample login process, how samples are tracked from receipt to completion, and the overall responsibilities of the Sample Control Officer.

3.4 SAMPLE VERIFICATION AND LOG-IN - A sample custodian receives a sample shipment or delivery. An alternate person is designated to receive samples if the Sample Control Officer is not available. The following procedures are followed and documented by a sample-receiving checklist.

3.4.1 The shipping container is inspected for damage.

3.4.2 The shipping container is opened (under an approved fume hood if needed). The condition of the shipping container and the samples received is noted on the Chain-of-Custody (COC).

3.4.3 The tests requested on the COC are reviewed to make sure that the tests are within the capabilities of the laboratory. Any discrepancies are relayed to the Project Manager or Laboratory Manager for clarification with the client.

3.4.4 The condition of custody seals on the shipping container and the samples is also noted on the COC.

3.4.5 Sample labels are compared to the COC to verify agreement regarding sample identification, sample matrix, sampling date and time, container type and sample preservation. Any discrepancies between sample labels and the COC are noted on the COC.

3.4.6 The COC accompanying the samples is signed and dated. If the samples are received without a COC, an ATLI COC is generated.

3.4.7 Any discrepancies found during this process are noted in the COC and the client is notified. Information such as listed below are recorded:

3.4.8 After sample verification, entries are made into the Sample Receiving Excel spreadsheet. It is the key tracking document containing the following information for every set

of samples received: ATLI batch number, client name, client billing account code (optional), date and time of collection and receipt, matrix of the samples, analyses requested and the disposition of the samples.

3.4.9 A project file is generated that contains all pertinent documents relating to the received samples. The project file may include: the COC, specific contract specifications regarding required QA/QC analyses, detection limits, turn-around-time for analytical results, etc. Information for specific sample handling, QA/QC, detection limits is documented in the “special instructions” section of the project folder. A separate folder for each group (GC or GCMS) is created and copies of all pertinent documents are enclosed. The folders are given to the lab. The project manager reviews the documentation in the project file and signs and approves project for analysis. The project manager review also includes: ability of laboratory to meet requests whether it be analytical capabilities, QAQC adherence, turn-around time requirement, etc.

3.4.10 SAMPLE LABELLING - Sample login begins by assigning an ATLI batch control number (ATLI laboratory number). To maintain sample identity, an ATLI batch number is assigned to the sample set and recorded on all documents received with the samples. This unique identifier is affixed to the sample container on a sample label and is recorded on the COC. The ATLI batch numbers assigned are recorded in the sample control logbook in ascending order.

3.4.11 CHAIN-OF-CUSTODY (COC) - used to establish a detailed legal documentation of all transactions in which the samples are transferred from the custody from one individual to another. Custody tracking begins from the point at which the samples are collected, transferred to the laboratory, analyzed, and to its disposal. A COC form documents sampling efforts and sample transfer from the field to a testing facility or between testing facilities. An example of an ATLI chain-of-custody form is shown in [Appendix E](#).

3.4.11.1 An ATLI COC form is used for a set of samples received without a client's COC or equivalent form. It is used to document any sampling and analysis information contained on the sample label or as provided via FAX or mail by the client.

3.4.11.2 If samples need to be sent to a subcontractor, a second ATLI COC form, cross-referencing the original COC, is generated to accompany samples delivered to outside laboratories.

3.4.11.3 The samples are tracked through all the custody transfers by use of the ATLI laboratory number and client sample identification.

3.4.12 Sample traceability from Sample Control to the chemist is documented on the ATLI Internal Chain-of-Custody (COC). The Internal COC is used to document the analyst's initials, date, time, and which sample(s) were checked-out. Upon returning the samples to Sample Control, the return date, time and initials are recorded.

3.4.12.1 Sample traceability continues through the analysis, data reduction, data validation, final report generation, and sample disposal by the use of the ATLI laboratory number. All result templates, folders, invoices, and final reports document the ATLI laboratory number for all samples.

3.5 SAMPLE STORAGE

Samples received in the laboratory are stored in a designated storage area that is free of temperature extremes.

3.6 SAMPLE DISPOSAL

3.6.1 At a minimum, the laboratory stores samples collected in stainless steel canisters until several days after the client receives results, after which the contents of the canisters are vented to a fume hood and submitted for cleaning.

3.6.1.1 Some projects require that the samples be stored for a specified number of days. In the case of canisters which the laboratory would like to clean prior to the storage date, the client is contacted for approval.

3.6.2 Samples collected in Tedlar bags are stored for at least 30 days and then sliced open under a fume hood and entombed in an industrial strength trash bag and disposed of in the facility's trash receptacle.

3.6.3 Laboratory sample disposal is in accordance with the local, state, and federal regulations.

3.6.4 See Sample disposal SOP ATLI-GP-009 latest revision for additional details.

3.7 SAMPLE CONTAINERS AND LABWARE PREPARATION

3.7.1 Stainless steel canisters are cleaned according to method guidelines (see Canister Cleaning SOP ALTI-GP-005 latest revision).

3.7.2 Each batch is certified clean by analyzing the canister that contained the highest contamination. The batch is clean if no target analytes are detected above method reporting limits (refer to Canister Cleaning SOP ALTI-GP-005 latest revision).

4 DOCUMENT CONTROL

A document control program is established to ensure that all documents (both paper and electronic) received from external sources, or internally issued or generated at ATLI are accountable and traceable, and protected against unauthorized access. Examples of external documents are hard copies of latest versions of the TNI standards and the DoD QSM, DoD and TNI accreditation body relevant documents, reference methods SOPs, and equipment manuals. Examples of internal documents are ATLI SOPs and Forms. It is accomplished through the use of a centralized repository or area where designated personnel are responsible for its maintenance. Listed below are the general qualities of the document control program.

The QA Manager and Technical Director (or designee) are authorized to review and approve original documents and any changes to those documents. They will have access to pertinent background information upon which to base their review (e.g. methods, internet, etc.)

4.1 Changes to documents

4.1.1 Documents are periodically reviewed by the QA Manager and Technical Director or designee, where necessary, revised to ensure continuing suitability and compliance with applicable requirements

4.1.2 Documents that have been changed are assigned a new revision #

4.1.3 Personnel are informed or trained on any revisions that affect procedures applicable to their duties. They are informed/trained during one of the routine laboratory meetings. Subsequent meetings are used to assess the effectiveness of the training, and that the revisions have been implemented.

4.2 Maintenance of documents

4.2.1 Only current documents are made available to personnel.

4.2.2 Invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use as described in detail below. Invalid or obsolete documents are identified with an "obsolete" sticker or stamp.

4.3 Control of documents

4.3.1 Computerized documents are write-protected and stored on the company server in folders with access limited to QA Manager and Technical Director or designee. All documents are assigned unique document #s.

4.3.2 Hardcopy documents are stored in the document control room. Document access is documented in the document control access logbook. Other hardcopy documents are stored in the QA office.

4.3.3 LOGBOOKS/NOTEBOOKS/FORMS -

The general guidelines for documentation or entries are:

4.3.4 All logbooks are to be hardbound and paginated. All entries signed or initialed and dated by the person responsible for performing the activity at the time the activity is performed, and all entries are recorded in chronological order.

4.3.5 All forms are assigned a Form Number which is maintained in the Forms Master List. All forms must have visible the Form #, revision, date of issue, issuer, and total page numbers

(if applicable).

4.3.6 Legibility: All entries must be legible. Printing is preferable, but writing is acceptable for all characters, including notes.

4.3.7 Recording Entries: All entries are made using indelible ink pens, preferably blue or black.

4.3.8 Review all forms before entering information.

4.3.9 Initial(s) or signature(s) must identify the originator(s) of all entries. In most cases, there are specific fields on the data sheet for documentation of such information.

4.3.10 Any blank fields must contain a diagonal line or "Z" out with initials and date.

4.3.11 The use of abbreviations is kept to a minimum. Only nationally accepted abbreviations (e.g., mg/Kg, mL, µg/Kg) and chemical formula abbreviations (e.g., NaOH, HCl) may be used without further clarification. Other abbreviations can be used providing the abbreviation can be traced to the corresponding abbreviation explanation.

4.3.12 As much as possible, all mistakes are corrected at the time the error is discovered. Cross out with a single line so as to remain legible. Do not erase, write over, or use correction material. Each cross out is initialed and dated. If the reason for the change is not obvious, it must be stated. [Note: If there is insufficient space for all or part of the correction information, enter a footnote call out near the incorrect data and enter the required information as a comment elsewhere on the data sheet, notebook page, etc.].

4.3.13 The cover page of each logbook must contain information that clearly identifies the purpose of the logbook (i.e. instrument, method, procedure, etc). Each logbook must also contain a table listing all personnel approved to make entries. Entries must be legible and with sufficient detail as to permit repeating of the work by someone other than the person(s) originally performing the activity. Each entry must record the date in which the data was recorded.

4.3.14 If there are any changes to the Logbook format itself, the affected personnel will be shown the changes upon implementation, or during the laboratory meeting.

4.4 STANDARD OPERATING PROCEDURES (SOP) and QA MANUAL

All documents issued to personnel in the lab as part of the management system are reviewed and approved for use by the QA Manager, Technical Director, or qualified designee prior to issue.

4.4.1 As defined by the EPA, an SOP is a written document that provides directions for the step-by-step execution of an operation, analysis, or action that is commonly accepted as the method for performing certain routine or repetitive tasks.

4.4.2 The SOP format for analytical methods consists of Scope and Application; Summary; Equipment and Reagents; Sample Preparation; Procedures; Quality Control; Data Reduction and Calculations; Preventative Maintenance; Sample Preservation, Safety, Hazards and Waste Disposal; Attachments and References.

4.4.3 Distribution - All SOPs for internal laboratory use are controlled and numbered documents. The Control Number A watermarked "Controlled Copy" is placed onto the cover page each page of the document. Document name, SOP code, date issued and initials are recorded into a "Control SOP" logbook.

4.4.4 SOPs and the Quality Assurance Manual are reviewed annually and revised if needed. Altered and new text in the latest document revisions are highlighted to identify the revisions/changes. . If there are no revisions, the cover page of the SOP will be stamped or a label affixed with the signature and date of review by the QA Manager and Technical Director. All controlled copy SOPs will have their cover pages replaced to show proof of review.

4.4.5 When revised SOPs are released into the laboratory, the “old” version is replaced with the “new” version. The “old” version **of the original** is marked “OBSOLETE” and archived by the QA department. All original, signed SOPs are stored in 3-ring binders according to categories: General Laboratory Practices, Analytical Methods. Within the 3-ring binder, page dividers partition each SOP.

4.4.6 All authorized original hardcopies of the SOPs are available in the QA Office indefinitely. Copies of the **current** SOPs are available at all locations where operations essential to the effective functioning of the laboratory are performed.

4.4.7 All electronic copies of the SOPs are located in the QA folder on the server. The computer is backed-up every two weeks and the computer is virus checked at all times to deter virus data corruption. A second electronic copy is stored on a specified directory on the network. Only the QA Manager, designee and Technical Director have access to this directory to create or change documents. The network is backed-up on a weekly basis followed by an incremental, daily back-up.

4.4.7.1 Maintaining the integrity of electronic data is described in the Data Back-up and Storage SOP, ATLI-GP-011 latest revision.

4.4.7.2 Any changes made to the SOPs prior to their periodic reviews, will be highlighted and communicated to the affected personnel prior to implementation by the QA Manager, designee or Technical Director, or during laboratory meeting.

4.4.7.3 Temporary manual changes can be made to SOPs by the QA Manager, designee or Technical Director. The QAM, designee or TD adds in pen the change to the appropriate section of the SOP. The change is dated and initialed. A copy of the changed page is inserted into the SOP binder and the lab personnel are notified of the change via email or during the lab meeting.

4.5 PROJECT FOLDER

4.5.1 Organization - A project file is generated for each set of samples received at ATLI. Sample Control initiates the collection or preparation of the documents for the project files. The sample control documentation includes:

Chain of Custody

Any project specific information regarding: Detection limits, QA/QC analyses, Reporting, Invoicing, Extended storage, etc.

4.5.1.1 This information group is compiled and put into each respective color-coded folder. The SOP for Sample Login (Sample Receipt, Log-in, and Equipment Returns ATLI-GP-001 latest revision) describes the process of logging samples and developing the project folder.

4.5.2 Project File Archival

Once the final report has been mailed to the client, the project folder (which contains information such as the chain-of-custody, correspondences, raw data, reports, etc.) is archived to a file room that has limited access. The Document Control Officer is responsible for the

archiving/retrieval of the project folders. The Data Back-up and Storage SOP ATLI-GP-011 latest revision describes how documents are archived and retrieved by the Document Control Officer.

4.5.2.1 Project files are archived as such:

Hazardous Waste Projects:	5 years
DOD Projects:	10 years
Other Projects:	5 years or per contract requirement

4.5.2.2 In the event of the laboratory going out of business, all clients will be notified in writing, and given 30 days to determine project folder disposition.

4.5.2.3 In the event of the laboratory changing ownership both seller and buyer must agree in writing to be accountable and liable for work performed and reports generated during their respective ownerships. Further, the new owner must agree in writing to assume archiving responsibility for all reports and data currently archived as per section 4.5.2.1 above.

4.6 REQUESTS, TENDERS, AND CONTRACTS

Request, tenders, and contracts (e.g. Chain of Custody, Request for Proposals, QAPPs, Sampling Plans, Task Orders, Master Service Agreements, Sub-Contracts, etc.) must be reviewed and approved by the General Manager, Laboratory Director or other authorized laboratory representative prior to receipt of any samples. The review process is initiated when a customer submits the applicable document to the laboratory.

4.6.1 The authorized representative in consultation with other laboratory personnel (project manager, lab chemists, QA Manager) determines if:

- a) the requirements of the contract, including the methods to be used, (also QC requirements, reporting requirements, deliverables) are adequately defined and documented;
- b) the laboratory possesses the necessary capacity, personnel and information resources,
- c) the laboratory's personnel have the skills and expertise necessary for the performance of the environmental tests in question.
- d) the laboratory has the necessary experience to handle the project or contract requirements. The review may encompass results of earlier participation in inter-laboratory comparisons or proficiency testing and/or the running of trial environmental test programs using samples or items of known value in order to determine uncertainties of measurement, detection limits, confidence limits, or other essential quality control requirements. The current accreditation status of the laboratory must also be reviewed. The laboratory must inform the client of the results of this review if it indicates any potential conflict, deficiency, lack of appropriate accreditation status, or inability on the laboratory's part to complete the client's work.
- e) the appropriate environmental test method is selected and capable of meeting the clients' requirements. Any differences between the request or tender and the contract must be resolved before any work commences.

4.6.1.1 The contract is also reviewed for possible subcontracted work. The review must ensure that the subcontracted lab(s) has the required accreditations and certifications for the methods and analytes being contracted, that the subcontracted lab agrees to abide by the requirements of the contract, carries the necessary insurance.

4.6.2 Once the document has been approved, a file is created containing the final signed document along with all supporting documents and communications regarding the document.

Communication records include phone logs, faxes, and emails. All contract documents are stored on the server.

4.6.3 Once work has commenced, any modifications to the contract initiates the process again and all modifications are communicated to lab personnel via lab meetings. If the laboratory initiates the modification, the client is notified immediately. Verbal communications with clients are recorded on the client communication form and filed in the project envelope.

4.6.4 (DoD) Waivers from QSM requirements must be requested in writing from the appropriate DoD Chemist or Contractor Project Chemist (however named) on a project-specific basis and shall include technical justification relating to the specific project for the waiver. Documentation of approval for the waiver must be maintained by the laboratory and readily available for review.

4.7 Maintaining Confidentiality

4.7.1 Original, signed reports are printed on ATLI's letterhead. The original report is released to the client as specified on the Chain-of-Custody. ATLI's client confidentiality policy assures that reports and associated documentation will only be released to the original client. ATLI will only release data to other entities with a written authorization from the client. For written requests from a regulatory agency or from a court-of-law, the laboratory is obligated to submit all information, but will notify client of any such request.

4.7.2 All employees are required to sign and adhere to a non-disclosure agreement annually. The non-disclosure agreement details the activities and information that are to be protected against unauthorized access or dissemination.

4.7.3 Electronic results are write-protected.

4.7.4 All files and customer-related correspondence are access controlled (see Document Control). The retrieval of files from file storage is recorded in the Access Log book by document control personnel.

4.7.5 Client emails are protected by log-in and password procedures.

4.7.6 CONTROL OF RECORDS All records (including those pertaining to test equipment), certificates, and reports are safely stored in the document control room, file cabinets, on the server, and held secure and in confidence to the client.

Records for each test contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test to be repeated under conditions as close as possible to the original (e.g. raw data, logbooks, electronic data, SOPs, etc.)

4.7.7 All records are available to the accrediting authority.

4.7.8 All records are retained for a minimum of five years from generation of the last entry in the records, and follow all appropriate regulatory and state legal requirements concerning laboratory records. All information necessary for the historical reconstruction of data (instrument calibrations, sample data, QC data, logbooks, etc.) is maintained by the laboratory. The hardcopy instrument calibration data is stored in bankers boxes. The computer data is stored on tape or electronic media backup for ten years DOD Projects and for five years for Hazardous Waste and other Projects.

4.7.9 Records which are stored only on electronic media (e.g. GC, GCMS data) are supported by the hardware and software that is necessary for their retrieval. The hardware and software are retained by the laboratory.

4.7.10 Records that are stored or generated by computers or personal computers have hard copies or write-protected backup copies. Examples of computer generated records is the laboratory sample receiving Excel spreadsheet, report templates, etc. All electronic data is routinely backed up to tape or electronic media storage.

4.7.11 Laboratory instrument logbooks, standard logbooks, maintenance logbooks are assigned logbook #s and stored indefinitely in the QA office when no longer in use. Records for data reduction, validation, storage and reporting are stored in the project envelopes and kept in the document control room for a minimum of 5 years or per client requirements.

4.7.12 Access to the archived information is documented in the document control logbook. The record storage meets all local and state and federal fire codes, and are stored away from any damaging conditions.

4.7.13 . The laboratory building is locked 24/7 and the property grounds are patrolled 24/7 by security guards which protects against theft. Electronic records are stored on magnetic tape or electronic media away from harmful electronic or magnetic sources in the computer room.

4.7.14 If the laboratory transfers ownership, all clients will be informed of the ownership change and be required to state how they would like their records to be maintained (i.e. retained by the new ownership, transferred to them, etc.)

4.7.15 Should the laboratory permanently shut down, all clients will be notified in writing, and given 30 days to determine project folder disposition. Efforts to inform the customers of the pending closure will be made, as well as efforts to transfer documents as is feasible. All unclaimed records will be destroyed by a qualified document disposal company.

4.7.16 LOGBOOK MAINTENANCE AND ARCHIVING

4.7.17 All logbooks are to be reviewed on a monthly basis by QA personnel or chemist peers. Any deficiencies are corrected by the same individual that made the entry to be corrected. The reviewer initials and dates each page of the logbook signifying that the page is closed.

4.7.18 All logbooks are assigned a unique logbook tracking number via the Master Logbook Log.

4.7.19 Analyst Notebooks: Each analyst maintains a personal bound notebook. The analyst is able to keep notes during training sessions. Whenever the analyst's logbook becomes full, it is the analyst's responsibility to get a new replacement logbook from the QA Manager or designee. These logbooks are subject to audits.

4.7.20 Instrument Maintenance Logbooks: Each instrument must have an associated logbook to record maintenance (routine and unscheduled) and repairs. These logbooks are audited for complete entries during inspections. The logbook is replaced and archived by the QA Manager or designee. The maintenance logbooks are archived for 5 years or per client requirements.

4.7.21 Standard Prep Logbooks are required to keep records of standard traceability and sample preparation. These logbooks are audited for completeness, standard traceability, standard preparation, correct QC sample batching, etc. The logbooks are replaced and archived by the QA Manager or designee. The Standard Prep Logbooks are archived for 5 years or per client requirements.

4.7.22 Injection Run Logbooks (runlogs) are used to record the sequence of the sample run, corresponding standards with standard codes and corresponding QC samples. The runlogs are replaced and archived by the QA Manager or designee. The runlogs are archived for 5 years or per client requirements.

4.7.23 ATLI Sample Receipt Logbook: This logbook is used to record the unique ATLI sample identification, date and time sampled, turn-around-time, project, matrix type, client, client's sample identification, test, preservation, sample container type, and initials of login personnel. The logbook is audited for completeness during inspections. The logbook is replaced and archived by the QA Manager, designee or Lab Manager. The Sample Login logbooks are archived for 5 years or per client requirements. This logbook is in electronic format, subject to normal electronic data backup and validation.

4.7.24 Miscellaneous Logbooks: Refrigerator temperature log, balance check log, distilled water check, etc. are used to record various laboratory equipment. The logbooks are audited for daily monitoring and completeness. The logbooks are replaced and archived by QA Manager or designee. The logbooks are archived for 5 years or per client requirements.

4.7.25 All logbooks are considered controlled records. They will each have a unique serial number, and tracked in a master list. The master list will contain, at a minimum, logbook description, serial number, and date issued and completed. They will be issued individually and archived by the QA department.

4.8 COMPUTER DATA / LIMS Management

4.8.1 The technical director assigns individual user names and passwords for all LIMS users. LIMS passwords are changed annually.

4.8.2 New employees undergo initial training in computer security awareness and have ongoing refresher training on an annual basis. Records of the training are maintained and available for review.

4.8.3 Monthly inspections of the Computers/LIMS are performed by an ISO certified information management system company as selected by the Technical Director to ensure the integrity of electronic data. The computer company maintains records in a binder of inspections and submits reports to laboratory management, noting any problems identified with electronic data processing stating the corrective actions taken. The information management system company must comply with the laboratory's overall management system, must comply with the requirements of the QSM, and are subject to review/approval by the DoD customer.

4.8.4 Any changes to the LIMS software or hardware configuration that would adversely affect customer electronic data are communicated to the client via email or phone call with sufficient time for the client to evaluate the effects of the change.

4.8.5 Spreadsheets used for calculations are verified before initial use and after any changes to equations or formulas, including software revision upgrades, by either the QA Manager or Technical Director or designee. Records of the verification are available for review. Formula cells are write-protected to minimize inadvertent changes to the formulas. Printouts from spreadsheets include all information used to calculate the data via the raw analytical data.

4.8.6 ATLI electronic data security measures ensure:

- 4.8.6.1** Individual user names and passwords are assigned and maintained by the Technical Director. Passwords are changed annually.
- 4.8.6.2** The Technical Director assigns operating system privileges and file access to restrict the user of the LIMS data to users with authorized access.
- 4.8.6.3** All LIMS Users are trained in computer awareness security on an annual basis.
- 4.8.6.4** System events, such as log-on failures or break-in attempts are monitored by the computer company contracted to perform the monthly computer network system.
- 4.8.6.5** The electronic data management system is protected from the introduction of computer viruses via monthly updates and virus scans by the computer company.
- 4.8.6.6** System backups occur on a regular and published schedule and can be performed by more than one person within an organization.
- 4.8.6.7** Testing of the system backups are performed and recorded to demonstrate that the backup systems contain all required data.
- 4.8.6.8** By locating the servers in a separate room in a secure facility, physical access to the servers is limited.

5 ANALYTICAL METHODOLOGY

5.1 ANALYTICAL PROCEDURES

Analytical procedures used for various laboratory analyses are in accordance (when applicable) with the EPA approved methods, or other governing agency (e.g. ASTM, NIOSH, South Coast Air Quality Management District, California Air Resources Board). Any variances in the methods have been documented for equivalency based on accuracy and precision data. All variances in the analytical methods are noted in all corresponding SOPs. These SOPs are available to the analyst under controlled copies. New methods and/or SOPs are distributed throughout the laboratory by issuing control copies. Old methods/SOPs are collected before the new documents are given to the chemists. [Appendix H](#) lists the current laboratory methods and its certifications.

5.1.1 Deviations from test methods occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer.

5.1.2 ATLI uses the latest valid edition of a standard unless it is not appropriate or possible to do so, and, when necessary, the standard is supplemented with additional details to ensure consistent application.

5.1.3 When the customer does not specify the method to be used, ATLI selects the appropriate methods that have been published either in international, regional, or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment. Lab-developed methods or methods adopted by the lab are used if they are appropriate for the intended use and if they have had an acceptable initial DOC perform (5.1.5)

5.1.4 The customer is informed as to the method chosen.

5.1.5 ATLI confirms that it can properly operate standard methods before introducing the tests via the Demonstration of Capability (DOC) described in Section 1.2.3.4.1. If the standard method changes, the DOC is repeated.

5.1.6 The introduction of test methods developed by ATLI for its own use is a planned activity and assigned to qualified personnel equipped with adequate resources. Plans are updated as development proceeds and is communicated among all personnel involved in the weekly lab meetings.

5.1.7 When it is necessary to use methods not covered by standard methods, these are subject to agreement with the customer and includes a clear specification of the customer's requirements and the purpose of the test.

ATLI may perform initial DOCs on non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use, depending on the application and scope required by the client or lab personnel. The Technical Director and QA Manager reviews the DOCs to ensure that the validation is as extensive as is necessary to meet the needs of the given application or field of application. The laboratory records the results obtained, the procedure used for the validation, and a statement that the method is valid for its intended use. As much as is possible, the initial validation of non-standard methods includes

- i) Scope;
- ii) Calibration;
- iii) Interferences/Contamination;

- iv) Analyte identification;
- v) Analyte quantitation;
- vi) Selectivity;
- vii) Sensitivity;
- viii) Precision; and
- ix) Bias.

5.1.8 The range and accuracy of the values obtained from validated methods (e.g. the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object), are relevant to the customers' needs.

5.1.9 For DoD projects, the use of non-standard methods must be approved by the client prior to start of a project.

5.1.10 If method modifications cause changes in stoichiometry, technology, mass tuning acceptance criteria, or quantitation ions to occur, the validation steps listed (i-ix) are performed.

5.2 CALCULATION OF DATA QUALITY INDICATORS

All data generated at ATLI are assessed for data quality in terms of accuracy, precision, completeness, representativeness, and comparability, depending on the scope of work.

Precision, accuracy, and completeness are calculated following the equations presented below. The results are reported in QC tables with the final reported results. The QC Criteria for each type of QC sample is determined by method or project requirements.

5.2.1 MEASUREMENT UNCERTAINTY –Determination of Uncertainty ATLI-GP-014 latest revision

5.2.2 *Precision:* A measure of mutual agreement among individual measurements of the same property, usually under prescribed similar conditions. Precision can be expressed in terms of the relative percent difference (RPD), relative standard deviation (RSD) and/or standard deviation. Analytical precision is measured by replicate analyses of individual samples. If calculated from two replicates, use RPD.

$$RPD = \frac{(C_1 - C_2)}{[(C_1 + C_2)/2]} \times 100$$

Where:

RPD = the relative percent difference

C₁ = the larger of the two observed values

C₂ = the smaller of the two observed values

If calculated from three or more replicates, use RSD or coefficient of variation.

$$RSD = \frac{s}{Y} \times 100\%$$

Where:

RSD = the relative standard deviation

s = the standard deviation

\bar{Y} = mean of replicate measurements

Standard deviation, s, is defined as follows:

$$s = \text{SQRT}\left(\frac{\sum (Y_i - \bar{Y})^2}{n - 1}\right)$$

Where:

s = standard deviation

SQRT = square root

Y_1 = measured value of replicate

\bar{Y} = mean of replicate measurements

n = number of replicates

5.2.3 Accuracy: A measure of the bias of a system or measurement. It is measured by blank spikes (laboratory control samples (LCS)) and, when available, standard reference material (SRM). For measurements where LCSs are used, use percent recovery.

$$\%R = 100 \times \frac{S - U}{C_{sa}}$$

Where:

%R = percent recovery

S = measured concentration in spiked aliquot

U = measured concentration in unspiked aliquot

C_{sa} = actual concentration of spike added

For situations where an SRM is used instead of, or in addition to, matrix spikes, calculate the percent recovery based on certified value = 100%.

5.2.4 Completeness: A measure of the amount of valid data obtained from a measurement system compared to the amount that was expected to be obtained under normal conditions. Defined as follows for all measurements:

$$\%C = 100 \times \frac{V}{n}$$

Where:

%C = the percent completeness

V = the number of measurements judged valid

n = the total number of measurements necessary to achieve a specified statistical level of confidence in decision making.

5.2.5 METHOD DETECTION LIMIT (MDL)

Based on the EPA 40 CFR 136 - Definition and Procedure for the Determination of the Method Detection Limit. ATLI redefines the limit of detection for each parameter annually. The

calculation for MDL is defined as follows for all measurements:

$$\text{MDL} = t_{(n-1, 1-\alpha=0.99)} \times s$$

Where:

MDL = the method detection limit

s = the standard deviation of the replicate analyses

$t_{(n-1, 1-\alpha=0.99)}$ = the Students' t-value appropriate to a 99% confidence level and a standard deviation estimate with n-1 degrees of freedom.

5.2.6 CONTROL CHARTS

Quality control can be maintained by monitoring the responses of the parameters using control charts. The procedures and control limits are specified by the methods. Control charts are maintained for two purposes: (1) to show the limits within which measurements must fall and (2) to chart daily shifts and trends.

5.2.6.1 For many air testing methods, control charts may not be representative of actual analytical methodology. Conclusions from control charts rely on a statistical analysis of independent samples. The fact that some air testing standards can be used for a much longer period than those for soil or water tests leads to possible bias in control chart results. Any limits or conclusions drawn from control charts should be reviewed carefully before use.

5.2.6.2 Control charts must be created for every analyte with respect to laboratory control samples (LCS) and surrogates (if applicable). A minimum of 30 measurements is necessary to construct a control chart. In lieu of the 30 required points, default limits of 70% - 130% recovery and 30% RPD can be used. The primary function of the control charts is to define control limits for the individual methods. Failed LCS recovery data and statistical outliers are not excluded from the calculation, unless there is a scientifically valid and documented reason. The control limits determination are based on the following equations:

$$\text{Upper Control Limits} = M + 3 \times S \text{ (UCL)}$$

$$\text{Upper Warning Limits} = M + 2 \times S \text{ (UWL)}$$

$$\text{Lower Warning Limits} = M - 2 \times S \text{ (LWL)}$$

$$\text{Lower Control Limits} = M - 3 \times S \text{ (LCL)}$$

Where: M = the average of the values

S = the standard deviation of the values

5.2.6.3 The control chart is an effective tool to assess data quality of analytical results in a real-time manner at the point of data generation. It is a means to evaluate trends in data quality that may not be readily apparent when judged against static performance criteria.

5.2.6.4 The control chart may be readily examined by the chemist for trends that indicate a statistical trend that may lead to loss of control. These trends are:

- any point outside the control limit
- any three consecutive points between the warning and control limit
- any eight consecutive points on the same side of the mean

- any six consecutive points increasing
- any six consecutive points decreasing
- any obvious cyclic, repeating pattern

If any of these trends are observed, then production may be stopped until the problem can be evaluated. If an out-of-control situation is determined, a non-conformance form is filled out and is immediately given to the supervisor and to the QA Manager. Return to control must be established by re-analyzing the QC Sample.

5.2.6.5 Control limits are monitored on an on-going basis for shifts in mean recovery, changes in standard deviation, and development of trends. Representative compounds may be chosen for the purpose of trend analysis. The QA officer or designee reviews control charts quarterly for out-of-control conditions and initiates appropriate corrective actions. Data analysis software may also be used for the statistical evaluation of data for trends and biases.

ATL uses its in-house statistically established LCS control limits for the purpose of trend analysis and may use in-house control limits as a component in estimating measurement uncertainty. In the absence of client-specified LCS reporting criteria, the LCS control limits outlined in the QSM Appendix C tables are used when reporting data for DoD projects.

Sporadic marginal exceedances are not allowed for target analytes without project-specific approval. DoD considers the same analyte exceeding the LCS control limit two (2) out of three (3) consecutive LCS to be indicative of non-random behavior, which requires corrective action and re-analysis of the LCS.

For analytes that are not listed in the QSM Appendix C control limits tables, ATL uses their in-house control limits for batch control and data reporting. For DoD ELAP accreditation, ATL develops in-house control limits for all analytes on their scope of accreditation. In-house control limits are used for trend analysis, and batch control for those analytes not listed in the QSM Appendix C LCS tables.

6 CALIBRATION PROCEDURES AND FREQUENCY

Calibration is the process by which a specific response of an analytical instrument to a specific analyte can be correlated to a specific amount of that analyte.

ATLI has established procedures for the calibration of each laboratory instrument and equipment. They are calibrated according to the requirements of the specific methods of analysis. All calibrations and acceptance criteria are checked for conformance to these method requirements. The data resulting from the instrument calibration and the associated continuing calibration checks are used to determine the frequency of the calibration process.

6.1 CALIBRATION PROCEDURES FOR ORGANIC ANALYSES (Non-DoD)

6.1.1 Gas Chromatography Methods (GC), ASTM D1946, EPA 3C, EPA 25C, EPA TO3, RSK175, etc. Refer to method SOPs latest revisions for calibration details.

6.1.1.1 Calibration of the chromatographic system is accomplished by preparing standards at a minimum of five concentration levels for each analyte. The low level standard is at or near the established LOQ.

6.1.1.2 The results of standard calibrations for each analyte are tabulated with respect to response versus concentration. The ratio between response and concentration, known as response factor (RF), can be used to prepare a calibration curve for each compound. Alternately, if the RF is constant (less than the 25% relative standard deviation) over the working range, linearity can be assumed and the average RF can be used in place of a calibration curve for each compound.

6.1.1.3 The linearity of the initial calibration may also be determined by using the linear regression equation that does not pass through the origin (0,0). The regression calculation will generate a correlation coefficient (r) that is a measure of the "goodness of fit" of the line. The r value must be greater than or equal to 0.99.

6.1.1.4 The initial calibration curve must be validated prior to the analysis of samples through the analysis of an Initial Calibration Verification standard (ICV) which is prepared from a second source. The ICV must meet the criteria of the method, SOP, or client-requirements. The LOQ and the highest calibration standard of a multi-level calibration curve establishes the quantitation range.

6.1.1.5 Other calibration standards such as closing standards may be analyzed. The frequency and acceptance criteria followed is stated in each method SOP.

6.1.2 Gas Chromatography/Mass Spectrometry (GC/MS), EPA TO14A, TO15. – Refer to method SOPs latest revisions for calibration details.

6.1.2.1 The first step in the calibration of the GC/MS system is to tune, or verify, isotope ratios and fragmentation stability through the analysis of 4-bromofluorobenzene at the beginning of each 24-hr shift (12-hrs for DoD, unless otherwise specified by project requirements). Validation is performed by comparison of the mass spectra of the tuning compound with that of the BFB tuning criteria specified in the Determination of Toxic Organic Compounds in Ambient

Air-EPA Method TO14A/TO-15 ATLI-SOP-001 latest revision (see method SOP).

6.1.2.2 Calibration of the GC/MS is established and validated by the injection of EPA-traceable standards at a minimum of five concentration levels over the range of likely sample concentrations. The low level standard is at the established reporting limit. Internal Standards are used to adjust for response variability. The Relative Standard Deviation, RSD, of each analyte response factor, RF, is determined. If the RSD of the RF is less than or equal to 30% linearity can be assumed and the average RF can be used for quantitation of analyte concentrations. For TO-15 up to two compounds can have an RSD of up to 40%.

6.1.2.3 In general, the initial calibration curve must be validated prior to each 24-hour analysis batch (or more frequent per client or project requirements) by analyzing a tune standard and continuing calibration verification, CCV, standard. The response factor of the analytes in the CCV must be within 30% of the RF average. If any of the criteria fails for target compounds, then the instrument must be re-calibrated. The LOQ and the highest calibration standard of a multi-level calibration curve establishes the quantitation range. Samples associated with a failed initial calibration must be re-analyzed. If re-analysis of the samples is not possible, data associated with an unacceptable initial instrument calibration is reported and discussed in the report narrative.

6.2 CALIBRATION PROCEDURES FOR DEPARTMENT OF DEFENSE (DoD)

Refer to Appendix B of QSM 5.1 for calibration criteria.

6.2.1 The initial calibration (ICAL) consists of a minimum of five calibration points and includes all reported analytes and surrogates. All results are calculated based on the multi-point calculation. Refer to the individual method SOPs latest revisions for calibration preparation. Exclusion of calibration points without documented scientifically valid technical justification is not permitted. Refer to Appendix B of QSM 5.1 for ICAL criteria. If the ICAL criteria fails, troubleshooting and recalibration is required.

6.2.2 ICV - An initial calibration verification (ICV) is performed immediately after an ICAL through the analysis of a second source standard prepared at a concentration at or below the mid-point but above the LOQ. Refer to the individual method SOP latest revisions for ICV preparation. Refer to Appendix B of QSM 5.1 for ICV criteria. If the ICV fails, perform corrective action, rerun the ICV. If the rerun fails, recalibrate.

6.2.3 CCV - The ICAL must be validated prior to each 12 hour analysis batch by analyzing a tune standard and continuing calibration verification (CCV) standard, before any samples are analyzed. The CCV standard is prepared at a concentration at or below the mid-point but above the LOQ. Refer to the individual method SOP latest revisions for preparation of the CCV. Refer to Appendix B of QSM 5.1 for CCV criteria. If a CCV fails, the lab can immediately analyze two additional consecutive CCVs (immediately is defined as starting a consecutive pair within one hour; no samples can be run between the failed CCV and the two additional CCVs).

Any corrective actions that change the dynamics of the system requires that all samples since the last acceptable CCV be reanalyzed. Both of these CCVs meet acceptance criteria in order for the samples to be reported without reanalysis.

If either of these two CCVs fail, the associated samples cannot be reported and must be reanalyzed.

If the laboratory cannot immediately analyze two CCVs, then perform corrective action(s) and repeat the CCV and all associated samples since the last successful CCV.

Recalibration must occur if the above scenarios fail. All affected samples since the last acceptable CCV are reanalyzed.

Flagging of data for a failed CCV is only appropriate when the affected samples cannot be reanalyzed. The lab notifies the client prior to reporting data associated with a failed CCV

7 METHOD DETECTION LIMITS and REPORTING LIMITS

7.1 METHOD DETECTION LIMITS

7.1.1 METHOD DETECTION LIMIT (MDL) STUDIES

7.1.1.1 MDL studies are conducted by the laboratory on an annual basis. MDLs can be performed on a more frequent basis if significant changes have occurred to the analytical system, such as, detector cleaning, new column, new oven program, etc. MDLs are used to determine Limits of Detection (LOD).

7.1.1.2 The MDL is defined as the minimum concentration of a substance that can be measured and reported with a 99% confidence level that the analyte concentration is greater than zero. This procedure consists of analyzing seven (7) aliquots of a standard at 1 to 4 times the estimated MDL that is taken through the entire sample processing steps of the analytical method. The MDL is defined as the student T-factor times the standard deviation from the seven replicates. See [Section 5.2.5](#) for the equation to calculate the MDL.

7.1.1.3 Once the MDL is generated, the department supervisor, the General Manager and the QA Manager reviews and approves the MDL study as being valid. The QA Manager then collects and maintains all MDL studies.

7.1.1.4 Each MDL is compared to the current reporting limits. The MDL value must be at least 2 times lower than the current reporting limit. The spiking concentration must not exceed 10 times the MDL value. If the MDL fails to meet these criteria, the MDL needs to be re-prepped and re-analyzed.

7.1.1.5 Refer to the MDL file for current studies.

7.1.2 LOD VERIFICATION

The LOD is initially determined for the compounds of interest in each method in a quality system matrix in which there are neither target analytes nor interferences at a concentration that would impact the results or is the LOD performed in the quality system matrix of interest, i.e. prepared in a method blank.

The following requirements apply to the initial LOD establishment and to the LOD verifications

The apparent signal to noise (S/N) ratio at the LOD must be at least three and the results must meet all method requirements for analyte identification (e.g., ion abundance, second column confirmation, or pattern recognition). For data systems that do not provide a measure of noise, the signal produced by the verification sample must produce a result that is at least three standard deviations greater than the mean method blank concentration. This is initially estimated based on a minimum of four method blank analyses and later established with a minimum of 20 method blank results

The laboratory maintains documentation for all MDL determinations and LOD verifications. The MDL and LOD is reported for all analyte-matrix-methods suites, unless it is not applicable to the test or specifically excluded by project requirements.

7.1.3 The LODs are verified on a quarterly basis **for DoD projects, and on a yearly basis for non-DoD projects**. An LOD is also performed each time there is a change in the method that affects how the test is performed or when a change in instrumentation occurs that affects the sensitivity of the analysis, such as a change in column, sorbent trap, etc. In situations where

methods are setup and used on an infrequent basis, the laboratory may choose to perform LOD verifications on a one per batch basis.

7.1.4 A standard is prepared at 1-4x the claimed MDL and analyzed.

7.1.5 The LOD is valid if all analytes can be qualitatively identified. If the LOD verification fails, the laboratory must repeat the DL determination and LOD verification OR perform and pass two consecutive LOD verifications at a higher spike concentration and set the LOD at the higher concentration.

7.1.6 If the LOD is verified, then the spiked concentration of each analyte becomes the LOD.

7.2 LOQ

7.2.1 LOQ DETERMINATION

The LOQ is defined as the lowest concentration that can be reported accurately. The LOQ is at or near the lowest concentration in a multi-point calibration curve. It empirically demonstrates precision and bias at the LOQ for each suite of analyte-matrix-method, including surrogates. If the method is modified, precision and bias at the new LOQ will be demonstrated and reported

7.2.1.1 Some projects or contracts have set LOQ (i.e. contract-required reporting limits). These LOQ are valid to report if they are still within the calibration range of the method.

7.2.2 LOQ VERIFICATION

7.2.2.1 LOQs are verified (on a quarterly basis for DoD and on a yearly basis for non-DoD) through the analysis of a standard that is prepared at 1-2x the claimed RL (i.e. the concentration of the lowest calibration point). The LOQ undergoes the same sample-processing and analysis steps of the analytical method. If the method is modified, a new LOQ is performed to demonstrate precision and bias. In situations where methods are setup and used on an infrequent basis, the laboratory may choose to perform LOD verifications on a one per batch basis.

7.2.2.2 The LOQ is valid if the recoveries of all analytes are within 30% of the actual concentration, and the LOQ is higher than the LOD.

7.2.2.3 If the LOQ fails the verification analysis, a new LOQ verification sample must be analyzed, or a new LOQ must be established.

8 INTERNAL QA/QC PROGRAM AND DOCUMENTATION

The analysis of QC samples is designed to monitor the performance of the overall analysis by checking for matrix interferences, reagent purity, system cleanliness, cross contamination, accuracy, and precision. The results from the QC samples such as laboratory control sample/laboratory control sample duplicate (LCS/LCSD), and surrogates (if applicable) are compiled and graphed on control charts. The primary function of the control charts is to define control limits for the individual methods.

For GC/MS TO-15 scan and TO-15 SIM analyses: QSM Version 5.1 Appendix C QC limits will be used for DoD Projects, unless the client has its own Project QC limits.

8.1 The laboratory shall follow the minimum quality control requirements specified by each method (if and only if all parameters are the same). In general, these method quality control requirements will be used as a guideline to determine approximate limits until in-house limits can be generated. The laboratory will follow whichever limits are most stringent.

8.2 If the method does not specify limits or guidelines for quality control requirements, the laboratory will default to limits such as 70% - 130% recovery until in-house limits can be generated or other limits are required.

8.3 If the method only has guidelines for the quality control requirement, then the laboratory will use them strictly as guidelines and set default limits as stated above until in-house limits can be generated.

8.4 ANALYSIS OF QC SAMPLES

8.4.1 GC/MS Analysis

8.4.1.1 SURROGATE STANDARDS

8.4.1.1.1 Surrogate standards are added to every sample, blank, QC samples, and check standard. If required by the client, the percent recovery of each surrogate is calculated and must fall within the established client criteria or criteria of the method (see method SOP latest revisions). Surrogate compounds are chosen to represent the various chemistries of the target analytes in the method. They are often specified by the mandated method and are deliberately chosen for their being unlikely to occur as an environmental contaminant. Often this is accomplished by using deuterated analogs of select compounds.

8.4.1.1.2 If recovery is not within required limits, the following procedures are taken:

- ▶ Check to be sure that there are no errors in calculations, surrogate solutions or internal standards. Inspect instrument for any obvious problems. Inspect spectra for interferences.
- ▶ Recalculate the data and/or reanalyze the sample if any of the above checks reveal a problem.
- ▶ If re-analysis of sample does not correct problem, result is reported as is with a statement entered in the report narrative describing the failed surrogate recovery.
- ▶ Results reported from analyses with surrogate recoveries outside the acceptance criteria will be qualified

8.4.1.2 LABORATORY CONTROL SAMPLE (LCS)/Laboratory Control Sample Duplicate (LCSD)

8.4.1.2.1 A Laboratory Control Sample (LCS)/Laboratory Control Sample Duplicate (LCSD) are analyzed with each batch of samples.

8.4.1.2.2 If the LCS or LCSD falls out of limits, the samples must be re-analyzed. If the reanalysis passes, the sample results can be reported. [If the analyte that failed was Not Detected in the sample, AND, the %R was high, then the sample may not need to be re-analyzed. Consult client]

8.4.1.2.3 If the re-analysis fails, the samples must be re-processed (if sample amount permits).

8.4.1.2.4 If samples are reported with failed LCS or LCSD: A CAR must be filled out and submitted with the samples and discussed in case narrative, and the data will be qualified.

8.4.1.2.5 If surrogate recoveries (if applicable) of the LCS or LCSD are out-of-limits:

- ▶ Check to be sure there are no errors in calculations, internal standards or instrument

performance.

► Reanalyze the LCS/LCSD if none of the above reveals a problem.

► If reanalysis does not correct the problem, recalibrate and re-analyze all samples associated with the failed LCS/LCSD.

8.4.1.3 METHOD BLANKS - A method blank is analyzed each day following the continuing calibration standard, QC sample, or the analysis of a highly contaminated sample.

8.4.1.3.1 The method blank is acceptable if there are no analytes detected above the reporting limit, or the concentration of any target analyte (chemical of concern) in the blank does not exceed 1/2 the LOQ, or is less than 1/10th the amount measured in any associated sample, or is less than 1/10th the regulatory limit, whichever is greater; or the concentration of any common laboratory contaminant in the blank is less than the LOQ.

8.4.1.3.2 If a laboratory method blank exceeds these criteria, all samples with like contaminations must be reanalyzed. [Note: in certain instances, analytes present in the blank might not be present in the sample(s). The end use of the data may not be impacted and the data may be acceptable without qualification. Consult with client in those cases]

8.4.1.3.3 Method blanks that do not meet the criteria the source of contamination is investigated and measures taken to minimize or eliminate the problem and affected samples reprocessed or appropriately qualified.

8.4.1.4 SAMPLE DUPLICATES – 1 out of 20 client samples will be analyzed in duplicate to monitor analytical precision.

8.4.1.4.1 Poor performance in the duplicate analysis results may indicate a problem with sample composition and shall be reported to the client.

8.4.1.4.2 Precision between sample duplicates should be +/-30% but at or near the LOQ or LOD the precision can be as great as +/-100%.

8.4.1.5 Field, Trip, and Equipment Blanks

Air sampling plans may require the analysis of these types of samples. The purpose is to monitor the presence of contaminants introduced in the field or during transport. If contaminant analytes are detected in the samples at concentration of <5 times the concentration found in the highest associated blank, the results are flagged and are reported as estimated.

8.5 ANALYSIS OF QC SAMPLES – GC ANALYSIS

8.5.1 Laboratory Control Sample (LCS)/Laboratory Control Sample Duplicate (LCSD)

8.5.1.1 A Laboratory Control Sample (LCS)/Laboratory Control Sample Duplicate (LCSD) are analyzed with each batch of samples, as per method requirements. The LCS/LCSD sample is spiked with all target analytes or a representative subset depending on client requirements, and spiked at a level at or below the mid-point of the calibration curve (if client requirements are not specified).

8.5.1.2 If the LCS or LCSD falls out of limits, the samples must be re-analyzed. If the reanalysis passes, the sample results can be reported. [If the analyte that failed was Not Detected in the sample, AND, the %R was high, then the sample may not need to be re-analyzed. Consult client]

8.5.1.3 If the re-analysis of the LCS or LCSD fails, the associated samples must be re-analyzed as well (if sample amount permits).

8.5.2 If samples are reported with failed LCS or LCSD: A CAR must be filled out and submitted with the samples and discussed in case narrative .

8.5.2.1 If surrogate recoveries (if applicable) of the LCS or LCSD are out-of-limits:

▶ Check to be sure there are no errors in calculations, internal standards or instrument performance.

▶ Reanalyze the LCS/LCSD if none of the above reveals a problem.

▶ If reanalysis does not correct the problem, recalibrate and re-analyze all samples associated with the failed LCS/LCSD.

8.5.3 Method Blanks - A method blank is analyzed per analytical batch (not to exceed 20 samples).

8.5.3.1 The method blank is acceptable if there are no analytes detected above the reporting limit.

8.5.3.2 If a laboratory method blank exceeds these criteria, all related samples with like contaminations must be reanalyzed. *[Note: in certain instances, analytes present in the blank might not be present in the sample(s). The end use of the data may not be impacted and the data may be acceptable without qualification. Consult with client in those cases]*

8.5.3.3 **SAMPLE DUPLICATES** – 1 out of 20 client samples will be analyzed in duplicate to monitor analytical precision.

8.5.3.3.1 Poor performance in the duplicate analysis results may indicate a problem with sample composition and shall be reported to the client.

8.5.3.3.2 Precision between sample duplicates should be +/-30% but at or near the LOQ or LOD the precision can be as great as +/-100%.

8.6 DATA INTEGRITY SYSTEM

8.6.1 The ability of a laboratory to generate data of known quality relies not only on the proficiency of the analysts, technical precision of the equipment, knowledge of quality assurance; it also depends on the laboratory's ability to maintain data integrity – the ability to ensure that data is not compromise. It is the Data Integrity System that accomplishes this goal.

8.6.2 The data integrity system involves – 1) data integrity training, 2) signed data integrity documentation for all laboratory employees, 3) in-depth, periodic monitoring of data integrity, and 4) data integrity procedure documentation.

8.6.3 The data integrity system is described in SOP ATLI-QA-002 latest revision.

9 DATA COLLECTION, VALIDATION, REPORTING, AND ARCHIVING

9.1 Upon completion of all required analyses, the results are processed for report generation. At all stages of Data Handling (Data Collection, Validation, and Reporting), the laboratory staff and management check all data before the final deliverable package is released. The following steps detail the internal laboratory procedure that ensures the final report is correct and in a complete and concise format. The Lab Manager, Project Manager, or other designees approved by the Lab Manager are the only qualified personnel to approve the final report to be released to client.

9.2 The data review process is described in detail in SOP ATLI-GP-010 latest revision. Records of data review are maintained and available for external review.

9.3 DATA COLLECTION

9.3.1 Data Collection is the process by which all data is compiled and prepared for validation and reporting. Observations, data, and calculations are recorded at the time they are made and identifiable to the specific task (e.g. instrument injection logbook).

9.3.2 All raw data generated by the analytical instrument that is needed to reproduce the analytical result is collected by the analyst and organized in a orderly and logical fashion. Results of each analysis are recorded manually into reporting format used in-house prior to final report generation. All equations for the calculation of LCS, RPD, RF and final result concentration are referenced in all method SOPs.

9.3.3 All Bench Level (Level 1) steps are documented for each project in the Technical Review Checklist.

9.4 DATA VALIDATION

9.4.1 Data Validation is a three-tiered review process that ensures the final report is error-free and complete. These Data Validation procedures along with the method SOPs allow for the traceability of all measurements. The three-tiers or levels and brief descriptions are:

1st level: bench level chemist review of raw data and associated quality control data.

2nd level: peer or supervisor review of raw data and associated quality control data.

3rd level: review by project manager, lab manager, or other qualified designated personnel, to ensure that all project requirements are met, and that overall report data “makes sense”.

The identity of personnel responsible for the performance of the sampling, test and checking of results is recorded on the Technical Review Checklist.

9.4.2 1st Level Review – a checklist standardizes the review process. The reviewer acknowledges that initializing and dating the checklist have followed each step of the review.

9.4.2.1 Results of each analysis are recorded manually into reporting format used in-house prior to final report generation. All equations for the calculation of LCS, RPD, RF and final result concentration are referenced in all method SOPs.

9.4.2.2 All data are checked for accuracy. Results are reported in the appropriate units, i.e., ppbv or % v/v.

9.4.2.3 Results that are manually entered into spreadsheet reports are verified to have been entered correctly.

9.4.2.4 Documents are reviewed for completeness.

9.4.2.5 Quality control indicators such as blanks, surrogate recoveries, duplicate analyses, laboratory control sample analyses, etc. are reviewed. For control charting of these performance indicators, see [Section 5.2.6](#). The quality control indicators must be evaluated using specific criteria described in [Section 8.0](#). If any indicator is outside the acceptance criteria, then the chemist must follow the non-conformance procedure in Section 10.

9.4.2.6 All manual integrations must be documented per the procedures of Manual Integration of Chromatographic Data SOP ATLI-GP-004 latest revision. All manual integrations must be reported in the Case Narrative of the laboratory report.

9.4.2.7 In general, checklist items include, at a minimum:

- Correct sample identification on raw data
- Correct analytical method
- Correct analyte list to report
- Matrix type and Units
- Dilution Factors
- Calculations and Significant Figures
- MDL, DLR
- Correct and complete QA/QC
- Complete Technical check
- Typographical errors

9.4.2.8 All data must be reported, per test, in a consistent unit to allow comparability of results between different laboratories.

9.4.2.9 The standard units used to report data are:

- ppmv = parts per million volume
- ppbv = parts per billion volume
- ug/L = microgram per liter of air
- ug/m³ = microgram per cubic meter of air
- ppmc = parts per million as carbon
- % v/v = amount of analyte as a percent by volume.

9.4.2.10 Data is usually reported on an “as received” basis.

9.4.3 2nd Level Review – consists of all components of the 1st level review, done by a peer analyst, or qualified designee (e.g. QA Manager or QA assistant).

9.5 FINAL REPORT & REVIEW

The results of each test or series of environmental tests carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the environmental test.

9.5.1 The final report consists of the Cover Letter and Results page(s). The components of each are described in Date Reduction, Review and Reporting SOP ATLI-GP-010 latest revision.

9.5.2 3rd Level Review - performed by a qualified designee (e.g. project manager, lab manager, QA Manager)

9.5.2.1 On 10% of the reports, the 3rd level reviewer (QA Manager) follows the same procedure as the 1st or 2nd level reviewer.

9.5.2.2 The report is reviewed against the client or project requirements (e.g. QA/QC requirements, reporting format, units, MDLs, etc.). The results reported in a final report include

all the information requested by the customer and necessary for the interpretation of the test results. The results also include all information required by the method used, or otherwise agreed to in writing.

9.5.2.3 Data consistency is reviewed such as comparing effluent sample results with influent sample results, or comparing results with historical results (if possible, usually in a routine monitoring project).

9.5.2.4 If the final report is found to be incomplete or additional errors are found, it is then returned to the department supervisors for correction.

9.5.2.5 The final report is signed for approval and is released to the client.

9.5.2.6 Copies of the final report are kept in the project/batch file, and are then archived.

9.5.2.7 Reporting uncertainty (See Determination of Uncertainty ATLI-GP-014 latest revision)

9.5.3 AMENDMENTS

9.5.3.1 If a final report has been released to a client and later found to contain errors, or requires additional documentation, a procedure for correcting, documenting, and re-submitting the report is initiated.

9.5.3.2 If the client requests the amendment, he is required to submit the request in writing.

9.5.3.3 If the laboratory discovers the need for the amendment, a written notification is sent to the client. The client in turn responds in like manner requesting that the correction be made.

9.5.3.4 The amended report is reissued including a narrative describing the reason for the amendment, noting the change that was made, referencing the original report, and uniquely identified, and meet all requirements of the international standard.

9.6 CLIENT QUESTIONS

9.6.1 When a client has a question regarding analytical report, the project manager or lab manager works with both the client and lab personnel to resolve the issues. All communications with the client are documented and included in the project file (if project-specific) or client file. Documentation can include faxes, emails, or phone logs.

9.6.2 Should the resolution require the issuing of an amended report, the steps in 9.5.3 above are followed.

9.7 DATA ARCHIVING

9.7.1 All computer data necessary for the reconstruction of analytical data and reports are backed-up on a tape or electronic media backup or recordable disk as specified in the Data Backup SOP ATLI-GP-011 latest revision.

9.7.2 Printouts of data, raw data, or reports are maintained and stored in a secure location for a minimum of 5 years or per client requirements.

10 CONTROL OF NONCONFORMING WORK

10.1 IDENTIFYING THE NON-CONFORMANCE

10.1.1 A Non-Conforming event occurs when a procedure or policy operates outside of the criteria of the Quality System (e.g. instrument malfunction, analytical QAQC criteria not being met, when a performance or system audit reveals non-compliance, sample outside of holding-time, contamination in method blank, etc.)

10.1.2 Corrective actions are defined and taken once the non-conforming event has been identified, the Technical Director or QA Manager or designee is immediately contacted and they are solely responsible and authorized to manage the non-conforming work (including halting of work and withholding of test reports, as necessary).

10.1.3 The TD or QAM along with appropriate personnel (e.g. chemist, project manager) evaluate the significance of the nonconforming work.

10.1.4 Corrective action is taken immediately along with any decision about the acceptability of the nonconforming work. Where the data quality is or may be impacted, the client is notified via email, or verbally and recorded on the client communication form.

If data quality issues are discovered during the review, the client shall be notified within fifteen (15) business days of the discovery of the issue. Records of corrections taken or proposed corrective actions to resolve the nonconformance shall be submitted to the customer(s) within thirty (30) business days of discovery.

10.1.5 The TD and QAM are solely responsible for the resumption of work.

10.1.6 Since the Quality System pervades the laboratory operation, any laboratory personnel may identify a possible non-conforming event and initiate the corrective action procedure if it is required.

10.1.7 The QAM or TD is contacted immediately. The significance of the non-conformance is evaluated. If at this point it is decided that a corrective action plan needs to be implemented, a root cause analysis is performed and a Corrective Action Report (CAR) is initiated. The use of the CAR is described in more detail in 10.4.

10.2 ROOT CAUSE ANALYSIS

10.2.1 Root cause analysis is the process by which a systematic, non-conforming event is dissected to try to determine the main cause of the non-conformance so that a proper corrective action can be devised to prevent a re-occurrence.

10.2.2 The 5 Whys technique is an iterative question-asking technique used to explore the cause-and-effect relationships underlying a particular problem. The "5" in the name derives from an empirical observation on the number of iterations typically required to resolve the problem.

10.2.2.1 For instance, if a sample is analyzed outside the holding-time, the initial answer to the 1st "why" question would be that the chemist forgot to analyze the sample. A second iteration of the question could reveal that the holding-time tracking process relies too much on the chemist's memory. A third iteration of the question might conclude that holding-times are not a

priority of the laboratory.

10.2.2.2 The results of the root cause analysis is documented on the CAR.

10.2.3 Once the root cause has been determined, the selection and implementation of an appropriate corrective action is decided. The corrective action selected would be the most likely to eliminate the problem and prevent its recurrence, and to a degree appropriate to the magnitude and risk of the problem.

10.2.3.1 For example, in the example above, the corrective action might be to create a training program to emphasize the importance of holding-times, and to also create a holding-time tracking process to eliminate the need to memorize holding-times.

10.2.4 The corrective action is documented on the CAR.

10.3 DOCUMENTING THE CORRECTIVE ACTION –THE CORRECTIVE ACTION REPORT (CAR)

10.3.1 Once the possible non-conformance has been identified, the authorized designee is contacted. A Corrective Action Report (CAR) (See Appendix J) must be initiated and submitted to the QAM, TD, or designee.

10.3.2 The CAR is to contain the incident description, samples affected, possible root cause, corrective action, and proof of conformance.

10.3.3 The person who initiated and submitted the CAR, the supervisor, and QAM verified and approved the CAR. The QAM enters the date of the non-conforming event and assigns a completion date. The CAR is a spreadsheet tracked on the company server. If applicable, a paper copy of the completed CAR is placed into the project folder.

10.3.4 The CAR is subject to QA inspections.

10.4 TRACKING THE CORRECTIVE ACTION

10.4.1 Once the CAR is initiated, it is maintained/tracked by the QA Manager on a spreadsheet. The spreadsheet allows the QA Manager the ability to review Non-Conformances by department, analyst, test methods, matrix type, etc.

10.4.2 The QAM reviews the open CARs on a monthly basis and reviews them during the lab meetings. The completion due dates are reviewed to see if they are still valid or require extension.

10.5 CLOSING THE CORRECTIVE ACTION

10.5.1 The QAM, TD, or designee is responsible for closing a corrective action.

10.5.2 A corrective action is closed when the results of the corrective action are shown to have been effective. Proof of the effective is recorded on the CAR. The QAM or designee signs the “approved” section of the form. A Follow Up Date has been added on the CAR.

10.5.3 The CARs that are outstanding must be closed by the time the next report is issued to management. If these CARs are not closed, the QA Manager must audit the problem and close the non-conformance.

10.5.4 If a corrective action does not appear to be working, another root cause analysis is performed and the correction action process begins again utilizing a new CAR.

10.6 COMPLAINTS

10.6.1 Customer complaints are handled similarly to a non-conformance event. A complaint is initiated by the customer through communication via phone, fax, or email to the laboratory project manager, lab manager, or QA manager. Initial communications is documented on the Client Communication Record (Form-25), which documents the issue(s) brought to light by the Customer through its final resolution.

10.6.2 If the complaint results in the identification of a data problem or QC non-conformance, the complaint becomes a Non-Conforming event and initiates the Corrective Action procedure in section 10.2.

10.6.3 Copies of all communication with the customer are retained in the project envelope. Email communications are stored on the server as well.

10.6.4 The QA Manager reviews client complaints on a monthly basis through email correspondence with Project Manager and Technical Director.

10.7 COMMUNICATION TO CLIENT

10.7.1 Should management decide to permit departure from documented procedures, policies, or from standard specifications, the departure is recorded on the non-conformance form and included in the quality report to management. All associated data shall be qualified and the departure shall be included in the report narrative. The customer shall be notified of the departure within 24-hours.

10.7.2 All correspondence with the client is maintained in the project file.

11 HOLDING TIMES AND PRESERVATION

The laboratory conforms to all regulations for holding times and preservations. See [Appendix G](#) for tables of holding times and preservations

12 VERIFICATION PRACTICES

12.1 INTERLABORATORY COMPARISONS

For interlaboratory performance evaluation samples, ATLI utilizes the data to evaluate the chemist compared to other chemists in the area. The results of the interlaboratory comparison are recorded onto the chemist training file. If there are “unacceptable” results, the chemist must submit a Non-Conformance Form.

12.2 PROFICIENCY TESTING PROGRAMS

ATLI participates in ongoing PT programs with PT Providers that can demonstrate compliance with ISO Guide 34:2000, ISO Guide 43:1997, and ISO/IEC 17025:2005. The laboratory's management and all analysts ensure that all PT samples are handled (i.e., managed, analyzed, and reported) in the same manner as real environmental samples utilizing the same staff, methods as used for routine analysis of that analyte, procedures, quality control, equipment, facilities, and frequency of analysis. PT samples are entered into Lab's sample receipt log (Sample tracking may be initiated by laboratory personnel). The laboratory's management and all analysts ensure that all PT samples are handled in the same manner as real environmental samples, and diluted as instructed by PT provider and becomes the environmental sample. The results of PT samples will be reported to the PT provider per their specific reporting requirements. ATLI does not send PT samples or portions of PT samples to outside laboratories for the purposes of seeking accreditation. Nor does ATLI knowingly receive PT samples from outside laboratories for the purposes of seeking accreditation. Once a PT sample is received, laboratory management or staff do not communicate with other laboratories concerning the PT samples. Nor does management or staff attempt to obtain the assigned PT value from the PT provider. All data and records that are generated concerning the PT sample are retained by the laboratory for a minimum of 5 years or per client requirements.

PT samples for each analyte-matrix-method combination are analyzed two times per year at least 6 months apart.

If PT samples are required for corrective action to reestablish history of successful PT rounds, every attempt will be made so that the analysis dates of successive corrective action PT samples are at least fifteen (15) calendar days apart. However, if PT provider may not be able to provide the corrective action sample within the timeframe, the accrediting body will be informed.

NOTE: If a PT provider cannot be found for some compounds, the internal “blind” performance evaluation samples (see Section 12.4 Internal Quality Controls) will be analyzed in its place.

12.3 REFERENCE MATERIALS - Reference materials (e.g. second source standards) can be used in the laboratory to verify results against a certified value. These reference materials are purchased from NIST certified vendors. ATLI utilizes certified reference materials to validate methods, verify instrument performance, preparation procedures, standard preparation and calibrations. All documentation of reference materials is maintained in a Primary Standard logbook. Each reference material is given a unique identification number. Certificate of analysis of purchased standards and reference materials are kept in binders in the laboratory.

12.4 INTERNAL QUALITY CONTROLS – The QA Manager may conduct internal “blind” performance evaluation samples as part of the training program. These “blind” performance evaluation samples are submitted to the analyst after the initial training has been completed and every 6 months after proficiency has been established. All results from the internal performance evaluation samples are evaluated for accuracy. The results are graded on a “PASS/FAIL” system. All analytes that “fail” must have a corrective action and a subsequent sample **will be re-submitted after a minimum of 15-days from the initial analysis.**

13 INTERNAL LABORATORY AUDITS AND APPROVALS FROM OTHER AGENCIES

13.1 AGENCY AUDITS - ATLI retains the laboratory approval through National Environmental Laboratory Accreditation Program (TNI) administered through the Louisiana Department of Environmental Quality (LDEQ), Louisiana Environmental Laboratory Accreditation Program (LELAP), and Department of Defense (DoD) Environmental Laboratory Accreditation Program (ELAP). (See [Appendix H](#) for ATLI's Certification). The NELAC Institute (TNI) and DoD ELAP perform inspections of the laboratory every 2 years. Any recorded deficiencies are corrected and a response letter is submitted to TNI and DoD ELAP. All items identified in TNI Standard, Volume 1, September 2009, DoD QSM Version 5.1 or other quality standards shall be made available for on-site inspection or data audit.

Corrective actions are developed, approved, and implemented to address findings during TNI, DoD ELAP or other regulatory agency assessments. Any changes to approved corrective action plans are approved by those same bodies as appropriate.

Willful avoidance of approved corrective action implementation may result in loss of DoD ELAP accreditation. As a result, work may be discontinued until implementation is verified by the DoD ELAP AB.

13.2 CLIENT AUDITS - Clients can audit or inspect the laboratory for conformance to EPA methods and/or specific project requirements. After the audit, a formal letter describing any findings is submitted to the laboratory. All findings will require corrective actions and evidence or proof of conformance for the response letter.

13.3 INTERNAL LABORATORY AUDITS - Internal audits are performed by the QA Manger on a yearly basis to verify that its operations continue to comply with requirements of its quality system and client/agency standards. Internal audits may be performed more frequently if the QA Manager determines a need for more frequent audits. Internal audits encompass Sample Control, Laboratory, Project Management, and Purchasing. Audit items include, but are not limited to the following: Runlogs are checked for completeness, verification of calculations, raw electronic data files derived from test reports, and for standard traceability. Balances, oven temperatures, refrigerator temperatures are being recorded, and testing activities are witnessed and verified. Standard logbooks are checked for completeness and for traceability.

13.3.1 The audit personnel is trained and qualified in the specific quality system element or technical area under review. Documentation of training can be a certificate from the training, a resume that describes applicable training. The audit personnel is independent of the activity being audited and has sufficient authority, access to work areas, and organizational freedom necessary to observe all activities affecting quality and to report the results of such assessments to laboratory management.

13.3.2 The internal audit checklist (Appendix K is a partial list) details the items to be audited. The internal audit doesn't need to be performed at one time, it could be spread across the year (to ensure that all areas of the laboratory are reviewed).

The internal audit program address all elements of the management system, including the testing/calibration activities. It is the responsibility of the quality manager to plan/organize audits as required by the schedule and requested by management.

Reviews (internal or external) of management system are maintained and available for

assessment. DoD clients will be notified within fifteen (15) business days of discovery of any investigation during internal audits that casts doubt upon the validity of test results.

13.3.2.1 Sample Control

13.3.2.1.1 The logbooks associated with sample control (i.e. pressurization logbook, internal-chain-of-custody) are reviewed for proper entries, edits, missing information.

13.3.2.1.2 The sample log-in spreadsheet is reviewed for completion.

13.3.2.1.3 Pressure gauges are checked for current calibration

13.3.2.1.4 Refrigerator temperature logbook is reviewed

13.3.2.1.5 Can cleaning logbook is reviewed

13.3.2.2 Project Management

13.3.2.2.1 A raw data package is reviewed for completeness and accuracy

13.3.2.2.2 Client requirements are reviewed to verify that they are current

13.3.2.3 GC and GCMS

13.3.2.3.1 Instrument, maintenance, and standard logbooks are reviewed for completeness

13.3.2.3.2 All standards are checked for expiration

13.3.2.4 Training files are reviewed for completeness and that they are current

13.3.2.5 LODs/LOQs/MDLs are verified that they are current

13.3.3 Purchasing – approved vendors are reviewed to either add or remove from the list. Subcontract laboratories are reviewed to make sure their information (certifications) is up-to-date.

13.3.4 If evidence of inappropriate actions or vulnerabilities related to data integrity are discovered, it will be handled in a confidential manner until such time as a follow up evaluation, full investigation, or other appropriate actions have been completed and the issues clarified. All investigations are documented in the internal audit report, and will include disciplinary action involved, corrective actions taken, and all appropriate notifications of clients. All documentation of these investigations and actions will be maintained for at least 5 years or per client requirements.

13.3.5 A form report is generated based on the findings, and is then distributed to the General Manager and the department supervisors.

13.3.6 All deficiencies found during an internal audit are written into a report. The report is then given to the General Manager and the department supervisor. The deficiencies also generate a Corrective Action Report (CAR) as described in Section 10.3. All corrections must be completed within a time-frame determined based on the significance of the finding (see checklist for the specific timeframes). For instance, if a standard is found to be expired, the completion date might be “Now”. Or if a logbook is found to have not been reviewed, it could have a completion date of one month. A follow-up inspection is performed on the outstanding findings. Findings not completed are documented in the annual Management Review.

13.3.7 Clients are notified in writing within 24-hours of a deficiency that affects their results. Documentation of the deficiency is tracked through the use of a non-conformance form.

13.3.8 It is laboratory management's responsibility to ensure that these actions are discharged within the agreed timeframe

14 QUALITY ASSURANCE REPORTS TO MANAGEMENT

14.1 Data from formal performance audits of the laboratory's activities are reviewed directly by the QA Manager, General Manager, and the department supervisors.

14.2 All quality assurance or quality control issues are discussed among the QA Manager, General Manager, and the department supervisors during the monthly QA meetings. The report can be used as a focal point for discussion involving corrective action. Any corrective action taken is decided with the concurrence of the unit department supervisors, the QA Manager, and/or Project Manager, and the General Manager.

14.3 The QA Manager provides a QA/QC management report on a monthly basis to the General Manager. The report describes any significant quality assurance problem and/or solution, results of performance and system audits, assessment of accuracy and precision data, and health and safety issues.

14.4 The laboratory management shall conduct a review, at least annually, of its quality system and its testing and calibration activities to ensure its continuing suitability and effectiveness and to introduce any necessary changes or improvements in the quality system and laboratory operations. This review will include, as a minimum:

14.4.1 A summary of all QA related reports generated since the previous review from the QA Manager, laboratory director, and department supervisors as outlined in Section 14.1-14.3.

14.4.2 A summary of all internal and external audits conducted since the previous review, their corrective actions and implementation dates.

14.4.3 A summary of all interlaboratory comparisons and proficiency tests.

14.4.4 A summary of all non-compliance reports and any implemented corrective actions.

14.4.5 A review of new methods, discontinued methods, and any significant shift in sample or test make-up

15 MANAGEMENT REVIEWS

15.1 In accordance with a predetermined procedure (SOP ATLI-QA-001 latest revision), the laboratory's executive management shall annually conduct a review of the laboratory's quality system and environmental testing activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements. The review shall take account of:

- a) The suitability of policies and procedures;
- b) Reports from managerial and supervisory personnel; outstanding corrective action issues
- c) The outcome of recent internal audits;
- d) Corrective and preventive actions;
- e) Assessments by external bodies;
- f) The results of interlaboratory comparisons or proficiency tests;
- g) Changes in the volume and type of work;
- h) Client feedback;
- i) Complaints; and
- j) Other relevant factors, such as quality control activities, resources, recommendations for improvement, and staff training.
- k) Other relevant factors, such as quality control activities, resources and staff training-per DoD QAM Sec 14.5.1 management reviews requirement.

15.2 Findings from management reviews and the actions that arise from them shall be recorded. The management shall ensure that those actions are carried out within an appropriate and agreed timescale.

15.3 If the review discovers evidence of inappropriate actions or vulnerabilities related to data integrity, discovery of potential issues shall be handled in a confidential manner until such time as a follow up evaluation, full investigation, or other appropriate actions have been completed and the issues clarified.

15.4 All investigations that result in finding of inappropriate activity shall be documented and shall include any disciplinary actions involved, corrective actions taken, and all appropriate notifications of clients. All documentation of these investigation and actions taken shall be maintained for at least ~~five years~~ 5 years or per client requirements.

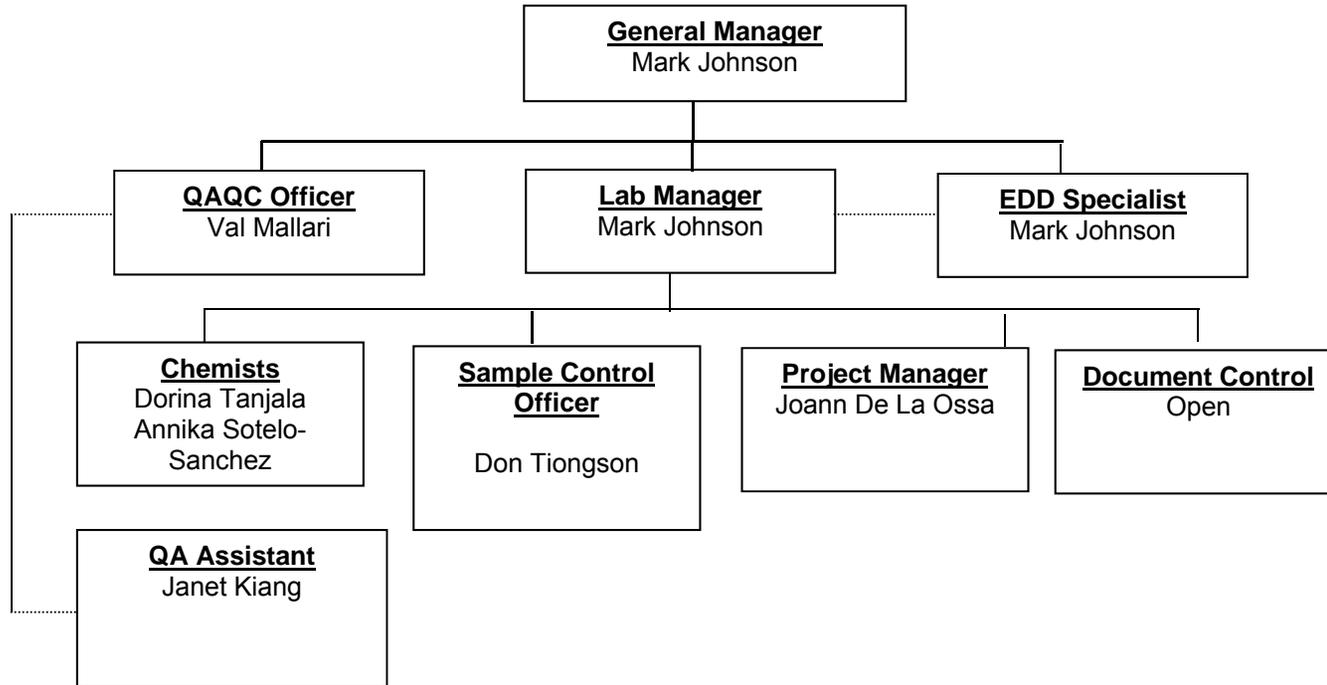
16 REFERENCES

- 16.1** USEPA, Compendium of Methods for the Determination of Toxic Organic Compounds in Ambient Air, 2nd Edition, January 1997
- 16.2** Federal Register, 40CFR Part 60, July 1, 2000, "Protection of Environment", Appendix A, Test Methods.
- 16.3** Taylor, John K., Quality Assurance of Chemical Measurements, Lewis Publishing, 1987.
- 16.4** National Environmental Laboratory Accreditation Conference, Chapter 5 "Quality Systems", Approved July 12, 2002, Effective July 1, 2004.
- 16.5** DoD Quality Systems Manual for Environmental Laboratories, Version 5.0, July 2013
- 16.6** Air Force Center for Environmental Excellence (AFCEE) Quality Assurance Project Plan (QAPP), Final Version 4.0.02, May 2006

17 REVISIONS

17.1 Revisions are highlighted in green (gray in black and white copies).

APPENDIX A
ORGANIZATIONAL CHART



APPENDIX B - Key Personnel Resumes and their deputies

<u>Key Position</u>	<u>Primary</u>	<u>Deputy</u>
Technical Director	Mark Johnson	Val Mallari
Lab Manager	Mark Johnson	Val Mallari
QA Manager	Val Mallari	Mark Johnson
Project Manager	Joann de la Ossa	Val Mallari

APPENDIX B (cont.)

Mark Johnson

General Manager/Lab Manager/EDD Specialist/Technical Director

Technical Specialties

Method development	Instrument design and troubleshooting
GC and GC/MS analysis of air samples	Technical consultant
Generating EDDs in IRPIMS, ERPIMS and NEDTS formats	Data validation to create error reports

Support managing of the Installation Restoration Program Information Management System (IRPIMS) databases and application software (IRPTool's).

Mr. Johnson is responsible for the efficient and productive daily operation of the air toxics testing laboratory. He provides technical support to clients when scheduling air testing sampling programs. He performs analyses, as well as reviews and approves laboratory results. Mr. Johnson also maintains and troubleshoots analytical instruments.

Qualifications

Mr. Johnson has over twenty seven years of experience in the environmental laboratory industry, twenty five of those years focused on the analysis of air samples. Mr. Johnson assisted in the start-up of an air laboratory in 1989 that eventually grew to become one of the industry-leaders in the analysis of air samples. His ability to maintain and design complex instrumentation allows the laboratory to function at peak capacity.

Mr. Johnson's experience includes the analysis of air samples for a wide-range of methods (EPA TO14/TO15, EPA 15/16, EPA 25C/3C, EPA TO3, ASTM D1945, ASTM D1946, Modified 8010, SIM-Mode GC/MS for trace level volatile organics, and others). He has performed analyses for a variety of complex Department of Defense projects including Air Force (AFCEE), Navy (NFESC), and Army Corp of Engineers. He is fluent in the strict QA/QC procedures required of DOD projects.

Work Experience

2001 – Present	Operations Mgr.	Air Technology, City of Industry, CA
1999 – 2000	Senior Chemist	Advanced Technology Laboratories, Industry, CA

1989 – 1999	Senior Chemist	Quanterra Environmental Services, Santa Ana, CA
1987 – 1989	Senior Chemist	C.L. Technology, Corona, CA
1982 – 1987	Gen'l Manager	Carris Candy Specialties, Inc., Riverside, CA

Education

B.S. Chemistry, University of California at Irvine

APPENDIX B (Cont.)

VAL MALLARI

QA/QC Officer/Project Manager

Technical Specialties

Method development

Trained service engineer for Varian GC and GCMS equipment

GC and GC/MS analysis of air samples

Technical consultant

Mr. Mallari is responsible for increasing the customer base for the laboratory and pursuing other markets that would increase the laboratory's analytical repertoire.

Qualifications

Mr. Mallari has nineteen years of experience in the environmental laboratory industry. He has been involved in the start-up of two laboratories and been laboratory manager for nine years and technical director and program manager for six years.

Mr. Mallari's unique combination of experience in the technical and management side of the laboratory business provides him with the necessary skills to understand the customer's needs and expectations. These skills have helped Mr. Mallari increase sales and customer base in several of the laboratories listed in his Work Experience summary.

Work Experience

2002 - 2004	Service Engineer	Varian, Inc.
2000 – 2002	Laboratory Manager	US Filter, Vernon, CA
1997 – 2000	Laboratory Manager	Advanced Technology Labs, City of Industry, CA
1993 – 1997	Laboratory Manager	Quanterra, City of Industry, CA
1991 – 1993	Technical Director	Terra Tech Labs, Santa Ana, CA
1987 – 1990	Technical Director, Program Manager	Earth Tech Labs, Huntington Beach, CA

Education

B.S. Chemistry San Diego State University

Special Training

OSHA 40 Hour Training for Hazardous Waste Activities

Varian GC and GCMS Service Engineer Training

APPENDIX B (cont.)

DORINA TANJALA

Senior Chemist

Technical Specialties

Gas Chromatography and GCMS - analyses of soil, water, and air

Ms. Tanjala is responsible for the analysis of environmental air samples and the performance and maintenance of the analytical instruments involved in the analysis. She is responsible for accurately reporting results and following all applicable QC procedures.

Qualifications:

Ms. Tanjala has been employed in the environmental laboratory industry since 1985. She has performed many complex organics analyses in the hazardous waste field such as pesticides and PCBs by EPA Method 8080, volatile organics by EPA Method 8260, TPH/BTEX by GC/FID/PID, and chlorinated and aromatic hydrocarbons by EPA Method 8010/8020.

She is proficient in the analysis of air samples for volatile organics (EPA TO14), TPH/BTEX (EPA TO3), sulfur compounds (EPA 15/16), fixed gases (ASTMD1946), and total non-methane organics in landfills (EPA 25C/3C), as well as dissolved gases in water (RSK175).

Ms. Tanjala is also knowledgeable in the QAQC requirements of NFESC/Navy projects.

Work Experience:

2004- Present	Senior Chemist	Air Technology Laboratories, Inc.
1995-2004	Senior Chemist	Advanced Technology Laboratories
1991 – 1995	Chemist	Positive Lab Service (a Smith-Emery company)
1985 – 1990	Senior Chemical Engineer	Biofarm, Bucharest, Romania
1980 – 1985	Senior Chemical Engineer	Chemical Research Institute, Bucharest, Romania

Education:

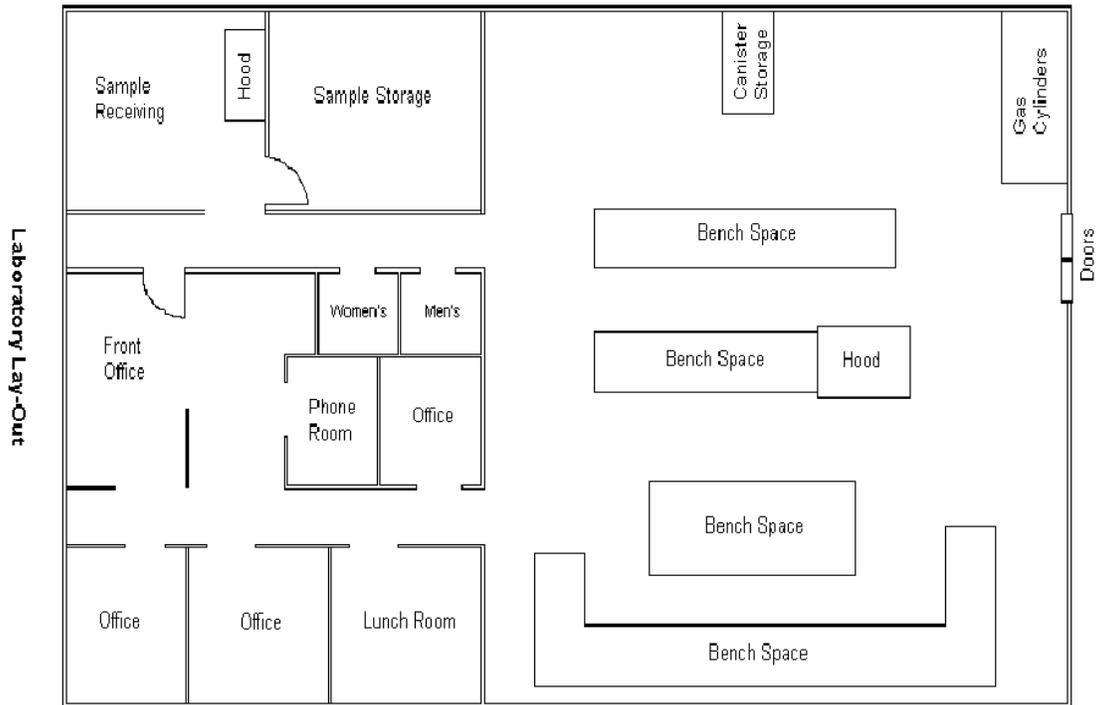
M.S. Chemical Engineering – Polytechnic Institute of Bucharest, Romania

Accomplishments:

Patent No. 69506, 12/17/1977 “Method of n-octanoyl chloride preparation” – used for herbicide synthesis.

Patent No. 65880, 1/31/1979 “Method of 3,5-dibromo-4-hydroxy-benzonitryl-preparation” – used for herbicide synthesis.

APPENDIX C: LABORATORY FLOORPLAN



APPENDIX D: LIST OF INSTRUMENTATION AND EQUIPMENT

Qty	Description	Manufacturer	Model and Serial Number (S/N)
EPA TO14/TO15, TO15-SIM - VOLATILE ORGANICS; OZONE PRECURSORS			
1	Mass Spectrometer Detector	Varian	Saturn 2000 Ion Trap
1	Gas Chromatograph	Varian	Model 3800 w/FID, sub-ambient oven
1	NIST library	--	--
1	Cold Trap Auto Sampler	Lotus Consulting	16-position automated air sampler
1	Computer	Dell	Pentium
1	Data system	Varian	Star 5.0 workstation, Stream Select Valve ver. 1.0
2	Printer	Hewlett Packard	LaserJet 2100
1	Mass Spectrometer Detector #2	Hewlett Packard	Model 5973: S/N US91422460
1	Gas Chromatograph #2	Hewlett Packard	Model 6890: S/N US00028067
1	Mass Spectrometer Detector #3	Hewlett Packard	Model 5973: S/N US33246090
1	Gas Chromatograph #3	Hewlett Packard	Model 6890: US00028414
1	NIST library	Hewlett Packard	--
1	AutoCan Auto Sampler #2	Tekmar	Auto16-position automated air sampler Model 14-ACAN-000: S/N 98170003
1	AutoCan Auto Sampler #3	Tekmar	Auto16-position automated air sampler Model 14-ACAN-000: S/N US06298006
1	Computer	Dell	Optiplex GXi

APPENDIX D: LIST OF INSTRUMENTATION AND EQUIPMENT

Qty	Description	Manufacturer	Model and Serial Number (S/N)
1	Data system	Hewlett Packard	Enviroquant Software: Version E.02.02.1431
TO3 - TVPH/BTEX, MTBE; Carbon Chain Speciation			
1	Gas Chromatograph #11	Varian	Model 3800 w/FID/PID: S/N 776
1	Auto Sampler	Lotus Consulting	16-position Automated Sampler
1	Computer	Dell	Optiplex GX 280
1	Data system	Varian	Star workstation Version 6.30: S/N 01147-7588-C69-24B1, Stream Select Valve, ver. 1.0
EPA 15/16 – Volatile Sulfur Compounds/Screening			
1	Gas Chromatograph #9 Screening	Varian	Model 3400 w/dual flame FPD, FID: S/N 3400-0571
1	Computer	Dell	Pentium
1	Data System	Hewlett Packard	Chem Station G1701AA, Version A.03.00
1	Gas Chromatograph #3	Varian	Model 3800 w/PFPD: S/N 3554
1	Computer	Hewlett Packard	Kayak XU
1	Data System	Varian	Star Workstation Version 6.30: S/N 01147-7588-C69-24B1
EPA 25C- TOTAL NON-METHANE ORGANIC COMPOUNDS			
EPA 3C & ASTM D1946 - FIXED GASES			
RSKSOP 175- Dissolved Gases			
1	Gas Chromatograph #8	Varian	Model 3800 w/FID/TCD: S/N 775
1	Auto Sampler	Lotus Consulting	32-position Automated

APPENDIX D: LIST OF INSTRUMENTATION AND EQUIPMENT

Qty	Description	Manufacturer	Model and Serial Number (S/N)
			Sampler
1	Computer	Dell	Optiplex GX 280
1	Data system	Varian	Star Workstation Version 6.30: S/N 01147-7588-C69-24B1,
Sampling & Field Equipment			
200	Stainless Steel Canisters	Restek	SilcoCan 6 liter
350	Stainless Steel Canisters	Restek	TO 6 liter
200	Stainless Steel Canisters	Restek	TO 1-liter
15	Stainless Steel Canisters	Scientific Instrumentation Specialists	6 liter
175	Flow Controllers	Restek	--
As needed	Tedlar Bags	SKC	1liter to 10 liter, polypropylene fitting
2	Canister cleaning manifolds	Proprietary	10 positions each (expandable)
Miscellaneous Equipment			
2	Fume Hoods	Hansen Lab Equipment	Custom built
2	Refrigerators	Kenmore	Coldspot
1	Copier	Minolta	Model 5050
1	Fax Machine	Canon	MultiPass L6000
2	Printers	Canon, Brother	
3	Computers	Dell, Toshiba	

Appendix F - Method Detection Limits

Please refer to the MDL file for the latest MDL study for a given method/instrument.

APPENDIX G

*HOLDING TIMES AND PRESERVATION

Sampling Media	Methods	Hold-Time	Preservation
Summa Canister	Volatile Organics, Fixed Gases	30-days	Room Temperature
Silco Canister	Volatile Organics Fixed Gases	30-days	Room Temperature
	Sulfur Compounds	7-days	
Tedlar Bags	Volatile Organics, Fixed Gases, Sulfur Compounds by EPA 15/16	3-days unless otherwise specified	Room Temperature Away from direct sunlight
	Sulfur Compounds by ASTM D5504 and SCAQMD 307-91	24-hours	
Water	Dissolved gases	14 days w/preservation 14 days w/o preservation (for detection of CO2)	HCl

* Unless otherwise specified in project-specific requirements

APPENDIX H

Summary of Methods and Certifications

Method	Description	Certification
EPA TO14A and TO15 (SIM and Scan)	Volatile Organics in Air	TNI, DoD ELAP
EPA TO3	TVPH as Gasoline, BTEX, MTBE	TNI, DoD ELAP
EPA 25C/3C	TGNMO as carbon and fixed gases	TNI
ASTM D1946	Fixed gases	TNI, DoD ELAP
ASTM D1945	Natural Gas analysis	
RSK175	Dissolved gases in water	TNI
CARB 410A	Benzene	
EPA 15/16	Hydrogen sulfide and sulfur compounds	
SCAQMD 25.1	TGNMHC as methane	
APH	Air Petroleum Hydrocarbons	

APPENDIX I

Subcontractor Information Form

Company Name:
Contact Name:
Address:
City, State, Zip:
Phone No.:
Fax No.:
Contact E-Mail address:

Certifications/Accreditations/Licenses:

Authorizing Agency	Certificate#	Expiration Date:	Fields of Testing

I attest that the above information is accurate and current as of the signature date below:

Print Name: _____ Date: _____

Signature: _____

Title: _____

APPENDIX J

Corrective Action Report

CORRECTIVE ACTION REPORT

CAR#	4021
Date Submitted	
Submitted by	
Date of Incident	
Test	
Corrective Action Due Date	
Date Closed	
Closed By	
Follow-up Date	
Verified by	
Verified Date	
QA AFFECTED	
Other (describe)	
INCIDENT DESCRIPTION	
BATCH #(S) AFFECTED	
SAMPLE(S) AFFECTED	
ROOT CAUSE ANALYSIS	
CORRECTIVE ACTION	
Reviewed by	
Reviewed by date	
Approved by	
Approved by date	

APPENDIX K

Partial Internal Audit Checklist

Internal Audit:
 Auditor(s)
 Audit: dkt(6)

Clause #	Requirements	Document References	Verified by/Date	Corrective Action	Corrective Action Date	Completion Date	Follow-up date to verify effectiveness of corrective action
ISO/IEC 17025 TNI: 2009 DoD-QSM 7.0							
2.1	Initial Accreditation To obtain initial accreditation for Department of Defense Environmental Laboratory Accreditation Program (DoD ELAP), has the laboratory analyzed at least two Proficiency Testing (PT) samples for each combination of analyte-matrix-method that corresponds to their scope of accreditation? Note: Laboratories that combine multiple methods into one Standard Operating Procedure (SOP) (e.g., SOP that combines Method 604 and Method 606) can report those methods with a single PT sample. All other analyte-matrix-method combinations require separate PT samples.						
DoD 2.1.1	Have the PT samples used for initial accreditation been obtained from PT providers that are accredited under International Organization for Standardization (ISO) 17043 (General Requirements for Proficiency Testing) from an International Laboratory Accreditation Council (ILAC) approved signatory Accreditation Body?						
DoD 2.1.2	Have laboratories seeking DoD ELAP accreditation obtained PT samples from the Micro Analyte Performance Evaluation Program (MAPEP)? Note: MAPEP is required for all laboratories that possess a radioactive materials license for analysis of radiological samples. When PT samples cannot be obtained from an ISO 17043 accredited PT provider, has the laboratory obtained permission to use non-ISO 17043 PT providers from their Accreditation Body prior to analyzing the PT sample?						
DoD 2.1.3	Note: The requirements and criteria from the PT provider must be met by the laboratory for the PT sample to be considered successful. When PT samples for an analyte-matrix-method combination cannot be obtained from any PT provider and the analyte-matrix-method combination is required for a scope of accreditation, has the laboratory submitted this fact in writing to the DoD ELAP Accreditation Body?						
DoD 2.1.4	Are other measures (e.g., precision, bias, and selectivity) as outlined in the appropriate 2009 TNI Standard Test Modules performed to satisfy the PT requirement until those PT samples are available? Are the PT samples analyzed by the laboratory for initial DoD ELAP accreditation shall be no more than twelve (12) months old. The analysis date between PT samples shall be at least fifteen (15) calendar days apart if two or more successive PT samples are performed?						
DoD 2.1.5	Do laboratories that participate in the MAPEP program follow the MAPEP program requirements?						
DoD 2.1.6	Is the success or failure of any analyte-matrix-method combinations for a PT study determined by the PT provider under the requirements of the governing regulatory or ISO 17043: statistically derived programs?						
DoD 2.1.7	Are the PT samples evaluated the same as regular environmental samples?						
DoD 2.1.7	Does the laboratory employ the same quality control, sequence of analytical steps, and replicates as used when analyzing routine samples?						

APPENDIX K

Partial Internal Audit Checklist

Internal Audit Auditor(s) Audit date(s)	Clause #	Requirements	Document References	Verified by/Date	Corrective Action	Corrective Action Due Date	Completion Date	Follow-up date to verify effectiveness of corrective action
	ISO/IEC 17025 TNI 2009 DSD-QSM-5.0							
	4.1.1	Is the laboratory/parent organization an entity that can be held legally responsible?						
	4.1.2	Is the laboratory carrying out testing/calibration activities to meet the requirements of the International Standard and satisfying the needs of customers, regulatory authorities, or organizations providing recognition?						
	4.1.3	Does the laboratory management system cover work carried out in the laboratory's permanent facilities, at sites away from its permanent facilities, or in associated temporary/mobile facilities? Please indicate which apply. If the laboratory is part of an organization performing activities other than testing or calibration, are the responsibilities of key personnel in the organization that have an involvement or influence on testing or calibration activities defined in order to identify potential conflicts of interest?						
	4.1.4	NOTE: When the lab is part of a larger organization, organizational arrangements should be such that departmental having conflicting interests (such as production, commercial marketing, or financing) do not adversely influence the lab's compliance with the requirements of the International Standard. NOTE: If the lab desires to be recognized as a third-party lab, it should be able to demonstrate that it is impartial and that it and its personnel are free from any undue commercial, financial, and other pressures, which might influence their technical judgment. The third-party testing or calibration lab should not engage in any activities that may endanger trust in its independence of judgment and integrity in relation to its testing or calibration activities.						
	4.1.5.a	Does the laboratory have managerial and technical personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including the implementation, maintenance, and improvement of the management system, and to identify the occurrence of departures from the management system or from the procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimize such departures (see also 5.2)?						
	4.1.5.b	Does the laboratory have arrangements to ensure management and personnel are free from any undue internal/external commercial, financial and other pressures and influences that may adversely affect the quality of their work?						
	4.1.5.c	Does the laboratory have policies and procedures to ensure protection of customers' confidential information and proprietary rights, including procedures for protecting electronic storage and transmission of results?						
	4.1.5.d	Does the laboratory have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment, or operational integrity?						
	4.1.5.e	Does the laboratory define the organization and management structure of the laboratory, its place in any parent organization, and relationships among quality management, technical operations, and support services?						
	4.1.5.f	Does the laboratory specify the responsibility, authority, and interrelationships of all personnel who manage, perform, or verify work affecting the quality of tests/calibrations?						
	4.1.5.g	Does the laboratory provide adequate supervision of testing and calibration staff, including training, by personnel familiar with methods and procedures, the purpose of each test and/or calibration, and with the assessment of the test or calibration result?						

APPENDIX L (APPLIES TO DOD ONLY)

Table B-21. GC/MS Analysis of Air Samples					
QC Check	Minimum Frequency	Acceptance Criteria	Corrective Action	Flagging Criteria	Comments
Canister Cleanliness Check	Each canister prior to shipment.	No reported analytes detected > ½ LOQ.	Correct problem, then repeat cleaning of canister and recertify.	Flagging is not appropriate.	Applicable only when laboratory supplies sampling canisters to client.
Tune Check	Prior to ICAL and prior to each 24-hour period of sample analysis.	Specific ion abundance criteria of BFB from method.	Retune instrument and verify.	Flagging is not appropriate.	No samples shall be analyzed without a valid tune.
Initial Calibration (ICAL) for all analytes	At instrument set-up, prior to sample analysis.	Calculated %RSD for the RRF of each target analyte in the calibration must be less than 30%; or Linear least squares regression for each analyte: $r^2 \geq 0.99$; or Non-linear least squares regression (quadratic) for each analyte: $r^2 \geq 0.99$.	Correct problem, then repeat ICAL.	Flagging is not appropriate.	Minimum 5 levels for linear and 6 levels for quadratic with one calibration point at the same concentration as the daily CCV. The lowest calibration standard concentration at or below the LOQ. No samples shall be analyzed until ICAL has passed.

APPENDIX L (APPLIES TO DOD ONLY)

Table B-21. GC/MS Analysis of Air Samples

QC Check	Minimum Frequency	Acceptance Criteria	Corrective Action	Flagging Criteria	Comments
Retention Time window position establishment	Once per ICAL and at the beginning of the analytical sequence.	Position shall be set using the midpoint standard of the ICAL curve when ICAL is performed. On days when ICAL is not performed, the initial CCV is used.	NA.	NA.	Calculated for each analyte.
Evaluation of Relative Retention Times (RRT)	With each sample.	RRT of each reported analyte within ± 0.06 RRT units of the mean RRT of the calibration standards. RRTs may be updated based on the daily CCV.	Correct problem, then rerun ICAL.	NA.	RRTs shall be compared with the most recently updated RRTs. After maintenance is performed which may affect retention times, RRTs may be updated based on the daily CCV.
Initial Calibration Verification (ICV)	Once after each ICAL, analysis of a second source standard prior to sample analysis.	All reported analytes within $\pm 30\%$ of true value.	Correct problem. Rerun ICV. If that fails, repeat ICAL.	Flagging is not appropriate.	No samples shall be analyzed until calibration has been verified with a second source.

APPENDIX L (APPLIES TO DOD ONLY)

Table B-21. GC/MS Analysis of Air Samples					
QC Check	Minimum Frequency	Acceptance Criteria	Corrective Action	Flagging Criteria	Comments
Continuing Calibration Verification (CCV)	Daily before sample analysis; after every 24 hours of analysis time; and at the end of the analytical batch run.	Concentration the same as the mid-point calibration standard (or lower). All reported analytes within $\pm 30\%$ of true value.	<p>Immediately analyze two additional consecutive CCVs. If both pass, samples may be reported without reanalysis.</p> <p>If either fails or if two consecutive CCVs cannot be run, perform corrective action(s) until a passing CCV is attained, and then reanalyze all associated samples since last acceptable CCV.</p> <p>Alternatively, perform an ICAL (including appropriate instrument QC) if necessary; then reanalyze all associated samples since the last acceptable CCV.</p>	If reanalysis cannot be performed, data must be qualified and explained in the Case Narrative. Apply Q-flag to all results for the specific analyte(s) in all samples since last acceptable calibration verification.	<p>Results may not be reported without valid CCVs. Flagging is only appropriate in cases where the samples cannot be reanalyzed.</p> <p>If the specific version of a method requires additional evaluation (e.g., average RFs), these additional requirements must also be met.</p>

APPENDIX L (APPLIES TO DOD ONLY)

Table B-21. GC/MS Analysis of Air Samples					
QC Check	Minimum Frequency	Acceptance Criteria	Corrective Action	Flagging Criteria	Comments
Internal Standards (IS)	Every field sample, standards, blanks, and QC sample.	<p><u>ICAL Standards</u></p> <p>The area response for each internal standard must be within 40% of the mean area response of the calibration standards for each internal standard.</p> <p>The retention time shift for each internal standard at each calibration level must be within 20 seconds of the mean retention time of the calibration standards for each internal standard.</p> <p><u>Field Samples, Blanks & QC</u></p> <p>RT of each IS must be within +/-0.33 minutes of the most recent initial calibration.</p>	<p>Inspect mass spectrometer and GC for malfunctions and correct problem.</p> <p>Reanalysis of samples analyzed while system was malfunctioning is mandatory.</p>	<p>If corrective action fails in field samples, data must be qualified and explained in the Case Narrative.</p> <p>Apply Q-flag to analytes associated with the non-compliant IS.</p> <p>Flagging is not appropriate for failed standards.</p>	Must include at a minimum bromochloromethane, Chlorobenzene-d5, and 1, 4-difluorobenzene.

APPENDIX L (APPLIES TO DOD ONLY)

Table B-21. GC/MS Analysis of Air Samples					
QC Check	Minimum Frequency	Acceptance Criteria	Corrective Action	Flagging Criteria	Comments
Method Blank (MB)	One per analytical batch (after the first CCV), prior to analysis of any field samples.	No analytes detected > ½ LOQ or > 1/10 th the amount measured in any sample or 1/10 th the regulatory limit, whichever is greater. Common contaminants must not be detected > LOQ.	Conduct investigation to determine the source of the contamination and take appropriate corrective actions. Rerun MB and all associated samples. If required, reprep and reanalyze MB and all QC samples and field samples processed with the contaminated blank.	If reanalysis cannot be performed, data must be qualified and explained in the Case Narrative. Apply B-flag to all results for the specific analyte(s) in all samples in the associated analytical batch. Flagging is only appropriate in cases where the samples cannot be reanalyzed.	The MB is a certified clean canister of the same type as the sample that has not left the laboratory. The blank has been pressurized with humidified zero air and carried through the same analytical procedures as a field sample. Results may not be reported without a valid MB. If a TIC search is required for any samples, then a TIC search is also required for the associated Method Blank.

APPENDIX L (APPLIES TO DOD ONLY)

Table B-21. GC/MS Analysis of Air Samples					
QC Check	Minimum Frequency	Acceptance Criteria	Corrective Action	Flagging Criteria	Comments
Laboratory Control Sample (LCS)/ LCS Replicate	One pair per analytical batch.	<p>One canister standard is analyzed two times in the analytical run.</p> <p>A laboratory must use the QSM Appendix C Limits for batch control if project specific limits are not specified.</p> <p>If the analyte(s) are not listed, use in-house LCS limits if project limits are not specified.</p> <p>RPD between the LCS and LCS Replicate for each target analyte must be < 30%.</p>	Correct problem, and then reanalyze the LCS and all samples in the associated analytical batch for failed analytes if sufficient sample material is available.	If reanalysis cannot be performed, data must be qualified and explained in the Case Narrative. Apply Q-flag to specific analyte(s) in all samples in the associated analytical batch.	<p>Must contain all analytes to be reported.</p> <p>Results may not be reported without a valid LCS. Flagging is only appropriate in cases where the samples cannot be reanalyzed.</p> <p>If the daily CCV is prepared in a canister, then the initial and closing CCVs can serve as the LCS and LCS Replicate as well. Both the CCV and LCS acceptance criteria would apply.</p>

APPENDIX L (APPLIES TO DOD ONLY)

Table B-1. Organic Analysis by Gas Chromatography (GC)					
QC Check	Minimum Frequency	Acceptance Criteria	Corrective Action	Flagging Criteria	Comments
Breakdown check (Endrin/DDT Method 8081 only)	Before sample analysis and at the beginning of each 12-hour shift.	Degradation of DDT and Endrin must each be \leq 15%.	Correct problem, then repeat breakdown checks.	Flagging is not appropriate.	No samples shall be run until degradation of DDT and Endrin is each \leq 15%.
Initial Calibration (ICAL) for all analytes (including surrogates)	At instrument set-up and after ICV or CCV failure, prior to sample analysis.	ICAL must meet one of the three options below: Option 1: RSD for each analyte \leq 20%; Option 2: linear least squares regression for each analyte: $r^2 \geq 0.99$; Option 3: non-linear least squares regression (quadratic) for each analyte: $r^2 \geq 0.99$.	Correct problem then repeat ICAL.	Flagging is not appropriate.	Minimum 5 levels for linear and 6 levels for quadratic. Quantitation for multicomponent analytes such as chlordane, toxaphene, and Aroclors must be performed using a 5-point calibration. Results may not be quantitated using a single point. No samples shall be analyzed until ICAL has passed.

APPENDIX L (APPLIES TO DOD ONLY)

Table B-1. Organic Analysis by Gas Chromatography (GC)					
QC Check	Minimum Frequency	Acceptance Criteria	Corrective Action	Flagging Criteria	Comments
Retention Time window position establishment	Once per ICAL and at the beginning of the analytical sequence.	Position shall be set using the midpoint standard of the ICAL curve when ICAL is performed. On days when ICAL is not performed, the initial CCV is used.	NA.	NA.	Calculated for each analyte and surrogate.
Retention Time (RT) window width	At method set-up and after major maintenance (e.g., column change).	RT width is ± 3 times standard deviation for each analyte RT from the 72-hour study or 0.03 minutes, whichever is greater.	NA.	NA.	Calculated for each analyte and surrogate. Only applicable if internal standard calibration is not used.
Initial Calibration Verification (ICV)	Once after each ICAL, analysis of a second source standard prior to sample analysis.	All reported analytes within established RT windows. All reported analytes within $\pm 20\%$ of true value.	Correct problem, rerun ICV. If that fails, repeat ICAL.	Flagging is not appropriate.	No samples shall be analyzed until calibration has been verified with a second source.

APPENDIX L (APPLIES TO DOD ONLY)

Table B-1. Organic Analysis by Gas Chromatography (GC)					
QC Check	Minimum Frequency	Acceptance Criteria	Corrective Action	Flagging Criteria	Comments
Continuing Calibration Verification (CCV)	Before sample analysis, after every 10 field samples, and at the end of the analysis sequence with the exception of CCVs for Pesticide multi-component analytes (i.e., Toxaphene, Chlordane and Aroclors other than 1016 and 1260), which are only required before sample analysis.	All reported analytes and surrogates within established RT windows. All reported analytes and surrogates within $\pm 20\%$ of true value.	Immediately analyze two additional consecutive CCVs. If both pass, samples may be reported without reanalysis. If either fails, or if two consecutive CCVs cannot be run, perform corrective action(s) and repeat CCV and all associated samples since last successful CCV. Alternately, recalibrate if necessary; then reanalyze all associated samples since the last acceptable CCV.	If reanalysis cannot be performed, data must be qualified and explained in the Case Narrative. Apply Q-flag to all results for the specific analyte(s) in all samples since the last acceptable calibration verification.	Results may not be reported without valid CCVs. Flagging is only appropriate in cases where the samples cannot be reanalyzed.
Internal Standards (IS)	If employed, every field sample, standard, and QC sample.	Retention time within ± 0.06 RRT UNITS from retention time of the midpoint standard in the ICAL; Internal standard signal (area or height) within -50% to $+100\%$ of ICAL midpoint standard. On days when ICAL is not performed, the daily initial CCV can be used.	Inspect GC for malfunctions and correct problem. Reanalysis of samples analyzed while system was malfunctioning is mandatory.	If corrective action fails in field samples, data must be qualified and explained in the Case Narrative. Apply Q-flag to analytes associated with the non-compliant IS. Flagging is not appropriate for failed standards.	NA.

APPENDIX L (APPLIES TO DOD ONLY)

Table B-1. Organic Analysis by Gas Chromatography (GC)					
QC Check	Minimum Frequency	Acceptance Criteria	Corrective Action	Flagging Criteria	Comments
Method Blank (MB)	One per preparatory batch.	No analytes detected > 1/2 LOQ or > 1/10th the amount measured in any sample or 1/10th the regulatory limit, whichever is greater.	Correct problem. If required, reprep and reanalyze MB and all QC samples and field samples processed with the contaminated blank.	If reanalysis cannot be performed, data must be qualified and explained in the Case Narrative. Apply B-flag to all results for the specific analyte(s) in all samples in the associated preparatory batch.	Results may not be reported without a valid Method Blank. Flagging is only appropriate in cases where the samples cannot be reanalyzed.
Laboratory Control Sample (LCS)	One per preparatory batch.	A laboratory must use the QSM Appendix C Limits for batch control if project limits are not specified. If the analyte(s) are not listed, use in-house LCS limits if project limits are not specified.	Correct problem, then reprep and reanalyze the LCS and all samples in the associated preparatory batch for failed analytes if sufficient sample material is available.	If reanalysis cannot be performed, data must be qualified and explained in the Case Narrative. Apply Q-flag to specific analyte(s) in all samples in the associated preparatory batch.	Results may not be reported without a valid LCS. Flagging is only appropriate in cases where the samples cannot be reanalyzed.
Matrix Spike (MS)	One per preparatory batch.	A laboratory must use the QSM Appendix C Limits for batch control if project limits are not specified. If the analyte(s) are not listed, use in-house LCS limits if project limits are not specified.	Examine the project-specific requirements. Contact the client as to additional measures to be taken.	For the specific analyte(s) in the parent sample, apply J-flag if acceptance criteria are not met and explain in the Case Narrative.	For matrix evaluation only. If MS results are outside the limits, the data shall be evaluated to determine the source(s) of difference (i.e., matrix effect or analytical error).

APPENDIX L (APPLIES TO DOD ONLY)

Table B-1. Organic Analysis by Gas Chromatography (GC)					
QC Check	Minimum Frequency	Acceptance Criteria	Corrective Action	Flagging Criteria	Comments
Matrix Spike Duplicate (MSD) or Matrix Duplicate (MD)	One per preparatory batch.	<p>A laboratory must use the QSM Appendix C Limits for batch control if project limits are not specified.</p> <p>If the analyte(s) are not listed, use in-house LCS limits if project limits are not specified.</p> <p>RPD \leq 30% (between MS and MSD or sample and MD).</p>	<p>Examine the project-specific requirements. Contact the client as to additional measures to be taken.</p>	<p>For the specific analyte(s) in the parent sample, apply J-flag if acceptance criteria are not met and explain in the Case Narrative.</p>	<p>The data shall be evaluated to determine the source of difference.</p> <p>For Sample/MD: RPD criteria only apply to analytes whose concentration in the sample is greater than or equal to the LOQ.</p>
Surrogate Spike	All field and QC samples.	<p>QC acceptance criteria specified by the project if available; otherwise use QSM Appendix C limits or in-house LCS limits if analyte(s) are not listed.</p>	<p>Correct problem, then reprep and reanalyze all failed samples for all surrogates in the associated preparatory batch if sufficient sample material is available.</p> <p>If obvious chromatographic interference is present, reanalysis may not be necessary, but the client must be notified prior to reporting data, and the failures must be discussed in the Case Narrative.</p>	<p>Apply Q-flag to all associated analytes if acceptance criteria are not met and explain in the Case Narrative.</p>	<p>Alternative surrogates are recommended when there is obvious chromatographic interference.</p>

APPENDIX L (APPLIES TO DOD ONLY)

Table B-1. Organic Analysis by Gas Chromatography (GC)					
QC Check	Minimum Frequency	Acceptance Criteria	Corrective Action	Flagging Criteria	Comments
Confirmation of positive results (second column)	All results > the DL must be confirmed (except for single column methods such as TPH by Method 8015 where confirmation is not an option or a requirement).	Calibration and QC criteria for second column are the same as for initial or primary column analysis. Results between primary and secondary column RPD ≤ 40%.	NA.	Apply J-flag if RPD > 40%. Discuss in the Case Narrative.	Use project-specific reporting requirements if available; otherwise, use method requirements if available; otherwise report the result from the primary column.

APPENDIX M (APPLIES TO DOD ONLY)

Table C-42. Method RSK-175 Water Matrix

CAS ID	Analyte	N Records	Mean	Standard Deviation	Lower Control Limit	Upper Control Limit
74-86-2	Acetylene	719	99.6	9.8	70	129
106-97-8	Butane	262	97.3	7.3	75	119
124-38-9	Carbon dioxide	441	100.8	6.9	80	122
74-84-0	Ethane	2240	102.6	9.6	74	131
74-85-1	Ethylene	2284	102.5	10.2	72	133
75-28-5	Isobutane	267	97.6	6.6	78	117
74-82-8	Methane	2459	99.2	8.7	73	125
74-98-6	Propane	900	98.1	8.2	74	123

Table C-43. Method TO-15 Gas Matrix

CAS ID	Analyte	N Records	Mean	Standard Deviation	Lower Control Limit	Upper Control Limit
630-20-6	1,1,1,2-Tetrachloroethane	1344	97.9	10.5	67	129
71-55-6	1,1,1-Trichloroethane	5436	96.7	9.5	68	125
79-34-5	1,1,2,2-Tetrachloroethane	5273	95.9	10.4	65	127
79-00-5	1,1,2-Trichloroethane	5332	95.9	7.7	73	119
76-13-1	1,1,2-Trifluoro-1,2,2-trichloroethane [Freon-113]	5351	96.1	10	66	126
75-34-3	1,1-Dichloroethane	5422	97	9.7	68	126
75-35-4	1,1-Dichloroethene	3503	97.3	11.9	61	133
96-18-4	1,2,3-Trichloropropane	465	99.6	8	76	124
120-82-1	1,2,4-Trichlorobenzene	4545	98.5	14.5	55	142
95-63-6	1,2,4-Trimethylbenzene	4699	99.2	11.1	66	132
106-93-4	1,2-Dibromoethane	4655	98.2	7.9	74	122
76-14-2	1,2-Dichloro-1,1,2,2-	4572	92.4	9.7	63	121

APPENDIX M (APPLIES TO DOD ONLY)

Table C-43. Method TO-15 Gas Matrix						
CAS ID	Analyte	N Records	Mean	Standard Deviation	Lower Control Limit	Upper Control Limit
	tetrafluoroethane					
95-50-1	1,2-Dichlorobenzene	4739	95.7	11	63	129
107-06-2	1,2-Dichloroethane	5467	96.8	10.5	65	128
78-87-5	1,2-Dichloropropane	4729	95.7	8.9	69	123
108-67-8	1,3,5-Trimethylbenzene	4679	98.3	10.4	67	130
106-99-0	1,3-Butadiene	3167	99.8	11.4	66	134
541-73-1	1,3-Dichlorobenzene	4737	97.1	10.9	65	130
142-28-9	1,3-Dichloropropane	165	105.2	14.4	62	148
542-75-6	1,3-Dichloropropene	560	100.7	8.1	77	125
106-46-7	1,4-Dichlorobenzene	4719	95.8	11.8	60	131
123-91-1	1,4-Dioxane	2656	96.5	8.6	71	122
540-84-1	2,2,4-Trimethylpentane [Isooctane]	3008	94.3	8.8	68	121
78-93-3	2-Butanone [MEK]	4635	98.4	10.4	67	130
95-49-8	2-Chlorotoluene	1092	101.9	9.2	74	130
591-78-6	2-Hexanone	4600	95.4	11	62	128
67-63-0	2-Propanol [Isopropyl alcohol]	3069	88.4	12.3	52	125
622-96-8	4-Ethyltoluene	4673	97.9	10.3	67	129
108-10-1	4-Methyl-2-pentanone [MIBK]	4646	98.5	10.5	67	130
67-64-1	Acetone	4600	92.7	11.6	58	128
75-05-8	Acetonitrile	1999	97.3	11.6	63	132
107-02-8	Acrolein [Propenal]	2469	93.8	10.6	62	126
107-13-1	Acrylonitrile	2105	103.7	10.9	71	137
107-05-1	Allyl chloride	2980	101.1	10.1	71	131
98-83-9	alpha-Methylstyrene	1976	97.3	10.2	67	128
71-43-2	Benzene	5436	93.8	8.4	69	119
100-44-7	Benzyl chloride	4419	98.7	16.2	50	147
75-27-4	Bromodichloromethane	4682	99.9	9.3	72	128
75-25-2	Bromoform	4638	102.3	12.1	66	139
74-83-9	Bromomethane	2657	98.6	11.8	63	134
106-97-8	Butane	587	96.2	10.9	64	129
75-15-0	Carbon disulfide	4756	95.6	12.7	57	134
56-23-5	Carbon tetrachloride	4202	99.6	10.7	68	132

APPENDIX M (APPLIES TO DOD ONLY)

Table C-43. Method TO-15 Gas Matrix						
CAS ID	Analyte	N Records	Mean	Standard Deviation	Lower Control Limit	Upper Control Limit
108-90-7	Chlorobenzene	4652	94.5	8	70	119
124-48-1	Chlorodibromomethane	4628	99.9	10	70	130
75-45-6	Chlorodifluoromethane	559	102.1	14.3	59	145
75-00-3	Chloroethane	5370	94.7	10.6	63	127
67-66-3	Chloroform	5481	95.3	9.3	68	123
74-87-3	Chloromethane	4540	95.2	12.2	59	132
156-59-2	cis-1,2-Dichloroethene	5320	95.6	8.4	70	121
10061-01-5	cis-1,3-Dichloropropene	4691	98.8	9.7	70	128
110-82-7	Cyclohexane	3178	93.5	7.7	70	117
124-18-5	Decane	1982	93.8	7.9	70	118
75-71-8	Dichlorodifluoromethane [Freon-12]	5307	93.6	11.5	59	128
108-20-3	Diisopropyl ether	2309	93.5	8	70	117
64-17-5	Ethanol	2981	91.8	11.1	59	125
141-78-6	Ethyl acetate	2835	96.4	10.5	65	128
100-41-4	Ethylbenzene	5420	96.8	9	70	124
142-82-5	Heptane	3163	95.7	8.9	69	123
87-68-3	Hexachlorobutadiene	4551	96.7	13.7	56	138
110-54-3	Hexane	3150	91.6	9.5	63	120
98-82-8	Isopropylbenzene	3022	95.6	9.3	68	124
179601-23-1	m/p-Xylene [3/4-Xylene]	5019	97.3	12.3	61	134
80-62-6	Methyl methacrylate	3037	98.9	9.7	70	128
1634-04-4	Methyl tert-butyl ether [MTBE]	4681	95.5	10	66	126
75-09-2	Methylene chloride	5314	88.8	8.9	62	115
71-36-3	n-Butyl alcohol	1981	97.5	11.7	62	133
104-51-8	n-Butylbenzene	2656	97.7	10.6	66	130
112-40-3	n-DoDecane	1932	104.4	14.1	62	147
103-65-1	n-Propylbenzene	2570	95.7	9	69	123
91-20-3	Naphthalene	2439	97.5	13.4	57	138
111-84-2	Nonane	2617	95.4	10.8	63	128
95-47-6	o-Xylene	5334	96.3	9.7	67	125
111-65-9	Octane	2514	95	8.7	69	121
Table C-43. Method TO-15 Gas Matrix						

CAS ID	Analyte	N Records	Mean	Standard Deviation	Lower Control Limit	Upper Control Limit
99-87-6	p-Isopropyltoluene [p-Cymene]	2694	98.1	10.5	67	130
109-66-0	Pentane	712	96.7	11.3	63	131
115-07-1	Propene	3193	96.6	13.3	57	136
135-98-8	sec-Butylbenzene	2665	96.4	9.6	68	125
100-42-5	Styrene	4735	100.1	9	73	127
75-65-0	tert-Butyl alcohol	2997	86.8	20.9	24	150
98-06-6	tert-Butylbenzene	2710	94.3	9.8	65	124
127-18-4	Tetrachloroethene	5432	95.2	9.7	66	124
109-99-9	Tetrahydrofuran	3192	93.7	9.8	64	123
108-88-3	Toluene	5406	92.7	8.8	66	119
156-60-5	trans-1,2-Dichloroethene	5411	95.5	9.5	67	124
10061-02-6	trans-1,3-Dichloropropene	4621	104	9.6	75	133
79-01-6	Trichloroethene	5478	96.7	8.7	71	123
75-69-4	Trichlorofluoromethane [Freon-11]	5376	93.7	10.6	62	126
1120-21-4	Undecane	1976	96.1	9	69	123
108-05-4	Vinyl acetate	4599	97.4	13.7	56	139
593-60-2	Vinyl bromide	1054	98.4	9.2	71	126
75-01-4	Vinyl chloride	5445	95.1	10.4	64	127

APPENDIX N – JOB DESCRIPTIONS/REQUIREMENTS

Duties and Responsibilities	General Manager
— Responsibilities for performing tests and/or calibrations;	Not applicable.
— Responsibilities for planning of tests and/or calibrations and evaluation of results;	Supervise and administer the quality assurance program and provide an environment, in which quality work is produced
— Responsibilities for reporting opinions and interpretations;	Resolve the approval/rejection of deliverable client sample data package and/or reports. Ensure that all general and client-specific quality assurance requirements are strictly followed.
— Responsibilities for method modification and development and validation of new methods	Provide planning and implementation support for method modification and development programs, which may include allocation of resources and capital.
— Expertise and experience required; minimum bachelor's degree in chemistry or related field, work experience in related field. — qualifications and training programs;	Minimum 5 years in managerial position in a laboratory. Minimum bachelor's degree in chemistry or related field.
— managerial duties	The General Manager has the overall responsibility for the general operations of ATLI, including but not limited to Administration, Business Office, Regulatory Affairs, and Technical Operations.

APPENDIX N – JOB DESCRIPTIONS/REQUIREMENTS

Duties and Responsibilities	Lab Manager/Technical Director
— Responsibilities for performing tests and/or calibrations;	Provide backup role in laboratory analysis
— Responsibilities for planning of tests and/or calibrations and evaluation of results;	Provide guidance in planning and scheduling sample analysis. Provide technical review of analytical results and reports.
— Responsibilities for reporting opinions and interpretations;	Responsible for reviewing reports and interpreting results when needed.
— Responsibilities for method modification and development and validation of new methods	Responsible for the planning and implementation of method development and validation of new methods.
— expertise and experience required; minimum bachelor's degree in chemistry or related field, work experience in related field. — qualifications and training programs;	The Technical Director shall have at a minimum a bachelor's degree in chemical, environmental, biological, or physical sciences or engineering; at least 24 semester hours college credit in chemistry & at least 2 years experience in environmental analysis of representative inorganic & organic analytes for which the laboratory is accredited (Master's degree or doctorate may substitute for 1 year of experience).
— managerial duties	Responsible for all day-to-day operations including analytical, quality of data deliverables, support services, production timeliness of reports, sales and marketing. QA/QC responsibilities are the same as the General Manager. Responsibilities also include supervision of testing staff, including trainees. The Lab Manager/Technical Director assures that the staff is familiar with methods and procedures, the purpose of each test, and the assessment of the environmental test. The Technical Director shall certify and document that personnel with appropriate educational and/or technical background perform all tests for which the laboratory is accredited, and that all procedures are in compliance with the QA Manual.

APPENDIX N – JOB DESCRIPTIONS/REQUIREMENTS

Duties and Responsibilities	QA Manager
<p>— Responsibilities for performing tests and/or calibrations;</p>	<p>For proper QA oversight, the QA Manager shall not have primary responsibilities in day-to-day laboratory operations. Due to the small size of the laboratory, occasional participation in lab operations are allowed on a temporary basis, such as to cover for vacationing or sick employees.</p> <p>The QAM or his/her designee shall have general knowledge of the analytical test methods for which data review is performed.</p>
<p>— Responsibilities for planning of tests and/or calibrations and evaluation of results;</p>	<p>Coordinate the analysis of performance evaluation (PE) samples (if applicable) for all analytical divisions on a periodic basis. Evaluate the results; report the results to the General Manager and appropriate Supervisors; and apply corrective actions as needed.</p>
<p>— Responsibilities for reporting opinions and interpretations;</p>	<p>Ensure that all data generated is scientifically sound, legally defensible, and of known precision and accuracy. Serve as the in-house client representative on all projects inquiries involving data quality issues.</p>
<p>— Responsibilities for method modification and development and</p>	<p>Ensure that new validated methods comply with QAM procedures</p>
<p>— expertise and experience required; minimum bachelor's degree in chemistry or related field, work experience in related field. — qualifications and training programs;</p>	<p>Minimum bachelor's degree in chemistry or related field. Minimum 2 years' experience in quality assurance position or related field.</p>
<p>managerial duties</p>	<p>The QAM reports to and is responsible directly to the General Manager for all matters on laboratory quality assurance. Specific roles include: Responsible for implementation and monitoring of the laboratory quality assurance program. Monitor the QA plan on a periodic basis to ensure compliance with the QA objectives of the laboratory.</p> <p>Develop and implement new QA procedures within ATLI to improve data quality and the quality system.</p> <p>Conduct audits and inspections of all division sections on a periodic basis; report the results of the audits to the General Manager; and implementation of corrective actions to ensure compliance with the QA plan.</p> <p>Establish and maintain statistical and data records that accurately reflect the quality assurance performance of all analytical divisions.</p> <p>Maintain and oversee the master sources of all SOPs, training logs, and completed/full laboratory notebooks.</p> <p>Use available tools, such as audit and surveillance results, control charts (if applicable), proficiency testing results, data analysis, corrective and preventive actions, customer feedback, and management reviews in efforts to monitor trends and continually improve the quality system.</p>

APPENDIX N – JOB DESCRIPTIONS/REQUIREMENTS

Duties and Responsibilities	Project Manager
— Responsibilities for performing tests and/or calibrations;	Not applicable.
— Responsibilities for planning of tests and/or calibrations and evaluation of results;	Assist in prioritization of scheduling samples and updating management on upcoming projects.
— Responsibilities for reporting opinions and interpretations;	Proofread and reviews overall report for compliance with customer requirements.
— Responsibilities for method modification and development and validation of new methods	Not applicable.
— expertise and experience required; minimum bachelor's degree in chemistry or related field, work experience in related field. — qualifications and training programs;	Minimum bachelor's degree. Minimum 2 years experience in customer service, project management, or related field.
— managerial duties	<p>The Project Manager has the overall responsibility for the technical completeness, cost control, and adherence to project schedules, and also acts as liaison between the Client and the Lab. Specific responsibilities include:</p> <p>Implement the appropriate quality procedures for project activities in support of the QAPP.</p> <p>Communicate with the Lab Manager and/or QAM relating to QA/QC activities.</p> <p>Maintain the day to day operations of data handling to ensure that clerical errors are kept to the very minimum, and that all analytical data and QC data are properly collated into the reports.</p>

APPENDIX N – JOB DESCRIPTIONS/REQUIREMENTS

Duties and Responsibilities	Senior Chemist
— Responsibilities for performing tests and/or calibrations;	Responsible for analyzing samples per the appropriate methods in accordance to standard operating procedures, QAM, QSM, TNI standards, or other project-specific requirements as needed.
— Responsibilities for planning of tests and/or calibrations and evaluation of results;	Responsible for day-to-day lab analysis, scheduling, staff training, QAPP implementation, etc. of their respective group. The Senior Chemists are responsible for: Enforce the QA/QC procedures and requirements within their respective activities and areas of specialization. Maintain an environment that emphasizes an intelligent and responsible approach to producing high data quality and accuracy based on the SOPs carried out.
— Responsibilities for reporting opinions and interpretations;	Must understand the principles of the analytical method and procedures necessary to interpret results and trouble-shoot analytical issues.
— Responsibilities for method modification and development and validation of new methods	Recommend process improvements and corrective actions.
— expertise and experience required; minimum bachelor's degree in chemistry or related field, work experience in related field. — qualifications and training programs;	Minimum bachelor's degree in chemistry or related field. Minimum 2 years laboratory experience.
— managerial duties	Assist in staff training in the procedures described in the standard operating procedures (SOPs) as they apply to the assigned responsibilities of the staff. Provide oversight in the daily activities of analytical staff, and assist in trouble-shooting of instrument problems.

APPENDIX N – JOB DESCRIPTIONS/REQUIREMENTS

Duties and Responsibilities	Sample Control Officer
<p>— Responsibilities for performing tests and/or calibrations;</p>	<p>Responsible for receiving samples in compliance with laboratory SOPs and its Quality Assurance manual. Responsible for cleaning, certifying, and maintaining the canister inventory and other sampling accessories. Responsible for shipping equipment orders. Responsible for disposal of samples per laboratory SOPs.</p>
<p>— Responsibilities for planning of tests and/or calibrations and evaluation of results;</p>	
<p>— Responsibilities for reporting opinions and interpretations;</p>	
<p>— Responsibilities for method modification and development and validation of new methods</p>	
<p>— expertise and experience required; minimum bachelor's degree in chemistry or related field, work experience in related field. — qualifications and training programs;</p>	
<p>managerial duties</p>	

APPENDIX N – JOB DESCRIPTIONS/REQUIREMENTS

Duties and Responsibilities	Document Control Officer
— Responsibilities for performing tests and/or calibrations;	Responsible for the filing, retrieval and storage of the reports (project envelopes), and maintaining proper chain-of-custody of those files.
— Responsibilities for planning of tests and/or calibrations and evaluation of results;	
— Responsibilities for reporting opinions and interpretations;	
— Responsibilities for method modification and development and validation of new methods	
— expertise and experience required; minimum bachelor's degree in chemistry or related field, work experience in related field. — qualifications and training programs;	
— managerial duties	

APPENDIX N – JOB DESCRIPTIONS/REQUIREMENTS

Duties and Responsibilities	Chemist
— Responsibilities for performing tests and/or calibrations;	Responsible for analyzing samples per the appropriate methods in accordance to standard operating procedures, QAM, QSM, TNI standards, or other project-specific requirements as needed.
— Responsibilities for planning of tests and/or calibrations and evaluation of results;	Schedule workload to meet client and QAQC requirements.
— Responsibilities for reporting opinions and interpretations;	Report results on-time with a minimum of errors.
— Responsibilities for method modification and development and validation of new methods	Implement method modification and development, and validation of new methods per procedures derived by the Technical Director or designee.
— expertise and experience required; minimum bachelor's degree in chemistry or related field, work experience in related field. — qualifications and training programs;	Minimum Bachelor's Degree in chemistry or related field.
— managerial duties	

APPENDIX N – JOB DESCRIPTIONS/REQUIREMENTS

Duties and Responsibilities	QA Assistant
— Responsibilities for performing tests and/or calibrations;	General understanding of the tests being performed. Provide support to the QA Manager and Technical Director in implementing the QAM and related QA standards. Assist during site audits and prepare the response to any findings. Monitor and ensure that QAQC calendar items are completed. Maintain LOD/LOQ studies. Update quality control charts.
— Responsibilities for planning of tests and/or calibrations and evaluation of results;	Not applicable
— Responsibilities for reporting opinions and interpretations;	Assist in the 2nd level of review of data.
— Responsibilities for method modification and development and validation of new methods	Assist in the QAQC aspects of method modification and new method development.
— expertise and experience required; minimum bachelor's degree in chemistry or related field, work experience in related field. — qualifications and training programs;	Minimum Bachelor's Degree in chemistry or related field. Experience in a laboratory environment or in the quality department of related field.
— managerial duties	