RTI Laboratories, Inc.
LABORATORY QUALITY ASSURANCE PLAN

RTI Laboratories, Inc.
31628 Glendale
Livonia, Michigan 48150

Facility Locations:

Environmental Sciences	**Material Sciences**
31628 Glendale **Livonia, Michigan 48150**	**33080 Industrial Avenue** **Livonia, Michigan 48150**

Issue Date: December 26, 2018
Revision 13.5, December 26, 2018

Document ID: QAP_122618_R13.5

Reviewed and Approved by

Celeste Hoitash – QA Manager — Date: December 26, 2018

Celeste Hoitash

Fred Hoitash – Director, Environmental Sciences — Date: December 26, 2018

Fred J Hoitash

Steve Suchar – Lab Manager — Date: December 26, 2018

Stephen A. Suchar

Lloyd Kaufman – Director, Materials Sciences — Date: December 26, 2018

The current controlled version of this document resides electronically on the RTI Laboratories, Inc. company server. All forms of this document, hardcopy, electronic or other must be verified as the most recent version prior to any use or reference of the document

TABLE OF CONTENTS

QAP – Revision 13.5 - QA Plan Elements

1.0 INTRODUCTION

1.1 Policy Statement

RTI Laboratories, Inc. is committed to providing quality service to our clients. All levels of management, laboratory staff, and associated administrative personnel adhere to the guidelines detailed in this Quality Assurance Plan (QAP).

The management system established by RTI Laboratories is designed to ensure that the quality policies and procedures contained in this document are adequate for compliance with all regulatory and accreditation requirements and are responsible for implementing, monitoring and enforcing all aspects of the program.

RTI Laboratories' goals are to protect our clients' interests by providing them with fully verifiable, legally defensible data that can be used for sound scientific decisions; shelter our company's two most important resources, our people and our reputation, by maintaining an environment that fosters excellence and; guard against and correct performance shortcomings which could compromise data or technical quality. All work is performed in a professional manner and all data is scientifically valid, of known precision and accuracy and supported by a level of quality control (QC) to meet the objectives of individual projects.

1.2 Quality Assurance Plan Manual

This document will be maintained by the RTI Quality Manager. The QA Manager will be responsible for ensuring this QAP is current and for review and revision as required. The QA Manager will review this document at least annually and will update the content as needed.

The RTI QAP establishes the policies and procedures required to conform to Standards for accreditation, maintain data and personal integrity, ensure a level of data quality consistent client expectations and provide guidelines for all aspects of the operations.

All employees are provided a copy of this QAP electronically and are required by signature to acknowledge receipt. In addition, by signing the appropriate document employees attest that they will read, understand and comply with all policies contained in this document.

1.3 Ethics Policy Statement

Employees are expressly forbidden from accepting any form of compensation (financial or otherwise) directly or indirectly from clients in exchange for data alterations, special performance or any other service that would constitute a conflict of interest.

All data and any proprietary information pertaining to a client is considered strictly confidential and must not be disseminated to anyone that is not authorized by the client to receive such data or information.

Laboratory management will maintain an environment in which staff can perform its duties free from both internal and external influences, and at high levels of quality.

1.4 Ethical Practices Statement

RTI Laboratories, Inc. is committed to providing an atmosphere that promotes good science and ethical behavior. The Laboratory Director and/or others as designated by the General Manager are required to complete training through the American Council of Independent Laboratories (ACIL), or an equivalent program. All other employees are given 1 to 2 hours of annual ethics and data integrity training to prevent unethical practices and instruction in how to remain free of any pressures, internal or external, commercial or financial that may affect the quality of RTI data. Part of this training is the continuing affirmation to all employees that no one can personally gain from unethical behavior, and that all individuals at RTI are dependent on the actions of others for their livelihood and maintaining professional stature in this organization and the community. After training, the employee is required to sign a statement agreeing to abide by RTI's ethics policies.

Data integrity will be continually monitored through a system of peer review, supervisory review and review by Quality Assurance personnel. Review procedures are specified in detail in Section 9 of this document. RTI prohibits employees from engaging in any of the following practices.

1. Falsifying, fabricating or misrepresenting data in any manner.

2. Any manipulations of date or time from the actual.

3. Changes to analytical conditions, software used during the analytical events or tampering of samples that are inconsistent with standard laboratory practices or unapproved.

4. Handling or reporting of QC samples in a manner inconsistent with laboratory policies.

5. Establishing calibration conditions that do not comply with SOP or method requirements or are not consistent with laboratory policies and procedures.

6. Failure to correct or report observed or known problems with analytical systems, samples or improper actions.

RTI follows the ACIL Code of Ethics as the basis for training and operations. It is reprinted below.

1. To cooperate in elevating and maintaining the professional status of independent scientific, engineering and testing firms and in securing recognition of the value of services rendered by them.

2. To assert competency only in work for which adequate equipment and personnel are available or adequate preparation has been made.

3. To have a clear understanding with the client as to the extent and kind of services to be rendered, especially in fields where different grades or characters of services are offered.

4. To endeavor in reports to make clear the significance and limitations of findings reported.

5. To safeguard reports as far as possible against misinterpretation or misuse, and to contend against such misinterpretation or misuse.

6. To oppose and to refrain from incompetent and fraudulent inspection, sampling, analysis, testing, consultation, development and research work.

7. To deal honestly and fairly in all business and financial matters with employees, clients and the public.

RTI maintains a policy of zero tolerance for unethical behavior from any employee, manager or officer. An 'open door' policy among employees and managers provides an environment where any individual can approach management to discuss any condition that appears to be either unethical or unsafe. Key to this policy is the ability of the individual to come forward without fear of repercussion or loss of job responsibilities and/or employment. RTI recognizes that a positive approach and recognition of proper practices is the best deterrent for unethical practices.

1.5 Facility Description

1.5.1 Floor plans for the laboratories are maintained at the facilities and are available on request.

1.5.2 The two main RTI laboratories are located in Livonia, Michigan. RTI laboratories are full service laboratories involved in the analysis of Air, Soil, Groundwater, Waste, Metallurgy and Industrial samples.

1.6 Program Objectives

1.6.1 This QAP outlines the fundamental guidelines for Laboratory operation. The following sections will provide the foundation for ensuring that all aspects of the laboratories meet basic Quality Assurance criteria and generate analytical data of the highest quality achievable.

1.6.2 Establish a system through documented policies and procedures designed to ensure data quality and client satisfaction. Assess and document the effectiveness through meeting notes, corrective action plan, internal and external audits and proficiency testing.

1.6.3 Laboratory management is committed ensuring effective implementation of the policies and procedures established and to continual improvements in the quality program. Meeting client expectations and ensuring that the laboratory provides data that complies with statutory requirements is an integral part of the RTI quality assurance program (Refer also to Sec 2.1).

1.6.3.1 The Directors communicate these goals to staff during quarterly meetings that assess laboratory performance against established criteria.

1.6.3.2 The Director, Sales and Field Services monitors client satisfaction through client feedback from the LIMS Flashpoint system and direct communication with clients.

1.6.3.3 Weekly management meetings provide the forum for discussion of quality and production related issues and emerging or changing regulatory requirements that enable supervisors to communicate these items with staff.

1.6.3.4 Data review practices ensure compliance with data integrity procedures.

1.6.3.5 Periodic staff meetings provide the mechanism for disseminating information to all personnel.

1.6.4 The RTI QAP provides the basis for developing standard operating procedures (SOPs) specific to the method/analyte of interest. These SOPs delineate the specifications for the appropriate analytical technique and contain method specific QA/QC protocols and evaluation of QC samples.

1.6.5 This and other supplemental documents have been established to comply with ISO17025-2005, ISO 17025-2017, DoD QSM Version 5.0 July 2013, DOD QSM Version 5.1.1 2018, NELAC TNI Standard 2009 and various State specific certification requirements and all other applicable regulatory, accreditation or certification requirements.

1.6.5.1 RTI will be familiar with and use only the current advertising policy of A2LA with regard to the use of the term A2LA and the A2LA Accredited Symbol. Any use of these terms and symbols will be governed by A2LA policies including approval by A2LA prior to

use. Personnel involved in the use of the terms or symbols will have access to the A2LA web site for review of the current policy.

1.7 Testing Scope

1.7.1 RTI maintains primary and secondary accreditation for several programs and accreditation bodies. The list of methods for which accreditation testing is performed is maintained in the individual scopes for each authority and are incorporated by reference in this document. The scopes of each accreditation with the applicable methods are maintained on the RTI web site for review.

1.8 Supplemental Operational Documents

1.8.1 In addition to this QAP, other documents have been developed to address operational aspects required by RTI or regulation. These include the ethics program document, the Employee Handbook and the Chemical Hygiene Plan. These documents are maintained to supplement the information in this QAP and are available to all employees.

1.9 Departures from QAP Policies and Procedures

1.9.1 Departures from documented policies and procedures are not allowed unless requested directly to the Quality Manager and approved in writing by the Manager.

1.9.2 All SOPs both administrative and technical will not contain language, procedures or policies that would conflict with or override any of the policies or guidelines in this document.

1.10 Notification to Accrediting Bodies

1.10.1 Accrediting bodies will be notified within 30 days of any significant changes in:

1.10.1.1 Legal, commercial, ownership or organizational status.
1.10.1.2 Top management or key personnel – defined as Director level personnel.
1.10.1.3 Main policies – defined as policy changes that would affect the accreditation status of the laboratory.
1.10.1.4 Resources or premises – defined as loss of physical resources that would affect the ability to perform procedures under the scope of accreditation.
1.10.1.5 Scope of accreditation.
1.10.1.6 Any matter that may affect the ability of the laboratory to fulfill accreditation requirements.

1.11 Impartiality

1.11.1 The Management of RTI Laboratories is committed to maintaining impartiality in all laboratory activities. Pressures arising from commercial, financial or other sources will not be allowed to affect the impartiality of any aspect of the operation. RTI Laboratory Management will, on an ongoing basis, assess risks to this policy of maintaining impartiality.

1.11.2 Policy and guidelines for impartial treatment of activities will be communicated to employees through initial orientation and during the annual Ethics/Data Integrity training sessions.

1.11.3 Policies stated above regarding acceptance of compensation for special considerations, ethical behavior in all aspects, prohibiting the exertion of pressure for performance and conflicts of interest are designed to assist in maintaining an impartial atmosphere in the operation.

1.11.4 Laboratory Management will assess risks to impartiality through:

1.11.4.1 Monitoring staff interactions with clients and peers.
1.11.4.2 Routine discussions with clients and laboratory staff.
1.11.4.3 Communication with employees during training sessions covering ethics and proper employee behavior.
1.11.4.4 Observation for signs that special considerations are afforded in a manner that is inconsistent with impartial treatment.

1.11.5 Risks to impartiality will be minimized and eliminated through staff training and monitoring practices.

1.11.6 If risks to impartiality are identified though the routine monitoring process actions will be taken to address and eliminate such risks. Actions will include but may not be limited to employee counselling or disciplinary actions. In addition Management will assess the cause of the risk and take any necessary steps to prevent reoccurrences. These may include changes to policy, additional training or enhanced monitoring of laboratory activities.

1.11.7 When any risks are identified Laboratory Management will document those risks along with any actions taken.

1.11.8 Laboratory Management staff will be trained on the importance of maintaining an impartial operation and on ways to identify risks to impartiality.

2.0 ORGANIZATION AND RESPONSIBILITY

2.1 LABORATORY OPERATIONS

RTI Laboratories electronically maintains the company organization chart and resumes listing the qualifications and experience summaries for key professionals and applicable staff within RTI. The Directors and Managers are responsible for and work in conjunction to set the policies and procedures for the Laboratory and have the authority and resources to fully implement the quality system. This includes but is not limited to laboratory documents pertaining to the operation of the Laboratory (i.e. QAP, SOPs, etc.). These policies and procedures are communicated to all laboratory staff through staff meetings, individual instructions, posting of documents electronically and providing copies as applicable. Laboratory staff have accessibility to management personnel for discussing any issues pertaining to the work being performed. The laboratory will maintain sufficient supervisory and management personnel in a ratio to the analytical staff that ensures adequate supervision and compliance with established policies. The Laboratory currently maintains staff to supervisor ratios in the range of 2:1 – 7:1.

2.1.1 TECHNICAL DIRECTOR (DIRECTOR, ENVIRONMENTAL SCIENCES/ DIRECTOR, MATERIALS SCIENCES)

2.1.1.1 The Director (Technical/Laboratory Director) is a full time member of the staff and has overall responsibility for laboratory operations. This position requires education and experience that meet the requirements of Accreditation Bodies. The Director is responsible for ensuring that all personnel strictly adhere to policies and procedures enacted to maintain laboratory data integrity, client confidentiality, the quality standards set forth in this document and compliance with accreditation Standards specified in Sec. 1.6.5. The Director manages the technical aspects of the operation either directly or through appointed supervisors reporting to the Director, is responsible for providing the resources required to comply with the policies contained in this QAP and monitors laboratory performance with regard to quality assurance adherence to ensure data accuracy. The Director maintains oversight of all personnel and ensures that the qualifications and experience are suited to the position of the employees. The Director approves all staff training and authorizes individuals to perform the tasks assigned. Staff oversight is documented through required signature on hiring and method approval. The Director maintains the organization structure of the staff through formulation of organization charts and direct assignment of duties. Other duties include special project management, client consultation and oversight of laboratory safety.

2.1.2 **QUALITY MANAGER**

2.1.2.1 The Quality Manager (QA Manager) reports to the General Manager and is responsible for establishing, implementing and maintaining the Quality Assurance Program, defining the policies required to comply with the objectives of the program and ensuring that achievement of the objectives can be documented. The Manager maintains the authority to cease the production of laboratory data that does not conform to the objectives of this QAP and has the freedom from influences either internal or external that could compromise the duties of this position. Other duties include auditing QC functions to ensure compliance with the laboratory protocols, reviewing record keeping and ancillary documents, maintaining quality control materials, and management of proficiency testing samples to ensure that these samples are analyzed and reported in accordance with the program requirements. The Manager is additionally responsible for:

- Ensuring that all personnel understand the objectives of the program and their part in contributing to the effectiveness of the quality system.
- Maintaining communication with all levels of staff to monitor the effectiveness of the program.
- Using the measures incorporated in the QAP (i.e. internal audits, PT studies, control charts, corrective action, client complaints and all other available tools) to monitor trends and continually improve the system.
- Evaluating the effectiveness of training through review and approval of initial demonstrations of proficiency, routine data review, review of proficiency testing data, audits demonstrating compliance with policies and procedures and participation in weekly management review.

2.1.3 **SUPERVISOR, LABORATORY OPERATIONS**

2.1.3.1 The Supervisor reports to the Technical Director and is responsible for supervision of laboratory analytical staff, daily scheduling, monitoring work progress and tracking work orders. The Supervisor is responsible for ensuring that samples arriving at the laboratory are received in accordance with acceptable sampling programs and for timely logging and storage of samples. The Supervisor tracks and schedules work throughout the laboratory in order to ensure compliance with hold time requirements and client expectations. The Operations Supervisor is responsible for working with the Director, Quality Management in generating, approving and reviewing laboratory SOPs, technical compliance with the SOPs and assessment and evaluation of instrumentation. The Supervisor is further responsible for investigating analytical problems, formulating

and implementing corrective actions when required and monitoring the efficacy of the corrective actions. The Supervisor works closely with the QA Manager to ensure corrective actions are sufficient to both solve the initial problem and prevent future occurrences. Other duties include client consultation on technical project requirements and review and approval of laboratory reports.

2.1.4 GROUP LEADER/DEPARTMENT COORDINATOR

2.1.4.1 Group Leaders/Departments Coordinators report to the Supervisor, Laboratory Operations on matters regarding the status and progress of work in progress and those pertaining to technical aspects of the operation. Group Leaders are responsible for overseeing the work performed by the technical staff. Responsibilities include coordination with the Supervisor on workload scheduling, supervision of senior staff, technical monitoring of method performance, client consultation and select project management, supply procurement and approval and, in conjunction with the QA Manager, reviewing, evaluating and implementing corrective actions.

2.1.5 DOCUMENT CONTROL OFFICER

2.1.5.1 The Document Control Officer reports to the Technical Director and is responsible for maintaining and reviewing all documents (either internal or external) relating to the production and quality of data generated by the laboratory. The Document Control Officer maintains a master listing of all documents in current use by the laboratory and ensures that obsolete documents have been removed from use. The Document Control Officer further reviews documents for completion, adherence to correct procedures for entering and correcting information transcribed and approves (or obtains approval from the QA Manager) prior to issuance of new or revised documents.

2.1.6 LABORATORY INFORMATION MANAGEMENT SYSTEMS (LIMS) ADMINISTRATOR

2.1.6.1 The LIMS Administrator reports to the General Manager and is responsible for maintaining the computer based laboratory management information system. The LIMS Administrator ensures the proper functioning of the system, maintains the databases within the LIMS, performs, verifies and maintains the required backup of electronic data, programs the LIMS for customized changes and verifies both system performance and modifications to the LIMS. The LIMS Administrator is further responsible for maintaining the security of the system, assignment of rights within the system (in concert with

the Directors) and ensuring that all electronic data is maintained in a manner that protects data integrity and client confidentially. The LIMS Administrator is additionally charged with training of employees in both the basic use of the system and when updates or revisions are made to the LIMS. The LIMS Administrator is responsible for documenting the verification process on installation and when revisions or modifications are made to the system.

2.1.7 **CHEMISTS/ANALYSTS/TECHNICIANS**

2.1.7.1 Senior Staff

2.1.7.1.1 Chemists or Analysts that have the prerequisite academic and practical experience are considered capable of functioning independently and supervising technicians and laboratory assistants in the performance of laboratory procedures related to their area of expertise. Senior staff will report to a Manager or Department Coordinator. Senior staff are responsible for notifying the QA Manager of any situation that may impact data quality, institute corrective action procedures and implement appropriate actions according to instructions by a Manager or Director. As a general policy staff do not directly communicate with clients. However, in special instances or specific areas of expertise senior staff may consult with clients on matters regarding the status and progress of work in progress and those pertaining to technical aspects of the operation.

2.1.7.2 Chemists/Analysts/Technicians

2.1.7.2.1 Personnel in these positions report to the assigned individual and are responsible for the preparation and analysis of samples or ancillary duties relating to the functioning of the laboratory.

2.2 ADMINISTRATIVE OPERATIONS

2.2.1 **GENERAL MANAGER**

2.2.1.1 The General Manager maintains responsibility for the overall operation of the facility. The main areas of responsibility are strategic planning, business development, resource allocation, and profit and loss. It is the General Manager's responsibility to obtain and develop financial resources in an effort to maintain quality services and to match resources with the market demands.

2.2.2 ADMINISTRATIVE/OFFICE MANAGER

2.2.2.1 The Administrative Manager reports to the General Manager and is responsible for maintaining personnel files, general accounting related to the business activities of RTI Laboratories, Inc., managing accounts receivable and payable and supervising the administrative support staff.

2.2.3 DIRECTOR, SALES AND FIELD SERVICES

2.2.3.1 Director, Sales and Field Services is responsible for communicating with clients or designating appropriate staff to consult with clients to ensure that all project requirements meet client specifications and coordinating and managing all field services activities. The Director oversees client requests for services, issues price quotations, manages the sample receiving staff, assigns and supervises request for sample containers and serves as that point of contact for client inquiries. The Director, Sales and Field Services works with the Technical Director/Supervisor to verify that resources and personnel are sufficient to successfully manage projects. The Director receives and if needed delegates client requests from the on-line client service module (Omega – Flashpoint). The Director will receive client concerns and complaints and in conjunction with the laboratory staff will address all client issues.

2.3 POSITION DESCRIPTIONS

2.3.1 RTI maintains job descriptions and position classifications for Laboratory and Administrative personnel.

2.3.1.1 Job descriptions detail the primary duties and responsibilities of personnel working in a particular position classification.

2.3.1.2 Position classifications set forth the minimum academic and experience qualifications necessary to qualify for a specific position.

2.3.1.3 Technical Directors are responsible for formulating and maintaining the position descriptions.

2.4 TRAINING

2.4.1 All newly hired employees receive initial training for the following items. This training occurs before beginning specific training noted below.

2.4.1.1 Laboratory safety

2.4.1.2 Hazard Communication Standard
2.4.1.3 Computer Security Awareness
2.4.1.4 Provided access to the Laboratory Quality Assurance Plan and the Data Integrity/Ethics Manuals. Employees are required to sign receipt of the document access location and acknowledge that they will read, understand and abide by the policies contained in the documents.

2.4.2 RTI personnel are provided with the necessary training essential to the performance of the duties assigned. In general all Laboratory employees receive and are required to abide by the policies set forth in the following documents:

2.4.2.1 RTI Policy Handbook
2.4.2.2 Laboratory Quality Assurance Plan
2.4.2.3 Chemical Hygiene Plan
2.4.2.4 Method SOPs

2.4.3 Analytical personnel are trained in both general laboratory practice and specific test methods. In the latter instance, a training form (Figure 2-1) is completed to document proficiency in particular methodologies. Training forms will be maintained in the analyst's file with appropriate demonstration of proficiency and must be approved by the Technical Directors and QA Manager. In addition, the file will contain a list of methods for which the analyst is approved. This approval authorizes the analyst to operate the equipment and instrumentation specified in the laboratory SOP for that procedure. Elements of the training program include:

2.4.3.1 Review of applicable SOPs
2.4.3.2 Review of method references
2.4.3.3 Demonstration of method familiarity
2.4.3.4 Demonstration of method proficiency
2.4.3.5 Specific requirements for methods or accreditation/certification programs

2.4.4 During training analysts will work under the supervision of an experienced analyst that will assume responsibility for the data generated as documented by the electronic signature in the LIMS analytical sequences. Analysts undergoing training will not be provided direct access to the LIMS or computer workstations and will be unable to enter analytical data under their name.

2.4.5 In addition to internal training, RTI employees are provided with opportunities for auxiliary training. Examples of this type of training are:

2.4.5.1 Manufacturer's instrument training
2.4.5.2 Organizational courses
2.4.5.3 Seminars, conferences and workshops
2.4.5.4 Internal in-service sessions

2.5 CONTINGENCY PLAN FOR ABSENCE OF PERSONNEL

2.5.1 In the event the Technical Director and/or QA Manager is/are absent from the laboratory, the Director will designate individuals to assume the duties of these positions as required. Generally the Technical Director and QA Manager (both maintain the qualification for either position) will assume the duties of both positions in the absence of the other for any period of time. Extended absences may require the appointment of senior staff or managers to assist with the responsibilities of the absent Director. Full-time employees that are required to assume Director responsibilities will be chosen based on the ability to meet the accreditation qualifications for the position. If the absence of the Technical Director exceeds 35 consecutive calendar days the Accreditation Bodies will be informed in writing.

2.5.2 The absence of other key management personnel will be accomplished by the following assignment of responsibilities:

2.5.2.1 General Manager will assign any required functions to Director level staff or other employees as determined by the General Manager.

2.5.2.2 The Technical Director will assume responsibilities for Group Lead or Supervisory staff or will appoint qualified senior staff.

2.5.2.3 The Director, Sales and Field Services will assume duties of an absent Project Manager or assign duties to another Project Manager.

2.5.2.4 LIMS system administration will be appointed to the IT specialist in the absence of the QA Manager.

2.5.2.5 Administrative management will be assumed by the General Manager or employee designated by the General Manager in the absence of personnel.

2.6 SELECTION OF PERSONNEL

2.6.1 The Technical Director in consultation with the General Manager is responsible for maintaining adequate staff for performing laboratory functions both technical and administrative. RTI complies with all Federal, State and Local regulations and guidelines governing equitable, non-discriminatory and fair employment practices. The following guidelines are used in the selection of Company personnel.

2.6.1 Needs of the laboratory for maintaining adequate staff for all functions.
2.6.2 Specific position required to be filled.
2.6.3 Academic and employment experience of the applicants.
2.6.4 Review of resume, employment application and academic credentials

when required.

2.6.5 Verification of applicant suitability for the position through interview.

2.6.6 Contact of applicant provided references when deemed necessary.

2.6.7 Mutually agreement on compensation and perceived ability of applicant to perform the required duties of the position.

Figure 2-1
RTI Laboratories, Inc.
ANALYST TRAINING FORM

Analyst: _____

Date:_____

Method/Test Name/Matrix/Parameters: _____

Method Reference: _____

Approval for this method is based on the following completed program.

___ Has read and understood the RTI Standard Operating Procedure (SOP) for the test/method.

___ Has read the official method referenced above.

___ Has become familiar with this method by observing an experienced analyst at work,

___ Has performed the method while being observed by an experienced analyst.

Has demonstrated analytical proficiency in the method by completing one or more of the following options as noted:

____ Performed a one (1) time demonstration of analytical proficiency in accordance with the precision and accuracy specifications of the official reference method.

____ Successfully analyzed ten (10) daily batches including method blanks, laboratory control samples, duplicate and spiked samples.

____ Successfully analyzed a blind performance evaluation sample.

Other Specify: _____

RTI Laboratories, Inc. certifies:

That the analyst identified on this form, using the cited test method, which is in use at this facility for the analyses of samples under the National Environmental Laboratory Accreditation Program, has met the Demonstration of Capability.
The test method was performed by the analyst identified on this form.
A copy of the test method and the laboratory-specific SOP is available for all personnel on-site.
The data associated with the demonstration of capability are true, accurate complete and self-explanatory.
All raw data (including a copy of this form) necessary to reconstruct and validate these analyses have been retained at this facility, and the associated information is organized and available for review by authorized assessors.
The approval signature below authorizes the analyst to perform the procedures and operate the equipment associated with the method.

Analyst`: _____
Signature Date

Approved By: _____
Signature Title Date

Approved By: _____
Signature Title Date

3.0 QUALITY ASSURANCE TARGETS FOR PRECISION, ACCURACY, REPRESENTATIVENESS, COMPARABILITY AND UNCERTAINTY

RTI strives to achieve the highest level of quality attainable. The targets listed below pertain to goals for assessment of sample, matrix or method criteria. Strict adherence to calibration protocols (Section 6.0), data evaluation (Section 9.0 and 13.0) and compliance with the requirements documented in the QAP are fundamental to successfully monitoring the items below. The following are assessed through specific routines described in Section 12.0. These guidelines in conjunction with the generation of Standard Operating Procedures as specified in Section 7.0 form the process for planning, implementing and assessing work performed by RTI Laboratories, Inc.

3.1 PRECISION

3.1.1 Precision is defined as the variation between multiple measurements made on a single sample. This defines the ability of a measurement method to produce data that has a statistically determined closeness between replicate analyses.

3.1.2 The laboratory objectives for precision are:

3.1.2.1 The laboratory strives to develop methods capable of producing the highest degree of precision attainable.

3.1.2.2 Establish statistical control limits not to exceed the precision data published in the applicable method.

3.1.2.3 In the absence of published data the laboratory adopts a target of 25% and a maximum limit of 40% with respect to internally generated precision data.

3.1.2.4 Internally developed methods or published methods that have not assessed precision of the method may generate data that exceeds 40%. The QA Manager will evaluate these methods prior to use by the laboratory.

3.1.3 Precision data for individual analytes can be found in the specific SOPs and the associated LIMS test codes.

3.1.4 Monitoring of precision is accomplished through the use of duplicate measurements on a sample or a duplicate spiked sample and calculation of the relative percent difference (RPD) for the two results (refer to Section 12.0 for additional details). RPD limits for duplicates (Omega sample types DUP, MSD and LCSD) are incorporated in the LIMS for the individual test codes in the Specs tab for the above designated sample types.

3.1.5 Statistical limits can be calculated, reviewed and adopted through the LIMS. The QA Manager will review the LIMS calculated control limits. Obvious anomalous data points that are typically found due to sample homogeneity issues, high variation associated with results near the MDL or other problems that cause extreme elevation in the control limit will be excluded at the discretion of the reviewer.

3.1.6 Since statistical precision data has a high probability of bias due to matrix interference and high or low sample concentrations precision limits are set according to the following guidelines.

3.1.6.1 Method specified (ex. EPA 1664A).

3.1.6.2 Precision data set according to the RPD values published in the most current version of the DoD QSM for analytes or procedures cited in that document. Laboratory precision data must demonstrate compliance with the QSM limits by being as stringent as the QSM limits or demonstrating that the data points fall within the QSM limits. QSM limits are adopted and entered in the applicable test code.

3.1.6.3 Default limits set to 25%.

3.1.7 For analytes or methods that by the nature of the testing procedure consistently produce RPD statistical limits in excess of 50% RTI may continue to use the default limit of 25% for control purposes. This will be based on review of the data set where the statistical data is influenced by some matrix affected samples or induced by variation that impacts the standard deviation yet produces results generally less than 20 – 40 % RPD. This decision will reside with the QA Manager and will be consistent with RTI policy for striving to produce precise data, maintain the strictest practical control limits and allow for stringent review of data generated.

3.1.8 Precision at the reporting limit is assessed by analysis of four spiked samples at the LOQ concentration annually. The QA Manager will review the data generated and assess the calculated percent relative standard deviation. Method or laboratory control limits will be established for assessing the acceptability of the precision data.

3.2 ACCURACY

3.2.1 Accuracy is defined as the ability of a measurement system to produce data that reflects the true value of the analyte in a sample.

3.2.2 The laboratory objectives for accuracy are:

3.2.2.1 Develop methods capable of producing the highest degree of accuracy attainable.

3.2.2.2 Establish control limits not to exceed the accuracy data published in the applicable method.

3.2.2.3 In the absence of published data the laboratory adopts default accuracy criteria for recovery of the spiked concentration for laboratory control samples and for recovery of the spiked concentration for matrix spikes (Refer to Sec. 3.2.4).

3.2.2.4 Internally developed methods or published methods that have not assessed method accuracy may exceed the criteria in 3.2.2.3. The QA Manager, prior to use by the laboratory, will evaluate the accuracy data generated by the laboratory.

3.2.3 Accuracy data for individual analytes can be found in specific SOPs and in the associated LIMS test codes.

3.2.4 Monitoring of accuracy is accomplished through the use of spiked measurements on a sample or laboratory matrix and calculation of the percent recovery (refer to Section 12.0 for additional details). Recovery limits for laboratory control samples or spikes (Omega sample types MS, MSD, LCS and LCSD) are incorporated in the LIMS for the individual test codes in the 'Specs' tab for the above designated sample types and are set according to the following guidelines.

3.2.4.1 Method specified (ex. EPA 1664A).

3.2.4.2 Recovery data set according to the control limit values published in the most current version of the DoD QSM for analytes or procedures cited in that document. Laboratory accuracy data must demonstrate compliance with the QSM limits by being as stringent as the QSM limits or demonstrating that the data points fall within the QSM limits. QSM limits are adopted and entered in the applicable test code.

3.2.4.3 When the above are unavailable default limits set according to the guidelines below.

3.2.4.3.1 Metals and wet chemistry analyses – 80 – 120% or 90 – 110 % based on method specifications.

3.2.4.3.2 Gas chromatography and high pressure liquid chromatography analyses – 70 -130% or 40 -130% herbicide analyses.

3.2.4.3.3 Gas chromatography/mass spectrometry – 70 – 130% volatiles and 50 – 130% semi-volatiles.

3.2.4.4.4 Statistically calculated control limits. For analytes or methods that by the nature of the testing procedure consistently produce extremely wide statistical limits or are cited as problem analytes in the associated method RTI may continue to use or establish default limits for control purposes. This will be based on review of the data set where the statistical data is influenced by some matrix affected samples or induced by variation that impacts the standard deviation yet produces results more consistent with the default/method limits. This decision will reside with the QA Manager and will be consistent with RTI policy for striving to produce accurate data, maintain the strictest practical control limits and allow for stringent review of data generated.

3.2.5 Accuracy data for LCS samples are evaluated against the control limits published in the most current version of the DoD QSM for the analytes cited in that document. Laboratory accuracy data must demonstrate compliance with the QSM limits by being as stringent as the QSM limits or demonstrating that the data points fall within the QSM limits. QSM limits are adopted and entered in the applicable test code for LCS and MS/MSD recovery limits.

3.2.6 Accuracy at the reporting limit is assessed by analysis of four spiked samples at the LOQ concentration annually. The QA Manager will review the data generated and assess the calculated mean recovery. Method or laboratory control limits will be established assessing the acceptability of the recovery data.

3.3 Control Charting and Evaluation of Data Trends

3.3.1 The control charting function in Omega is able to calculate recovery and precision data, statistical control limits and plot control charts for all analytes for individual test codes. The QA Manager reviews the LIMS calculated control limits. Obvious anomalous data points that are typically found due to sample matrix issues, high variation associated with some analytes or other problems that cause extreme elevation in the control limits will be excluded at the discretion of the Director for evaluating control limits. While every attempt is made to use all associated data in the calculation of statistical control limits and assessment of recovery and precision data, it is not the intent of RTI to base quality control evaluation on extreme limits due to statistical calculation of the limits. RTI does not set lower control limits at values less than 10% and upper control limits at values greater than 200%. RTI refrains from setting upper and lower control limits beyond 20 – 180%.

3.3.2 Control charting can be used to assess trends related to analyte or method performance. Generation and review of control charts can be conducted to investigate potential trends or bias in analytical procedures for the following cases.

3.3.2.1 Quarterly review by the QA Department.

3.3.2.2 Analysts observations of changes in response for analytes.

3.3.2.3 Data reviewer evaluation of QC data that may indicate a change in analyte performance.

3.3.2.4 Historical performance.

3.3.3 Routine practice at RTI is to identify data changes on occurrence. Daily review of quality control data by experienced staff is designed to prevent the occurrence of negative trending of analytical results. Data reviewers will investigate instances of abnormally high or low recoveries or elevated precision data. Corrective actions, when required, will be instituted to prevent trends that negatively impact data quality.

3.3.4 Evaluation of control charts and statistical data will assess data trends based on the following guidelines.

3.3.4.1 Definite trends as observed by several data points over time that exhibit a consistent increasing or decreasing of the value and are not beginning to exhibit a reversal. These trends will be investigated and corrective actions taken.

3.3.4.2 Shifts in data sets where values have exhibited a definite change in value over time, remain consistently high or lower than prior data and exhibit normal variation over time. Shifts can be assessed positively when recovery data for analytes demonstrate an improvement in the performance for that analyte. Shifts are assessed negatively when a high or low bias is noted. These shifts will be investigated and corrective actions taken.

3.3.4.3 Mean recovery data can be monitored to detect changes in analyte performance or to ensure analyte recovery is maintained at expected levels. Recovery data inconsistent with that expected for an analyte will be investigated and any necessary corrective actions taken.

3.3.4.4 Percent RSD data can be observed to assess the variability in analyte response. Instances of extreme variation in analyte response will be investigated.

3.3.4.5 Calculated warning and control limits can be assessed for suitability with the limits assigned.

3.4 REPRESENTATIVENESS

3.4.1. Representativeness is defined as data that accurately depicts the distinguishing characteristics of the sample source.

3.4.2 Laboratory objectives are to produce data representative of the sample submitted.

3.4.2.1 This is accomplished by standard operating procedures that ensure a representative portion of the sample is used for analysis.

3.4.2.2 Representativeness is assessed by duplicate analysis of a method-defined percentage of the samples analyzed.

3.5 COMPARABILITY

3.5.1 Comparability is defined as the agreement of analytical data between similar sample sets.

3.5.2 Laboratory objectives for comparability are to produce data with a high degree of precision and accuracy so that similar sample sets will demonstrate the field objectives for comparability.

3.5.3 The laboratories assess comparability through routines to assess precision and accuracy and through quality control checks.

3.5.4 The Omega LIMS has the ability to produce sample historical data.

3.6 UNCERTAINTY

3.6.1 Uncertainty is defined as the component of the measurement process that produces a dispersion of values that are attributed to the analytical event.

3.6.2 Laboratory objectives are to produce data with a high degree of accuracy and precision that will in turn minimize the uncertainty associated with analyses.

3.6.3 The Laboratory assesses uncertainty through the analysis of laboratory control samples with calculation of mean recovery, standard deviation and control limits. For certain procedures LCS samples may be not applicable. In these instances the published uncertainty in the method will be used.

3.6.4 When applicable or required analytical reports will be issued with LCS quality control summary data.

3.6.5 For methods with specific limits and specification for presentation of reported values uncertainty measurements do not apply provided the test method and reporting instructions are followed.

3.6.6 Reported sample results that are below the laboratory reporting limit but above the established MDL are flagged with a J qualifier on the analytical report. The case narrative notes that J flagged results have greater uncertainty associated with the values reported.

3.6.7 For instances where a sample result exceeds the upper calibration range and additional analysis cannot be performed to dilute the sample into range the result is flagged with an E qualifier on the analytical report. The case narrative will note that E flagged results have greater uncertainty associated with the values reported.

3.6.8 Field sampling procedures are monitored for uncertainty through manufacturer specifications for field equipment, field meter control samples and field duplicate measurements.

4.0 SAMPLING PROCEDURES

RTI will perform field-sampling services for some clients and projects. Sampling services include providing personnel to assist in sampling events, collection of wastewater samples and limited air monitoring. In the above instances RTI staff will adhere to guidelines and protocols established by the site/project manager or client representative and conform to established standard procedures that ensure sample integrity and a high level of quality control throughout the sampling event.

The laboratory frequently consults with clients regarding sampling methods, procedures and supplies. Sampling procedures are available in the laboratory and are used as a basis for providing clients with proper materials and methods for the collection of samples. Sampling instructions are maintained on the server in - RtiStorage on Glendaless\User\Environmental Sciences\CustomerField\Customer Service\Sampling instructions.

Collection procedures for drinking water samples supplied by the Michigan Department of Environmental Quality (DEQ) are maintained and provided to clients for sample collection.

The following sub-sections contain information on sample handling, materials, containers, preservatives, and shipping. This information is available to all clients requesting assistance for sampling projects and is used by RTI staff during collection of samples when required.

4.1 GENERAL SAMPLING GUIDELINES

4.1.1 Sample containers that are provided by the laboratory may contain measured volumes of preservative. Such containers should not be rinsed prior to filling with sample.

4.1.2 Sample containers for volatile organic analyses (VOA), pH, dissolved oxygen and Total Organic Halides (TOX) must be completely filled with no headspace. All other sample analyte containers should be filled to approximately 95% capacity.

4.1.3 VOA samples must be collected in a manner that minimizes disturbance of the sample and potential for volatilization. Vials are filled until the formation of a convex meniscus at the top of the vial. The septum cap is carefully placed on the vial and the vial is inverted and checked for the presence of air bubbles.

4.1.4 Field sampling equipment should be appropriately decontaminated before and after use to prevent cross contamination of samples.

4.1.5 During the collection of samples appropriate personal protective items should be worn. Gloves and safety glasses are generally the minimum acceptable level of PPE to be worn.

4.1.6 Pre-cleaned, laboratory prepared sampling containers should be used for the collection of samples whenever possible.

4.1.7 Air sampling media is maintained and provided to clients. This includes solid sorbent tubes, membrane filters (tared, untared or treated) and impinger solutions. This media should be used in conjunction with the appropriate method using the recommended flow rate and volume guidelines.

4.1.8 Sample collection for low level Mercury will follow the procedures specified in EPA Methods 1631E and 1669.

4.2 SAMPLING CONTAINERS

4.2.1 The measurement of trace constituents in environmental samples demands methods capable of maximum precision and sensitivity. The selection and proper care of laboratory glassware and sample containers is an important part of the quality control program to eliminate errors due to contamination from improper cleaning procedures.

4.2.2 Only containers constructed of materials that are compatible with and non-reactive with the material to be sampled will be used. RTI uses commercial sample containers that are certified pre-cleaned to EPA standards. These containers are shipped in sealed boxes with custody seals and certificates of compliance when required by the project.

Table 4-1 lists the container types, volume requirements and preservative. Also refer to specific analyte/method SOPs for additional information or for analytes/matrices not listed.

The definitive references for acceptable containers, correct preservation and holding times are 40 CFR Part 136 and SW-846. In the event of discrepancies between the listings in Table 4.1 or RTI SOPs and the references above, the citations in the documents above (i.e. 40 CFR and SW-846) and where applicable specific method references (i.e. Standard Methods, ASTM) supersede the Table and SOP.

The Laboratory maintains electronic versions of the most current reference documents.

4.2.3 The laboratory purchases air-sampling media consistent with method requirements. Cassettes used with membrane filter sampling are stored and assembled in a manner to avoid potential contamination. Cassettes are re-used only if visible soiling or damage is absent and are stringently cleaned according to procedures used for laboratory glassware (Section 6.0) prior to use.

4.2.4 Pre-weighed membrane filters are provided for gravimetric determinations. Both pre and post weighing are performed under conditions designed to obviate temperature and humidity effects.

4.2.5 Treated filters are prepared in the laboratory according to method specifications, stored under appropriate conditions and assigned an expiration date, where applicable. Purchased treated filters with expiration dates are discarded if not used by the specified date.

4.2.6 Sorbent tubes are stored under manufacturers' recommended conditions and used by the stamped expiration date or discarded on expiration.

4.2.7 Sampling containers or media for microbiological assays are prepared and stored in a manner that maintains sterility. Sampling media can be prepared for specific project requirements in consultation with the laboratory microbiologist.

4.2.8 Summa canisters are cleaned according to method requirements and are analyzed at a frequency of >10% to ensure proper cleaning. Evacuated canisters are leak checked prior to use or shipping. Documentation of clean checks are maintained for canister tracking and provided with the canisters supplied for sampling.

4.2.9 BottleVac containers are cleaned in batches of 20 according to the SOP and are checked at a frequency of 1 per batch to ensure proper cleaning. Evacuated BottleVacs are leak checked prior to use or shipping. Documentation of clean checks are maintained for container tracking and provided with the BottleVacs supplied for sampling.

4.3 SAMPLE PRESERVATION

4.3.1 Cooling, pH control, and chemicals to retard biological activity or to stabilize the chemical species of a sample are means to preserve the integrity of samples. Sample kits prepared by the laboratory include sample containers with the appropriate type and volume of preservative for the analyte(s) of interest. Addition of preservative to samples in the field is not normally required when using the prepared containers. This procedure minimizes the potential for incorrect or inadequate sample preservation.

4.3.2 The most common form of preservation is cooling the sample to <6° C using ice or refrigeration. Other common preservatives used include:

4.3.2.1 Hydrochloric acid
4.3.2.2 Nitric acid
4.3.2.3 Sulfuric acid

4.3.2.4 Sodium hydroxide
4.3.2.5 Sodium thiosulfate - for de-chlorination.
4.3.2.6 Methanol for volatile organics.
4.3.2.7 Sodium bisulfate for low level volatile organics
4.3.2.8 Brominemonochloride for low level mercury
4.3.2.9 Other preservative as stipulated by the Method (Refer to Table 4-1)

4.4 SAMPLE DOCUMENTATION

4.4.1 The laboratory provides sample kits containing pre-labeled and preserved sample containers. Each sample collected should be clearly labeled using waterproof ink with the following information:

4.4.1.1 Client name
4.4.1.2 Date and time of collection
4.4.1.3 Sample source
4.4.1.4 Preservative
4.4.1.5 Name(s) of sampler
4.4.1.6 Analyses requested
4.4.1.7 Sample identification

4.4.2 When assisting with or performing field sampling, personnel maintain complete and accurate records of all field activities. Bound field notebooks and/or field logs specific to the project are completed during sampling. All pertinent information on the sampling event is included in the field record.

4.4.3 Chain-of-custody: A completed chain-of custody form must accompany all samples when shipped or hand delivered to the laboratory. Information required on the chain-of-custody includes:

4.4.3.1 Name(s) of sampler(s)
4.4.3.2 Company reporting information
4.4.3.3 Sample ID
4.4.3.4 Project name and number
4.4.3.5 Analyses requested
4.4.3.6 Number of sample containers per sample
4.4.3.7 Signature and date of all individuals who have custody of the samples
4.4.3.8 Sample date and time
4.4.3.9 Requested turnaround time

4.5 SAMPLING EQUIPMENT DECONTAMINATION

4.5.1 In instances where field-sampling equipment is provided by the laboratory all items are appropriately pre-cleaned prior to use. Phosphate-free detergent, hot tap water, and analyte free rinse water is used for this cleaning. Cleaned equipment should be wrapped or enclosed to maintain cleanliness during

transport to the field. Adequate quantities of sampling equipment should be available for each sampling event to minimize the need for field decontamination.

4.5.2 Decontamination procedures for sampling equipment may include:

- 4.5.2.1 Phosphate-free detergent and tap water wash.
- 4.5.2.2 Rinse with tap water.
- 4.5.2.3 For equipment to be used for trace metals sampling rinse with 1:1 reagent-grade nitric acid solution. **Do not rinse stainless steel sampling equipment with nitric acid.**
- 4.5.2.4 For equipment used for low level mercury sampling rinse with 5% hydrochloric acid.
- 4.5.2.5 Rinse thoroughly with deionized water.
- 4.5.2.6 Rinse with isopropanol or methanol.
- 4.5.2.7 Thoroughly rinse with analyte-free water (if available).
- 4.5.2.8 Air dry.
- 4.5.2.9 Wrap securely to prevent contamination if equipment is to be stored or transported.

4.5.3 Information on specific decontamination procedures is available in sampling and analytical manuals and references maintained at the laboratory. Special decontamination procedures will be addressed as necessary, based upon contaminants encountered.

4.5.4 Equipment that is heavily soiled may require steam cleaning and/or high-pressure washing. Drilling equipment and other heavy equipment used in field sampling activities will likely require this type of cleaning. If equipment cannot be adequately decontaminated, it should be discarded.

4.6 FIELD WASTE DISPOSAL PRACTICES

4.6.1 Field generated waste is disposed as required by project specifications and in accordance with applicable local, state, and federal requirements. Wastes commonly generated include drill cuttings, drilling fluids, well development water, well purge water, decontamination fluids, and contaminated personal protective equipment.

4.6.2 Based upon site and project specific requirements, liquid wastes may be containerized for characterization and disposal or discharged directly to an appropriate discharge location. Solid wastes may be containerized and left on-site for disposal or, if appropriate, disposed as general refuse.

4.6.3 Prior to initiating any sampling activity the waste handling requirements should be determined to ensure timely disposal in compliance with regulatory requirements.

4.7 SAMPLE SHIPPING

4.7.1 When shipping of samples is necessary all samples should be packaged in a manner to prevent damage in transit.

4.7.2 When sample refrigeration is required, samples should be shipped in a container with wet ice and in a time frame (overnight courier) designed to maintain proper temperature.

4.7.3 Analytes that are photosensitive should be immediately packaged to minimize light exposure. This is in addition to collection procedures (foil wrapping, amber bottles, etc.) required to minimize sample degradation.

4.7.4 All coolers used for transporting samples will contain a temperature blank prepared by filling a 4 oz plastic bottle with tap water (on request a 40 ml VOC vial may be supplied for the temperature blank).

Table 4-1

Sample Containers and Preservation

CONVENTIONAL - WATER

PARAMETER	MINIMUM VOLUME (ml)	CONTAINER TYPE	PRESERVATIVE
Acidity	100	P, G	Cool, <6°C
Alkalinity	100	P, G	Cool, <6°C
Fixed Solids (ASH) @ 550 Degrees	100	P, G	Cool, <6°C
Ash Content @ 750 Degrees	100	P, G	Cool, <6°C
Biochemical Oxygen Demand	120	P, G	Cool, <6°C
Bromide	25	P, G	Cool, <6°C
BTU	100	P, G	Cool, <6°C
Formaldehyde	500	Amber G	Cool, <6°C
Chloride	25	P, G	Cool, <6°C
Chlorine, Total Residual	100	P, G	Cool, <6°C
Cyanide	250	P, G	Cool, <6°C, NaOH pH>12, ascorbic acid if oxidizers are present
Cyanide, Amenable to Chlorination	250	P, G	Cool,,4°C,NaOH pH>12
Cyanide, Available	100	P, G	Cool, <6°C Ascorbic acid, NaOH pH >12
Chemical Oxygen Demand	25	G	Cool, <6°C, H_2SO_4, pH<2
Color, Platinum-Cobalt	50	P, G	Cool, <6°C
Coliform, Fecal *	120	PA, G	Cool, <10°C, 0.0008% $Na_2S_2O_3$
Fecal Streptococcus *	120	PA, G	Cool, <10°C, 0.0008% $Na_2S_2O_3$
Coliform, Total *	120	PA, G	Cool, <10°C, C
Specific Conductance	100	P, G	Cool, <6°C
Corrosivity	250	P, G	Cool, <6°C
Corrosivity (pH)	40	P, G	Cool, <6°C
Chromium, Trivalent	200	P, G	Cool, <6°C, HNO_3, pH<2
Chromium, Hexavalent	100	P, G	Cool, <6°C, NaOH, pH>8
Dissolved Oxygen	300	P, G	Cool, <6°C
Fluoride	25	P, G	Cool, <6°C
Ignitability	75	P, G	Cool, <6°C
Fluoride, Total (Dist.)	300	P, G	Cool, <6°C
Hardness	100	P, G	Cool, <6°C, HNO3, pH<2
Iodide	100	P, G	Cool, <6°C
Surfactants (MBAS)	100	P, G	Cool, <6°C
Coliform Fecal (MF) *	100	PA, G	Cool, <10°C, 0.0008% $Na_2S_2O_3$
Nitrogen, Ammonia	100	P, G	Cool, <6°C, H_2SO_4, pH<2
Nitrogen, Nitrite	50	P, G	Cool, <6°C
Nitrogen, Nitrate	50	P, G	Cool, <6°C
Nitrogen, Nitrate-Nitrite	50	P, G	Cool, <6°C, H_2SO_4, pH<2
Nitrogen, Organic (TKN/NH3)	250	P, G	Cool, <6°C, H_2SO_4, pH<2
Threshold Odor	1000	G	Cool, <6°C
Oil and Grease	1000/500**	G	Cool, <6°C, H_2SO_4, pH<2
Petroleum Hydrocarbons	1000/500**	G Teflon Lined Cap	Cool, <6°C, H_2SO_4, pH<2
Percent Moisture	25	P, G	Cool, <6°C
Percent Solids	25	P, G	Cool, <6°C
Paint Filter Liquids Test	25	P, G	Cool, <6°C
Phenolics, Total	500	G	Cool, <6°C, H_2SO_4, pH<2
Phosphorus, Total	50	P, G	Cool, <6°C, H_2SO_4, pH<2
pH Lab	40	P, G	Cool, <6°C
Orthophosphate	50	P, G	Cool, <6°C
Reactivity, Cyanide	10	G	Cool, <6°C
Reactivity, Sulfide	10	G	Cool, <6°C
Settleable Solids	1000	P, G	Cool, <6°C

Table 4-1 (Cont'd)

Sample Containers and Preservation

CONVENTIONAL - WATER

PARAMETER	MINIMUM VOLUME (ml)	CONTAINER TYPE	PRESERVATIVE
Silica, Dissolved	100	P	Cool, <6°C
Specific Gravity	50	P, G	Cool, <6°C
Total (Organic) Sulfur	100	P, G	Cool, <6°C
Sulfide	500	P, G	Cool,4ºC,Zinc Acetate, NaOH,pH>9
Total Dissolved Solids	100	P, G	Cool, <6°C
Nitrogen, Total Kjeldahl	50	P, G	Cool, <6°C, H_2SO_4, pH<2
Total Organic Carbon	50	P, G,	Cool, <6°C, H_2SO_4, pH<2
Total Organic Halides (subcontracted)	100	Amber G	Cool, <6°C, H_2SO_4, pH<2
Total Solids	100	P, G	Cool, <6°C
Total Suspended Solids	100	P, G	Cool, <6°C
Turbidity	50	P, G	Cool, <6°C
Volatile Dissolved Solids	100	P, G	Cool, <6°C
Total Volatile Solids	100	P, G	Cool, <6°C
Volatile Suspended Solids	100	P, G	Cool, <6°C
Volatile Acids	150	P, G	Cool, <6°C

* $Na_2S_2O_3$ is required when chlorine may be present in the sample.

** 500 ml used for select wastewater sampling

VOLATILE ORGANIC (VOA) - WATER

PARAMETER	MINIMUM VOLUME	CONTAINER TYPE	PRESERVATIVE
EPA 600 or 8000 Series	40 ml	G Teflon Lined Septa Caps	Cool, <6°C, HCl, pH<2 0.008% $Na_2S_2O_3$ if residual chlorine present

SEMIVOLATILE ORGANIC - WATER

PARAMETER	MINIMUM VOLUME	CONTAINER TYPE	PRESERVATIVE
EPA 600 or 8000 Series	1000 ml	Amber G Teflon Lined Cap	Cool, <6°C
Petroleum Hydrocarbons	1000 ml	Amber G Teflon Lined Cap	Cool, 4° C, H_2SO_4, pH<2

METALS - WATER

PARAMETER	MINIMUM VOLUME	CONTAINER TYPE	PRESERVATIVE
All Metals (26)	250 ml	P, G	HNO_3, pH<2
Mercury	100 ml	P, G	HNO_3, pH<2
Chromium, Hexavalent	100 ml	P, G	Cool, <6°C, NaOH pH>8

Table 4-1 (Cont'd)

Sample Containers and Preservation

TCLP - WATER

PARAMETER	MINIMUM VOLUME	CONTAINER TYPE	PRESERVATIVE
TCLP Volatiles	250 ml	G	Cool, <6°C
TCLP Semi-Volatiles	1000 ml	G	Cool, <6°C
TCLP Pesticides	1000 ml	G	Cool, <6°C
TCLP Herbicides	1000 ml	G	Cool, <6°C
TCLP Metals	500 ml	G	Cool, <6°C

AIR ANALYSES

PARAMETER	MEDIA
Metals	Mixed Cellulose Ester Filter
Total Dust	PVC Tared or Matched Weight (37mm)
Welding Fumes	MCEF Tared or Matched Weight (37mm)
Alkalinity (Sodium Hydroxide & Potassium Hydroxide)	Mixed Cellulose Ester Filter
Cyanide Aerosol (Cyanide gasses absorbing solution)	MCEF Untared (37mm)
Respirable Dust	Poly Vinyl Chloride
Silica	PVC Tared (37mm)
Chromium IV	Poly Vinyl Chloride PVC Untared (37mm)
Coal Tar Pitch Volatiles (Benzene Solubles)	Glass fiber
Oil Mist (by Weight or IR)	GF Tared (37mm)
Fluoride - Set	Untared MCEF & Treated pad (2 37mm cassettes)
Cyanide, gas	15mls, 0.1 N KOH
Gluteraldehyde	Treated filter
Isocyanates (MDI,TDI,HDI)	Treated filter
Sulfur (Dioxide/ Oxides of sulfur)	Treated filter
Acids	Cleaned silica gel sorbent tube
Particulates TSP	Glass Fiber Filter (8" x 10") - Tared
Particulates PM10	Quartz Fiber Filter (8" x 10") - Tared
Volatile Organics Solvents - Common IH	Coconut Shell Charcoal Sorbent Tubes
Volatile Organics - Ambient Air	Summa Canisters, BottleVac and Carbo Trap 300 Tubes
Volatile Organics - Other	Silica Gel, XAD Resins, etc., (Consult Appropriate Method)

Table 4-1 (Cont'd)

Sample Containers and Preservation

AIR ANALYSES

PARAMETER	MEDIA
Formaldehyde - IH 15ml 1% Sodium Bisulfate	Treated - XAD-2 (i.e., Orbo 23/24)
Formaldehyde - Ambient Air	DMPH Solution or DMPH Coated Cartridges
Polynuclear Aromatic Hydrocarbons - IH	Teflon Filter + XAD-2 Sorbent Tube
Polynuclear Aromatic Hydrocarbons - Ambient Air	Glass Fiber Filter /PUF/XAD/PUF
Polychlorinated Biphenols (PCB's) - IH	Glass Fiber Filter + Fluorosil
Polychlorinated Biphenols (PCB's) - Ambient Air	Glass Fiber Filter + PUF
Pesticides - IH	Glass Fiber Filter (May Require other media, Consult Method)
Pesticides - Ambient Air	Glass Fiber Filter + PUF
Other Semi-Volatile Organics	Various Media (Consult Method)
Microbiological sampling media	Prepared as requested

NOTE:

Tared filters have a identifying number affixed to the cassette

1. P = Polyethylene (preferred when acceptable).

2. G = Borosilicate glass with Teflon lined cap.

3. PA = Any plastic that can be sterilized (able to be autoclaved plastic).

3. Triple the volumes above for MS/MSD samples.

4. For treated filters or impinger solutions please contact the lab.

Soils

Soil sample containers are generally wide mouth glass (4-8 oz.). Soil volatile organics require methanol preservation or low-level preservation techniques (refer to 8260 SOP).

5.0 SAMPLE RECEIPT AND CUSTODY PROCEDURES

5.1 SAMPLE CUSTODY DEFINITION

5.1.1 A sample or evidence file is in a person's custody if one or more of the following occur:

5.1.1.1 The item is in actual possession.
5.1.1.2 The item is in view following actual possession.
5.1.1.3 The item was in actual possession but is locked up to prevent tampering.
5.1.1.4 The item is in a designated and identified secure area.

5.1.2 RTI Laboratories are maintained as secure locations with controlled access.

5.1.3 Under normal custody procedures all samples are considered in the possession of the sample custodian or laboratory personnel that have received the sample transfer as documented in the LIMS sample tracker module.

5.1.4 Custody procedures include:

5.1.4.1 Samples maintained under limited access conditions (sample custodian or designated personnel only have access until the samples are ready for preparation or analysis).

5.1.4.2 All transfers of samples will be documented.

5.1.4.3 The LIMS system provides for sample tracking and strict internal transfers of samples with appropriate documentation of the transfers

5.1.4.4 Procedures for legal/evidentiary chain of custody are established and specified in the SOP for sample receipt and custody.

5.2 SAMPLE RECEIPT

5.2.1 All samples received are accepted by and signed in the "received by Laboratory" section of the chain of custody by Laboratory personnel.

5.2.2 Samples or sample containers are delivered directly to sample log in immediately upon receipt.

5.2.3 RTI personnel that are assigned to pick up samples from a client location are required to ensure that the samples have been signed as relinquished, verify sample containers agree with the Chain of Custody and sign for receipt on the Chain of Custody. These personnel will then relinquish the samples to the Laboratory sample custodian.

5.2.4 Personnel that are assigned to collect samples will initiate and complete a Chain of Custody form and follow all appropriate procedures.

5.3 VERIFICATION AND INSPECTION

5.3.1 The sample custodian verifies that custody seals are in place (where applicable), notes any damage to exterior containers or to samples and ensures all documents have been included.

5.3.1.1 Damaged samples or containers are moved to a hood and a supervisor is notified.

5.3.1.2 Damage is assessed and samples are either rejected or accepted at the Laboratory Director's or designated supervisor's discretion. The client is notified if samples are rejected or if the damage may affect the analytical process.

5.3.1.3 Temperatures of samples are taken upon opening the cooler and recorded in the checklist for each work order. Checklists are maintained electronically in the LIMS for each work order and contain all the necessary information required to assess sample acceptance.

5.3.1.4 For damaged soil jars noted in containers originating from regulated areas (foreign or US regulated areas) under the United States Department of Agriculture (USDA) Compliance Agreement any loose material must be transferred to a container, segregated with the accompanying samples and disposed according to the procedures in Section 5.6.

5.3.2 The sample custodian verifies that the identification and number of samples match the chain of custody and that the chain of custody has been properly filled out. Any problems are brought to the attention of the client or sampler before proceeding.

5.3.3 The sample custodian compares the request for analysis to the samples received. The following are checked:

5.3.3.1 The proper container was used and enough volume submitted.

5.3.3.2 Methods requested by the client. If a method requested is inappropriate or out of date the client must be contacted.

5.3.3.3 Holding times have not been exceeded.

5.3.3.4 Preservative is noted on containers where appropriate to the analytical request.

5.3.3.5 Free chlorine determinations are conducted for analyses requiring the checking for the presence of free chlorine and noted on the sample receipt form.

NOTE: Proper preservation is verified on sample receipt. A small volume of sample is transferred to a separate container and the pH, chlorine concentration or other parameters as needed are checked and documented on the chain of custody and sample receipt check list. Under no circumstances will any device be introduced directly into the sample. This procedure does not apply to samples submitted for volatiles or other analyses that require maintenance of zero headspace. Preservation checking will be performed following analysis of the sample.

5.3.3.6 Drinking water samples received for bacteria testing must note any deficiency in the condition of the sample. Samples may be invalidated for the following conditions.

5.3.3.6.1 Time between collection and receipt at the laboratory has been exceeded.

5.3.3.6.2 Presence of disinfectant is noticed (i.e. odor).

5.3.3.6.3 Evidence of sample freezing.

5.3.3.6.4 Use of unapproved container.

5.3.3.6.5 Insufficient sample volume (i.e. <100 ml).

5.3.3.6.6 Presence of interfering contaminants if notices (i.e. hydrocarbons, heavy metals, etc.)

5.3.3.6.7 Sample temperature exceeds the maximum allowable.

5.3.4 The sample receipt checklist attached to the work order in the LIMS is completed and the notification form sent to the client when required.

5.4 SAMPLE LOG IN AND STORAGE

5.4.1 The sample custodian logs all samples into the Laboratory LIMS (Laboratory Information Management System - Omega) according to the SOP for Sample Receipt and Custody (SRC001-A).

5.4.2 The appropriate information is entered into Omega.

5.4.3 Sample numbers are automatically assigned by the LIMS and are unique for each sample and fraction. In addition the LIMS provides the ability to designate the number of containers associated with a sample and assigns a unique Container X of X designation for each container.

5.4.4 Sample labels and log sheets are printed.

5.4.5 Sample labels containing the Laboratory identification number are placed on the corresponding sample. This number will be used to track the sample through the analytical process. Samples received under the USDA soil permit are clearly labeled as such and segregated.

5.4.5.1 All necessary analytical sub sets taken from the original sample container will include this number.

5.4.5.2 All digestion solutions, extracts or other sample preparation aliquots will have this number on the appropriate containers.

5.4.5.3 Information entered into logbooks, computer data files, instrument data handling systems or any other will contain the applicable sample number.

5.4.5.4 Analytical data imported or entered into the LIMS will occur via the associated sample number.

5.4.5.5 This number will be used to track and identify the sample throughout the analytical process.

5.4.6 The client Project Manager or designated personnel will review all work orders for accurate logging of the samples submitted and enter the date of review in Omega. Required corrections to the work order will be made prior to completing login review. Once the login review process has been completed, changes to the work order cannot be made without the necessary authority assigned through specified user credentials incorporated in the LIMS. A Director, Project Manager or the LIMS Administrator are the only individuals with the authority to change a work order that has been log reviewed (Refer to SOP for login review - LOGREV-032318_R1.1).

5.4.7 Samples are placed in the walk-in refrigerator, designated area in the laboratory or segregated storage. Designated sample storage areas are incorporated into the LIMS and used to track the location of samples. Sample storage areas are under direct surveillance of the sample custodian or assigned laboratory personnel and are securely maintained.

5.4.8 The sample custodian will notify the appropriate laboratory personnel when samples are received with a quick turn-around-time request, short hold times, or a short amount of hold time is remaining.

5.5 INTERNAL TRANSFERS

5.5.1 All internal transfers are documented in the Sample Tracker module of the LIMS.

5.5.2 All persons taking possession of the sample will document the transfer by posting the change in the Sample Tracker.

5.5.3 All transfers will contain the person or location that the samples were transferred from and the individual that is initiating the transfer.

5.5.4 Samples are tracked from log-in through disposal.

5.6 SAMPLE RETENTION/DISPOSAL

5.6.1 Samples and extracts will be stored in designated areas within the laboratory and all samples will be able to be tracked through the LIMS.

5.6.2 Sample and/or sample extracts are stored for a period of thirty (30) days (or as stipulated by contract). Exceptions are samples/extracts that are completely consumed or used for analysis (i.e. thermally desorbed air samples and carbon disulfide desorbed charcoal - no storage time beyond analysis).

5.6.3 Sample disposal logs are generated by the LIMS and supplied to the individual designated for disposing of samples/sample extracts.

5.6.4 At the expiration of the storage period, samples are disposed by the following means. All waste disposals, hazardous or otherwise, comply with all local, state and federal regulations.

5.6.4.1 Soil samples are composited and disposed to a sanitary landfill or composited into drums and disposed by a subcontracted disposal company.

5.6.4.2 Surface water, ground water and drinking water samples are discharged to the local POTW.

5.6.4.3 Highly acidic or basic extracts are composited in acid waste and alkaline waste drums respectively and disposed by a subcontract disposal company.

5.6.4.4 Organic solvents are composited in an appropriate metal drum and disposed by a subcontract disposal company.

5.6.4.5 Asbestos waste is double bagged in labeled asbestos bags and sent to an appropriate landfill.

5.6.4.6 Soil/solid samples received under the USDA soil permit (Refer also to SOP SRC001-A_R1) are disposed as follows:

5.6.4.6.1 Samples are heated in a drying oven for one of the specified times and temperatures below:

5.6.4.6.1.1	100 – 120.5	degrees C for 16 hours
5.6.4.6.1.2	121 – 154	degrees C for 2 hours
5.6.4.6.1.3	154.5 – 192.5	degrees C for 30 minutes
5.6.4.6.1.4	193 – 220	degrees C for 4 minutes
5.6.4.6.1.5	221 – 232	degrees C for 2 minutes

5.6.4.6.2 The heating time and temperature are recorded in the disposal logbook.

5.6.4.6.3 Samples are removed from the oven, allowed to cool and re-heated following steps 5.6.4.6.1 and 5.6.4.6.2 above.

5.6.4.6.4 Following heat treatment, samples are disposed according to 5.6.4.1.

5.6.5 The laboratory maintains manifest records for applicable waste disposal.

5.6.6 RTI maintains an EPA small generator number and is registered with local, state and federal agencies maintaining jurisdiction over waste disposal practices.

5.7 SAMPLE SECURITY

5.7.1 Sample storage areas are located within the laboratory portion of the individual facilities. Laboratories are controlled access areas within the facilities.

5.7.2 The main sample storage refrigerators are under strict controlled access and surveillance. Only selected personnel have access to the sample storage units and the area is monitored by the sample custodian or designated individual. All samples, extracts and digests will be stored in secured segregated areas.

5.8 LABORATORY BUILDING SECURITY

5.8.1 All access doors to the buildings, with the exception of the main entrances are posted with signs indicating No Admittance, Employees Only and instruct all visitors and vendors to the main entrance. Only RTI employees have keys to the access doors to the buildings. The main entrance is unlocked only on business days during established business hours. The facilities are also equipped with electronic alarm systems and employees are assigned unique pass codes for entry.

5.8.2 Employee Access

5.8.2.1 Employees are issued keys and can access the building through designated entrances. Keys and pass codes are required for the main entrance during non business hours.

5.8.3 Visitors, Vendors and Deliveries

5.8.3.1 All visitors to the office or laboratory must enter the main lobby through the main entrance and check in with the receptionist. A sign in log is located at the reception station. Visitors must be escorted at all times and in all areas of the facility.

5.8.3.2 Vendors and delivery personnel after check in may be directed to use the door to the Shipping and Receiving area. An RTI employee will provide access to this door and, upon entrance, the visitor must be escorted at all times.

5.9 SAMPLE SUBCONTRACTING/SHIPPING

5.9.1 For certain projects, it may be necessary for RTI to subcontract some analyses. In these instances, either prior arrangements will have been made with the client or the client will be contacted regarding the need to subcontract samples. Notification of sub-contracting will be provided to the client in writing (in cases where sample analyses are routinely sub-contracted and the client has approved the arrangements subsequent written notifications are not necessary). Client approvals for sub-contracting will be preferably maintained in written form and attached to the client electronic file in the liked files section in Omega. Samples will be shipped to the contracted laboratory in approved sample containers. Samples requiring refrigeration will be shipped in coolers containing a combination of ice packs and wet ice to maintain the temperature at 4°C.

5.9.2 All Chain of Custody forms and any pertinent paperwork will be included with the samples.

5.9.3 Subcontracted analyses will be sent to a laboratory specified by the client or when not specified to a laboratory that maintains the required certification (NELAC, DoD ELAP, etc.) applicable to the project.

5.9.4 Procurement of subcontract laboratories will occur by verifying the laboratory's certifications. The laboratory maintains a listing of sub-contractors in the vendor section of the LIMS with any notations of

certifications or any required documentation. For analyses that are either outside of the scope of the certifying authority or that do not require a specific certification the laboratory will be chosen based on one or more of the following:

5.9.4.1 Ability to perform the required methodology.
5.9.4.2 Prior experience with the laboratory.
5.9.4.3 Laboratory reputation or client recommendation.
5.9.4.4 Review of PE data (where applicable).
5.9.4.5 Review of laboratory QAP and/or SOPs (when required).
5.9.4.6 On-site review of the laboratory (when appropriate).

5.9.5 Projects performed under certain programs or agencies (i.e. DoD, USACE, CLP, etc) require subcontracted work to be sent to laboratories approved by the agency or the client of the agency. In these instances, all documentation pertaining to the approval and subsequent subcontracting will be maintained.

5.10 CLIENT COMMUNICATIONS

5.10.1 Client contracts are reviewed by the General Manager, Director, Sales and Marketing or Laboratory Director to ensure that the laboratory can meet the requirements for a particular project.

5.10.2 RTI will maintain a strict policy of client confidentiality. Any information, results or communication with a client will not be disseminated to any outside party without authorization in writing from the client.

5.10.3 Procedures for client complaints and communication:

5.10.3.1 Identify and document client concern either within the LIMS work order, on the work order summary sheet or chain of custody.

5.10.3.2 Retrieve any necessary pertinent information.

5.10.3.3 Discuss problem with a Director or appropriate management personnel.

5.10.3.4 A Director, a Project Manager or designated individual will contact the client to discuss the findings of the laboratory.

5.10.3.5 If a change to the analytical report is required, the changes will be made (and if appropriate any changes on raw data logs will be initialed and dated by the person making such changes) and the report will be issued with a notation of revised report.

5.10.4 A Director, a Project Manager or designated individual will consult with the client on matters pertaining to project data quality objectives. These will include situations where incorrect methods may be requested, instances where sample matrix or type may impact method performance, clarification on project Data Quality Objectives (DQOs) and issues regarding sample collection and handling.

6.0 EQUIPMENT, CALIBRATION PROCEDURES, STANDARDS AND REAGENTS

6.1 INSTRUMENT CALIBRATION AND EQUIPMENT

6.1.1 Calibration procedures for specific instrumentation are documented in the method specific SOP. The initial calibration (including required number of data points), initial calibration verification and continuing calibration procedures and frequencies are specified (See summary Table 6-2 – in cases of inconsistencies with the method specific SOP, the procedures in the SOP will take precedence over the Table). In all instances the calibration requirements of the reference method, accreditation program or project specifications will be followed.

6.1.1.1 Proper use and operation of testing equipment is ensured through:

6.1.1.1.1 Instructions provided by the manufacturer on installation of equipment.

6.1.1.1.2 External training where applicable.

6.1.1.1.3 Internal training by supervisors or senior staff experienced in the proper operation of the equipment.

6.1.1.1.4 Quality control procedures designed to monitor equipment performance and detect deviations that could jeopardize analytical results.

6.1.1.1.5 Compliance with accreditation standards, regulatory requirements and reference methods. In instances where it is not apparent which standard is more stringent the requirements of the regulation or test method will be followed.

6.1.2 At a minimum all instruments undergo a calibration or calibration verification daily or with each use.

6.1.3 Initial calibrations must be performed using continuous standard data points. Dropping non-contiguous calibration standards is not allowed unless technical justification is documented. Standards used for calibration must be obtained from a vendor certified by ISO Guide 34 (when available). In addition the standard must appear on the vendor's scope of standards certified under ISO Guide 34

6.1.4 The lowest standard in a calibration must be at a level equal to or less than the Limit of Quantification (LOQ)/Reporting Limit (RL).

6.1.5 The criteria for evaluating the calibration (i.e. linearity, %RSD) and the acceptance values are contained within the appropriate section of the SOP and conform to method specifications where applicable.

6.1.6 All initial calibrations are verified with an independently prepared calibration verification solution at a concentration between the mid-point of the calibration curve and the lowest calibration standard. The second source standard must be from a different vendor unless no other source is available. In the case that a second vendor is not available for a particular standard a different lot from the calibration standards must be obtained. Standards used for verification must be obtained from a vendor certified by ISO Guide 34 when available. At a minimum when Guide 34 standards are available the calibration standard will be certified to Guide 34. The second source standard is not required to be Guide 34 certified but RTI will strive to procure both standards appropriately certified. If a second source standard is not available for a specific analyte a calibration verification standard is prepared independently from the calibration standards by one or more of the following:

6.1.6.1 Prepared by a different person.

6.1.6.2 Prepared by the same person using different apparatus.

6.1.6.3 Prepared by the same or different person using an independently prepared solution.

6.1.6.3 Prepared by the same person at a different time than the calibration standards.

6.1.6.4 In all cases the preparation must demonstrate that the preparation of the verification standard was independent of the calibration standard preparation and sufficiently documented.

6.1.7 Continuing calibration verification is performed after every ten samples analyzed unless specified otherwise in the method SOP.

6.1.8 All raw data records to allow reconstruction of the calibration and calibration verification will be maintained for 7 years.

6.1.9 Sample data must be quantified from the current and applicable initial calibration. Any situation that triggers the beginning of the recalibration process renders the prior calibration unusable for sample quantification. It is never acceptable to use a previous calibration curve to quantify samples after subsequent calibration events.

6.1.10 Calibration records are maintained for all initial calibrations performed and are able to be traced to any samples analyzed using that calibration. The LIMS calibration reference is included in the LIMS analytical sequence for all applicable sample results.

6.1.11 Instruments under service contract are serviced and calibrated at least annually by a service engineer. Instruments not covered are serviced by RTI staff according to the manufacturers recommended guidelines and documented in instrument logs (section 6.2)

6.1.12 Reference materials (such as thermometers and weights) are stored in such a manner as to prevent contamination or deterioration and in order to protect their integrity.

6.1.13 Balances are cleaned and calibrated annually by a subcontracted firm. Balance verification masses are certified annually by a subcontracted vendor. Balances are checked on each use and the weight recorded. Check weights must be within the criteria specified in Table 6-2.

6.1.14 Thermometers are verified once per year against a NIST standard thermometer. The NIST thermometers are calibrated once per year by an outside vendor. Verifications will be performed at two temperatures bracketing the temperatures of use or if used at a single temperature verification will be performed at the temperature of use. Electronic thermometers are verified on a quarterly basis at two temperatures bracketing the range of use. For devices with a narrow or single use range (ex. Incubators) the monitoring thermometer will be verified at the temperature of use. Logs for recording the verifications will include the following.

6.1.14.1 Serial numbers of the thermometer and the associated NIST thermometer.

6.1.14.2 Temperature of the thermometer and the temperature of the associated NIST thermometer.

6.1.14.3 Date of verification and initials of the person performing the check.

6.1.14.4 Correction factor if applicable.

6.1.14.5 Thermometer verifications that result in the necessity to apply correction factors will be recorded and the applicable factor applied to the readings.

6.1.14.6 Thermometers must meet specifications listed in Table 6-2.

6.1.15 Daily or prior to each use balances, ovens, refrigerators, freezers, water baths and hot blocks will be checked to ensure use at the specified value or continued acceptable performance. Checks will be documented on the appropriate log that will contain the acceptance criteria and date and person performing the verification. Specifications are listed in Table 6-2.

6.1.16 Equipment used in the analytical processes (refrigerators, freezers, balances, extraction apparatus, distillers, autoclaves, volumetric dispensing devices, ovens, incubators, etc.) must be calibrated and verified at least annually. Documentation of the calibration/verification must be maintained in the Omega equipment maintenance logs or on the applicable bench logs. Repair or maintenance activities will be recorded in the equipment maintenance logs.

6.1.16.1 All equipment as noted above and including pipettes, syringes, and other apparatus used in the analytical process are logged in the LIMS equipment section.

6.1.16.2 Equipment sets are established in the LIMS to include applicable apparatus associated with the use.

6.1.16.3 The equipment associated with a preparation or analytical procedure is linked in the LIMS preparation batch forms and in the analytical sequences and will designate all equipment that was used in the process.

6.1.17 Ovens, refrigerators and incubators used for sample storage or preparation have temperatures recorded on a continuous basis at specified frequencies. Logs are maintained electronically with the individual readings and the acceptable range.

6.1.18 Class A volumetric measuring devices (micro liter syringes are considered as Class A) must have a certificate with the accuracy determined by the manufacturer. Devices that do not have certificates must be assessed for acceptability of use by the laboratory and documented. Other measuring devices (Class B and non-volumetric) must be verified according to Table 6-2.

6.1.19 Mechanical measuring devices such as pipettes must be checked daily. This is performed by verifying the volume at the volume of use with three readings. The mean of the readings must be within 2% of the expected volume and the %RSD less than 1%.

6.1.20 Autoclave temperature, cycle time and pressure are monitored for suitability by appropriate indicators and recording of readings.

6.1.21 Instrumentation that has been deemed to be inoperable due to failure to meet the calibration requirements specified in the method or has demonstrated a condition that requires it to be removed from operation will be tagged to indicate that this instrument is not currently operable and cannot be used for any sample analyses.

6.20.1.1 Information will be visibly displayed to indicate that the equipment is "Out of Service" and the date that the instrument was removed from operation. Once the instrument has been tagged out of service only the Laboratory Director, QA Manager or Laboratory Supervisor can remove the tag following verification of the appropriate corrective action measures.

6.20.1.2 Any samples that were analyzed during an instrument malfunction are to be designated for re-analysis either by a backup instrument or by the original instrument when it becomes satisfactorily operational.

6.20.1.3 All corrective actions taken to restore an instrument to an operational condition will be documented in the LIMS maintenance logs. The QA Manager, Laboratory Director or Laboratory Supervisor will review the corrective actions and verify that adequate performance is attainable.

6.20.1.4 Acceptable corrective actions will be approved by the QA Manager, Laboratory Director or Laboratory Supervisor who will then remove the out of service tag from the instrument.

6.1.22 All apparatus and consumable supplies will be assessed to ensure that the requirements and specifications of any testing procedure will be met. Records of the verifications will be maintained. Procedures for ensuring materials are suitable for use include:

6.1.22.1 Certificates from the manufacturer reviewed for compliance.

6.1.22.2 Laboratory verifications for materials that are not certified by the manufacturer that ensure that the material is acceptable for use including volume checks, contamination checks, purity verification and any other required by the reference method.

6.1.23 Equipment services are provided by instrument manufacturer's technicians or other service representatives possessing the necessary qualifications and experience to service equipment. Laboratory management is responsible for securing the appropriate service companies.

6.1.24 Procedures for catastrophic failure of support equipment (e.g. refrigerators, freezers).

6.1.24.1 Catastrophic failure is defined as a situation where the equipment is not capable of maintaining acceptable performance to the degree that sample integrity cannot be maintained or assured or; any occurrence where the failure of the equipment has a potential deleterious effect on sample data.

6.1.24.2 Samples that are affected by the equipment failure must be identified and assessed for the degree of the potential impact.

6.1.24.3 In cases where it has been determined that samples have been compromised by the failure of the equipment the client will be notified.

6.2 EQUIPMENT/INSTRUMENT LOGS

6.2.1 All instruments are logged in the Omega LIMS with the applicable information for each instrument. Some analytical instruments may have logs that were initiated on installation or initial use (appropriate information is transferred to the LIMS with initial logs maintained for reference). The Omega instrument files contain any routine procedures and specified frequency required to maintain the instrument. Information in these files includes:

6.2.1.1 Instrument identification
6.2.1.2 Serial Number
6.2.1.3 Installation Date
6.2.1.4 Notations for required maintenance and date
6.2.1.5 Maintenance (preventative or problematic) performed either internally or by a manufacturer's service engineer.

6.2.2 All maintenance performed on an instrument including daily maintenance activities (i.e. septum changing, daily cleaning, etc.) are recorded in the LIMS maintenance logs.

6.3 CHEMICALS, STANDARDS AND STANDARD LOGS

6.3.1 All chemicals received at the laboratory are logged in the Omega LIMS chemical inventory and assigned a unique number that will be used to reference any uses of this material. The information in the chemical inventory will be entered completely and include identity, date received, lot number, expiration data and containers.

6.3.2 LIMS logs will include all information regarding the traceability, purity, dates of preparation, expiration dates, person preparing and unique identification. Expiration and storage information is specified in the applicable method SOP.

6.3.3 Upon receipt standards are immediately delivered to the area of the laboratory in which they will be used.

6.3.4 A supervisor or analyst will place the date received on the label and put the standard in the designated storage area and log the standard in the LIMS.

6.3.5 Standards will be segregated as to type (i.e. organics, acids, etc.) and stored under proper conditions. For example, volatile organic standards are stored in a separate freezer from samples or any other standard materials or reagents.

6.3.6 Certifications or lot analyses containing purity assays accompanying the standards are kept on file in the laboratory in proximity to the standard material or scanned and linked in Omega (in which case the hard copy certificate is not retained).

6.3.7 Standard logs are maintained electronically in the LIMS to document the preparation of stock, intermediate and working standards. All standards will be assigned a unique standard identification. These logs will contain at a minimum:

6.3.7.1 Standard Name
6.3.7.2 Analyte and lot number
6.3.7.3 Amount used
6.3.7.4 Dilution volume
6.3.7.5 Final concentration
6.3.7.6 Initials and date
6.3.7.7 Expiration date

6.3.8 Standards are purchased as neat materials, commercially prepared solutions or certified standard reference materials.

6.3.8.1 When neat materials are used to prepare a stock standard the appropriate information is noted on the standards section of the LIMS including the purity of the reference material.

6.3.8.2 Commercially prepared solutions used as stock standards are logged in the LIMS with the appropriate information on the standard log.

6.3.8.3 LIMS standard logs include primary (stock), secondary, tertiary and neat standards. All information for the preparation of the standards including any reagents used will be recorded in the LIMS standard log. Certificates of analysis are electronically attached in the LIMS standard log.

6.3.8.4 Standards are required to be obtained from a vendor certified by ISO Guide 34. Vendor certification is noted in the Vendor Section of the LIMS. Additionally the standard must be on the Guide 34 scope of standards for that vendor. Certificates stating the certification status for that standard are maintained with the material in the LIMS standards section. Guide 34 standards are required unless it is determined that no source for that standard is currently available.

6.3.8.5 The Laboratory as a general practice will obtain standards certified to Guide 34 for both the primary calibration standard and the second source verification standard. However, only one Guide 34 standard is required when available.

6.3.9 All intermediate and working standards prepared are logged in the LIMS. The preparation of the appropriate standard and the shelf life are specified in the SOP for the particular analyte.

6.3.10 All standards used for the analysis of samples are logged in the analytical sequence for each analytical event. All sample analysis will be able to be traced to the standards used for calibration and calibration verification.

6.3.11 Standards used in the preparation of quality control samples (LCS, MS/MSD) will be logged in the sample preparation section of the LIMS for each batch or in the analytical sequence if sample preparation is not a part of the procedure. All batch QC samples will be able to be traced to the standards used for the preparation of the quality control samples.

6.4 CONTROL OF PURCHASED ITEMS AND SERVICES

6.4.1 Laboratory vendors are chosen based on the quality of items provided and the ability to service the laboratory's need. All decisions to use any particular vendor are made by laboratory management.

6.4.2 Vendors approved for use by the Laboratory are logged in the Omega LIMS. Only vendors on this list can be used to obtain chemicals, supplies, equipment or services.

6.4.3 Analysts submit requisitions for supplies to the Laboratory Director for approval. A designated individual assigns a purchase order number and orders the requested items from the vendors used by the Laboratory. Individual items in excess of $500 require approval by the General Manager/President.

6.4.4 Vendors are qualified based on their ability to:

6.4.4.1 Stock and deliver the items normally requested by the Laboratory.

6.4.4.2 Possess the items required by the Laboratory in the necessary purity and level of quality required by the Laboratory.

6.4.4.3 Provide the most competitive price for the items and required level of quality.

6.4.4.4 Meet any applicable accreditation requirements.

6.4.5 Reagents and standards must meet the minimum requirements specified in the method or at minimum be within the specification noted below and within acceptable general laboratory practices.

6.5 REAGENTS

6.5.1 Upon receipt, reagents are immediately delivered to the area of the laboratory in which they will be used.

6.5.2 A supervisor or analyst will place the date received on the label and put the reagent in the designated storage area and enter the appropriate information in the LIMS chemical inventory as specified in Section 6.3.1.

6.5.3 Reagents will be segregated as to type (i.e. organics, acids, etc.) and stored under proper conditions. For example, volatile organic materials are stored in a cabinet designed for flammable chemicals, separated from samples or any other standard materials or reagents.

6.5.4 Certifications or lot analyses accompanying the reagents are electronically attached in the LIMS.

6.5.5 The grade of reagent purchased is consistent with the intended need for the method being employed. Ultra pure chemicals (i.e. acids and solvents) are used for trace analyses (i.e. ICP/MS, Trace volatile analyses, etc.). Most other reagents are reagent grade (AR) or conform to method specifications.

6.5.6 MSDS sheets provided with reagents are filed in the laboratory and are accessible to all laboratory personnel.

6.5.7 The LIMS reagent section is used to document the preparation of various solutions used in certain methodologies. Reagent preparation information is completed in the LIMS with traceability to the chemicals logged in the chemical inventory.

6.5.8 Reagent storage conditions are specified in the analytical SOP.

6.5.9 All reagents and standards prepared must be logged in the LIMS and labeled with a minimum:

6.5.9.1 Identity of the material
6.5.9.2 Concentration of the solution
6.5.9.3 Date prepared
6.5.9.4 Initials of analyst preparing the solution
6.5.9.5 Expiration date.

6.5.10 Deionized Water System

6.5.10.1 The DI water system is installed and maintained by an outside vendor and includes all filters, ion exchange tanks and charcoal tanks.

6.5.10.2 Tanks are exchanged on a schedule determined by the manufacturer or when required based on the indicator light or daily conductivity reading.

6.5.10.3 Conductivity of the DI water is monitored daily and must be <1 micro ohm/cm.

6.5.10.4 Water is monitored monthly for bacteria and residual chlorine. The heterotrophic plate count must be <1CFU/ml and the residual chlorine must be <0.2 mg/L.

6.6 GLASSWARE/STORAGE CONTAINERS

6.6.1 The type of glassware, pipettes, storage containers, etc. required for each method is specified in the SOP. In general, designated Class A volumetric glassware and pipettes are used for the following applications:

6.6.1.1 Preparation of primary standards

6.6.1.2 Preparation and dilution of stock standards

6.6.1.3 Reagent standardization

6.6.1.4 As specified in the method

6.6.2 All reusable glassware is scrupulously cleaned before reuse. Table 6-1 summarizes the general glassware cleaning procedures. This procedure is posted in the glassware washing area.

6.7 REGULATED SOIL EQUPMENT DECONTAMINATION

6.7.1 Soil samples received under the USDA permit for receipt of foreign or regulated domestic soil are clearly designated with a colored label indicating – Foreign or Restricted Soil.

6.7.2 Regulated soil samples are segregated and stored under controlled conditions. Samples must be returned to the designated storage location following each use.

6.7.3 All equipment or supplies that have contacted the soil must be decontaminated by one of the following procedures.

6.7.3.1 Soak material in a fresh 10% bleach solution for at least 30 min.

6.7.3.2 Soak material in 70% ethanol.

6.7.3.3 Surfaces that have come in contact with the soil must be wiped with 70% ethanol using suitable material wetted with the ethanol solution.

6.7.3.4 Water residues used in any processing of the soil sample must be sterilized in an autoclave at 121 degrees C for a minimum of 30 minutes ate 15 psi. Autoclave indicator tape must be used and the appropriate color change observed prior to disposal. If the autoclave does not achieve the minimum time or temperature or the indicator tape does not change color the autoclaving must be repeated with successful results prior to disposal.

6.7.4 Prior to disposal all regulated soil samples must be maintained as quarantined material until sterilized. Containers must remain closed and secure during storage.

6.7.5 All remaining portions of the samples and the containers must be decontaminated according to the procedure in Section 5.6.

TABLE 6-1
LAB GLASSWARE CLEANING PROCEDURES

Analysis/Parameter		Cleaning Procedure (in order specified)
Extractable Organics (including Pesticides and Herbicides)		1-3, 6, 7, 13
Volatile Organics		Use either disposable glassware or steps 1, 2, 3, 16, 4
Trace Metals -	glass	1-6,
	plastic	1-4, 15, 6
Nutrients		1-4, 12
Minerals, COD, BOD, Radiochemistry, Cyanide, Phenols		1-4, 12
Residues		1-4, 9 or 10, 12
MBAS		1-4, 14, 12
Petroleum Hydrocarbons		1-4, 7, 14, 13
Oil & Grease		1-4, 7, 14, 9, 13

Cleaning Procedures (bottles and septa):

1. Remove all labels using sponge or acetone.
2. Wash with hot tap water and a brush to scrub inside of glassware, stopcocks, and other small pieces, if possible, using a suitable laboratory-grade detergent.
   - Organics - Liquinox, Alconox or equivalents
   - Inorganic anions - Liquinox or equivalent
   - Inorganic cations - Liquinox, Alconox, Micro or equivalents
   - Bacteriologicals - must pass an inhibitory residue test
3. Rinse thoroughly with hot tap water.
4. Rinse thoroughly with deionized water.
5. Rinse or soak with 10% Nitric Acid.
6. Rinse 3 times with deionized water.
7. Rinse thoroughly with pesticide grade Acetone.
8. Rinse thoroughly with pesticide grade Hexane.
9. Bake at 105 ^{o}C for 3-4 hours.
10. Bake at 180 ^{o}C for 3-4 hours (prior to use as per method).
11. After use, rinse with last solvent used.
12. Store inverted or capped with suitable material or suitable container stopper.
13. Last step (prior to use) should be a rinse with the solvent used in analysis.
14. Rinse thoroughly with acetone.
15. Rinse or soak with 1:1 HCl (Hydrochloric Acid).
16. Rinse with purge and trap grade Methanol.

Table 6 -2
Instrument/Equipment Calibration/Verification Summary

Instrument	Method Reference	# Standards Initial Calibration	Acceptance Rejection Criteria – Initial Calibration	Frequency of Calibration	Frequency of Initial Calibration Verification	Acceptance/Rejection Criteria - Initial Calibration Verification	Frequency of Continuing Calibration Verification	Acceptance/Rejection Criteria – Continuing Calibration Verification
Thermometers	DoD QSM, Version 5.0	2 temps.that bracket the target temp. or at temp. of use for single temp. use	+/- 0.1 degree C or correction factor applied	On receipt			Annually for liquid in glass. Quarterly for electronic devices.	+/- 0.1 degree C or correction factor applied
Refrigerators/ freezers	DoD QSM, Version 5.0		Refrigerators – 0-6 degrees C Freezers - < -10 degrees C	On receipt			Daily (7 days per week)	Refrigerators – 0-6 degrees C Freezers - < -10 degrees C
Class B Volumetric Glassware or Class A when required for verification	DoD QSM, Version 5.0		2% of expected, <1% RSD, based on 10 replicates	Each lot before first use.	On evidence of deterioration			
Glass Microliter Syringes	DoD QSM, Version 5.0		Certificate with receipt		On evidence of deterioration			
Mechanical Pipettes	DoD QSM, Version 5.0		2%of expected – precision <1%RSD, based on minimum 3 replicates	Daily or each use				
Ovens	DoD QSM, Version 5.0		Within 5% of set temp.	On receipt			Each use	Within 5% of set temp
Non Volumetric Glassware	DoD QSM, Version 5.0		3% of expected, <3% RSD, based on 10 replicates	Each lot before first use.	On evidence of deterioration			
Balances	DoD QSM, Version 5.0		Passes service specifications	Annually			Daily (each use)	The larger of +/-0.1% or +/- 0.5 mg –Analytical The larger of +/- 2% or +/- 0.02 g – Top loading
Balance weights	DoD QSM, Version 5.0			Annually		Certificate from accredited vendor		

Table 6 -2
Instrument/Equipment Calibration/Verification Summary

Instrument	Method Reference	# Standards Initial Calibration	Acceptance Rejection Criteria – Initial Calibration	Frequency of Calibration	Frequency of Initial Calibration Verification	Acceptance/Rejection Criteria - Initial Calibration Verification	Frequency of Continuing Calibration Verification	Acceptance/Rejection Criteria – Continuing Calibration Verification
AA	EPA 200 series SW-846 7000 series	3-5	Correlation coefficient must be $\geq$ 0.995	At least daily, or as required (when CCV fails acceptance criteria)	Every Calibration	90-110%R	Every 10 analytical samples	80-120%R
AA	ASTM/ NIOSH/OSHA	3-5	Correlation coefficient must be $\geq$ 0.995	At least daily, or as required (when CCV fails acceptance criteria)	Every Calibration	90-110%R	Every 10 analytical samples	80-120%R
CVAA	SW-846	3-5	Correlation coefficient must be $\geq$ 0.995	At least daily, or as required (when CCV fails acceptance criteria)	Every Calibration	90-110%R	Every 10 analytical samples	90-110%R
CVAA	EPA CWA 245.1	3-5	Correlation coefficient must be $\geq$ 0.995	At least daily, or as required (when CCV fails acceptance criteria)	Every Calibration	95-105%R	Every 10 analytical samples	90-110%R
ICP, ICP/MS	SW-846	2 (blank and high std.) or 3 plus a blank	One point calibration or Correlation coefficient must be $\geq$ 0.995 for multi point calibration.	At least daily, or as required (when CCV fails acceptance criteria)	Every Calibration	90-110%R	Every 10 analytical samples	90-110%R
ICP, ICP/MS	EPA CWA 200.7/200.8	2 (blank and high std.) or 3 plus a blank	One point calibration or Correlation coefficient must be $\geq$ 0.995 for multi point calibration.	At least daily, or as required (when CCV fails acceptance criteria)	Every Calibration	90-110%R	Every 10 analytical samples	90-110%R

Table 6 -2
Instrument/Equipment Calibration/Verification Summary

Instrument	Method Reference	# Standards Initial Calibration	Acceptance Rejection Criteria – Initial Calibration	Frequency of Calibration	Frequency of Initial Calibration Verification	Acceptance/Rejection Criteria - Initial Calibration Verification	Frequency of Continuing Calibration Verification	Acceptance/Rejection Criteria – Continuing Calibration Verification
GFAA	SW-846	3-5	Correlation coefficient must be $\geq$ 0.995. Low standard at or below the RL	At least daily, or as required (when CCV fails acceptance criteria)	Every Calibration	90-110%R	Every 10 analytical samples	80-120%R
GFAA	EPA CWA	3-5	Correlation coefficient must be $\geq$ 0.995. Low standard at or below the RL	At least daily, or as required (when CCV fails acceptance criteria)	Every Calibration	95-105%R	Every 10 analytical samples	80-120%R
GFAA	ASTM/ NIOSH/OSHA	3-5	Correlation coefficient must be $\geq$ 0.995. Low standard at or below the RL	At least daily, or as required (when CCV fails acceptance criteria)	Every Calibration	90-110%R	Every 10 analytical samples	80-120%R
pH Meter	SW-846	3	$\pm$ 0.1 STD units of true value	Daily		$\pm$ 0.1 STD units of true value	Daily	$\pm$ 0.1 STD units of true value
GC/MS Volatiles	SW-846 8260/DoD QSM 5.0	5	%RSD > 15% or r^2>0.99 Linear or Quadratic SW-846 RRF>minimum	As needed	As needed following ICAL	QSM $\pm$ 20%D All Target compounds SW-846 $\pm$ 20%D – all compounds with no more than 20% exceeding compounds. RRF>minimum	Beginning and end of analytical sequence every 12 hr.	QSM $\pm$ 20%D All Target compounds - Initial $\pm$ 50%D All Target compounds - Ending. SW-846 – Same as ICV

Table 6 -2
Instrument/Equipment Calibration/Verification Summary

Instrument	Method Reference	# Standards Initial Calibration	Acceptance Rejection Criteria – Initial Calibration	Frequency of Calibration	Frequency of Initial Calibration Verification	Acceptance/Rejection Criteria - Initial Calibration Verification	Frequency of Continuing Calibration Verification	Acceptance/Rejection Criteria – Continuing Calibration Verification
GC/MS Volatiles	40CFR136,624	5	All Cmpds % RSD<35% or use calibration curve	As needed	As needed following ICAL	± 20%D All Target Compounds	Daily and every 24 hr.	± 20%D All Target Compounds
GC/MS Volatiles	TO15	5	% RSD <30%, 2 exceptions up to 40%	As needed	As needed following ICAL	± 30% Recovery	Daily and every 24 hr.	± 30%D
GC/MS Volatiles	TO1/TO2	3	% RSD <30%	As needed	As needed following ICAL	± 30% Recovery	Daily and every 12 hr.	± 30%D
GC/MS Volatiles	EPA 524.2	5	% RSD <20% or use calibration curve	As needed	As needed following ICAL	+ 20% Recovery	Daily every 8 hr.	All compounds RF %D <30%, ISID Areas >30%, <150% of initial cal.
GC/NPD	N-P containing pesticide EPA 507	5	RF <20% RSD or single point (single point must be within 20% of sample concentration)	As needed when CCV > 15% diff.	As needed following ICAL	20%D	2 times daily. beginning and end of day	15%D
GC/NPD	Organophosphorus pesticides SW-846 8141, DoD QSM 5.0	5	RF <20% RSD or Cal. Curve r^2>0.99 linear regression r^2>0.99 non-linear regression	As needed when CCV > 20%, >20% QSM 5.0	As needed following ICAL	20%D QSM 5.0 – 20% D	Daily, after every 10 field samples and at the end of the run.	20%D QSM 5.0 – 20% D

Table 6 -2
Instrument/Equipment Calibration/Verification Summary

Instrument	Method Reference	# Standards Initial Calibration	Acceptance Rejection Criteria – Initial Calibration	Frequency of Calibration	Frequency of Initial Calibration Verification	Acceptance/Rejection Criteria - Initial Calibration Verification	Frequency of Continuing Calibration Verification	Acceptance/Rejection Criteria – Continuing Calibration Verification
GC/FID	SW-846 8015	5	RF <20% RSD or Cal. Curve r^2>0.99 linear regression r^2>0.99 non-linear regression	As needed when CCV > 20% D	As needed following ICAL	20%D QSM 5.0 – 20% D	Daily, after every 10 field samples and at the end of the run.	20%D QSM 5.0 – 20% D
GC/FID	NIOSH/OSHA	5	RF <20% RSD or Cal. Curve	As needed when CCV >20%D	As needed following ICAL	20%D	Daily, 10%, ending	20%D
HPLC	EPA 531.1	5	RF <20% RSD or single point or calibration curve	As needed when CCV >20%D	As needed following ICAL	20%D	Min. of 2 1 beg. 1 end	20%D
HPLC	SW-846 8330B 8315	5	RF <20% RSD, <15% RSD QSM 4.2 for 8330B r^2>0.99 linear regression r^2>0.99 non-linear regression	As needed when CCV >15%D or every 6 months	As needed following ICAL	15%D	Daily, after every 10 field samples and at the end of the run.	15%D
HPLC	NIOSH/OSHA	3-5	RF <20%RSD or Cal. Curve	When CCV >20%D	As needed following ICAL	20%D CCV vs. cal. curve	Daily 10%	20%D
IC	EPA 300 Methods	5	Correlation Coefficient r $\geq$ 0.995	When CCV is > 10%D	As required by method or on preparation of new ICAL	10%D	Beg. and end of each sequence	10%D
General Wet Chemistry	Standard Methods	Method Specified	Method Specified	Method Specified	Method Specified	Method Specified	Method Specified	Method Specified

Table 6 -2
Instrument/Equipment Calibration/Verification Summary

Instrument	Method Reference	# Standards Initial Calibration	Acceptance Rejection Criteria – Initial Calibration	Frequency of Calibration	Frequency of Initial Calibration Verification	Acceptance/Rejection Criteria - Initial Calibration Verification	Frequency of Continuing Calibration Verification	Acceptance/Rejection Criteria – Continuing Calibration Verification
GC-ECD	EPA 508	3	Linearity <20% RSD	Each Run	As needed following ICAL	80-120% Recovery	Every fifth injection	Primary column %D <15. Conf. column %D <20 R.T. Shift. Capp. columns <0.3 % RT Shift Mega bore Columns <1.5% Breakdown criteria: DDT <20% Endrin <20%
GC-ECD	EPA 608	3	Linearity <10% RSD	As needed when CCV >15%D	As needed following ICAL	85-115% Recovery	Every 10 samples and ending	%D <15 Breakdown criteria: DDT <15% Endrin <15%
GC-ECD	SW-846	5	RF - <20% RSD or Cal. Curve $r^2 \geq 0.99$ linear regression $r^2 \geq 0.99$ non-linear regression	As needed when CCV > 20%, 20% QSM 5.0	As needed following ICAL	20%D QSM 5.0 – 20% D	Daily, after every 10 field samples and at the end of the run.	20%D QSM 5.0 – 20% D Breakdown criteria 8081: DDT <15% Endrin <15%
GC-ECD	NIOSH/OSHA	5	Linearity <20% RSD	Each Run		80-110% Recovery	Every ten samples	%D <20%

Table 6 -2
Instrument/Equipment Calibration/Verification Summary

Instrument	Method Reference	# Standards Initial Calibration	Acceptance Rejection Criteria – Initial Calibration	Frequency of Calibration	Frequency of Initial Calibration Verification	Acceptance/Rejection Criteria - Initial Calibration Verification	Frequency of Continuing Calibration Verification	Acceptance/Rejection Criteria – Continuing Calibration Verification
GC-MS Semi Volatiles	SW-846/DoD QSM 5.0	5	RRF - <15% RSD or Cal. Curve $r^2 \geq 0.99$ linear regression $r^2 \geq 0.99$ non-linear regression RRF > Method Table	As needed or on ICV Failure	As needed following ICAL .	± 20%D All Target compounds QSM 5.0 ±30%D SW-846 Breakdown criteria: DDT <20% Pentachlorophenol/ Benzidine Tailing <2	Beginning and end of analytical sequence every 12 hr.	QSM ± 20%D All Target compounds - Initial ± 50%D All Target compounds Ending SW-846 – RF > Method Table, <20% of cmpds, >20%D Breakdown criteria: DDT <20% Pentachlorophenol/ Benzidine Tailing <2

Note %D refers to percent difference for calibration using RSD of the response factors or percent drift when using regression calibration.

7.0 ANALYTICAL PROCEDURES

7.1 Methods and Standard Operating Procedures

RTI analytical methods are based on validated agency (EPA, NIOSH, OSHA, ASTM, etc.) methodologies where applicable. Prior to analyzing samples the laboratory conducts a method validation that addresses the items in the sub-sections below. The procedure for writing SOPs (SOP for generating SOPs) is specified below and throughout this section. It is understood that SOPs cannot conceivably address every situation that could possibly occur during Laboratory operations. RTI relies on the training, experience and judgment of its staff to handle specific situations consistent with established methods, laboratory practices and policies.

SOPs established as required for administrative functions (sample log in, sub-sampling, etc.) will follow the procedures specified in Sections 7.1.6 – 7.1.15 as applicable.

7.1.1 Data from the internal validation studies is compared to the published method with the goal of meeting or exceeding the performance criteria noted in that method. For methods in which no performance data is available, RTI has minimum target limits for evaluation (see Section 3.0).

7.1.2 Following successful completion of the validation studies and review by a Director, a SOP is generated, reviewed and approved for use. Figure 7-1 illustrates the table of contents for RTI SOPs and delineates the items incorporated into all analytical SOPs. Tables 7-1 through 7-3 summarize analytical procedures currently in use.

7.1.3 SOPs based on published reference methods will specify any applicable modifications from that method. All modifications must be documented in the SOP and must be approved. Modifications must be consistent with the method techniques (for example: GC techniques cannot be substituted for LC methods) and capable of meeting method performance criteria. Projects requiring or specifying published methods will require project-specific approval by the client for any modifications.

7.1.4 SOPs based on published reference methods will use the most recent approved version of the agency method.

7.1.5 Where no standard method exists the laboratory may with the approval of the Technical Director develop non-standard methods for requested testing. This will be performed in consultation with and approval by the client. Any client specifications must be clearly stated and understood prior to commencing method development. Procedures specified in the sections below will be followed in assessing the performance of laboratory developed non-standard methods. This also applies to methods requested to be used beyond their intended scope (using water specific methods for the analysis of solid

samples) or standard methods that have been significantly modified (generally for a specific use only – standard RTI methods typically do not contain significant modifications). RTI will record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.

7.1.6 Initial SOPs are generated either by the analyst, administrative personnel, a Director or a supervisor in the format specified in Section 7.1 (or as modified for administrative SOPs). Draft SOPs are reviewed by the QA Manager and the Technical Director or designated supervisor. Changes are discussed with the analysts and management and incorporated into the SOP. The QA Manager will generate the SOP and submit for review to an analyst or supervisor. After all reviews and changes are completed a final SOP will be generated. The Laboratory Director and QA Manager will sign and date the SOP approval log and the SOP will be posted electronically in the SOP section of the LIMS.

7.1.7 Revisions to SOPs are initiated by the analyst, QA Manager Technical Director or supervisor. These revisions will follow the review process noted above (Sec. 7.1.6) and will be posted electronically with the appropriate revision number. Prior versions will be removed from the current location and stored electronically in the archive folder. The archived documents are maintained in a secure location with limited access.

7.1.8 SOP status is maintained by the QA Manager in a spreadsheet designating the date for the next annual review. The QA Manager is responsible to ensure SOPs are reviewed and approved at least once per year. As revisions are made the file name will be updated to replace the existing SOP with the applicable revision number. SOPs that have been reviewed and accepted for continuing use will retain the same file name but will have the Reviewed and Approved Date updated on the SOP cover page.

7.1.9 Approval signatures will be maintained for all SOP revisions.

7.1.10 All prior versions of SOPs will be archived electronically.

7.1.11 SOPs are posted electronically in the LIMS and available for all analysts.

7.1.12 SOPs are maintained for analytical procedures and sample preparation procedures as applicable.

7.1.13 Laboratory procedural SOPs are based on the applicable reference method and conform to the specifications for that method.

7.1.14 SOPs will designate when specific laboratory environmental conditions are required for performance of a procedure. Testing will not be performed when the environmental conditions are outside of the range required in the SOP.

7.2 All methods must be capable of accurately identifying the presence of the analyte of interest and quantifying the amount of analyte present (except for qualitative determinations). The ability of a procedure to assess presence or absence of an analyte is based on the technique. The instrument or chemical/physical process must have suitable capability to distinguish an analyte. RTI procedures are based on reference methods and established scientific techniques that have demonstrated performance in determining the presence of the specific analyte. Prior to implementing a method RTI will ensure that the procedure will perform as intended through the analysis of standard reference materials.

While RTI does perform procedures that are qualitative in nature most of these methods require accurate quantification of an analyte. The process for establishing a method in the laboratory must include procedures for ensuring the measurement techniques meet the requirements for quantifying the desired parameters. Calibration protocols must be defined in the SOP in accordance with the following.

7.2.1 Calibration curves are constructed to encompass the concentration range of interest. Initial calibration curves are based on 3 – 5 (or more) points for most methods with the lowest standard at or below the LOQ (reporting limit) and the highest standard near the upper limit of the instrument range. Fewer calibration points are allowed in some techniques such as ICPMS and ICPOES. Calibration protocols are specified in Section 8 of the applicable SOP. All results must be quantified from the most recent calibration curve. Non-contiguous data points cannot be excluded from the initial calibration determination without technical justification and approval by the Laboratory or QA Manager. Refer to method SOPs for specific requirements for successful initial calibration.

7.2.2 Linearity of the calibration curve is assessed by %RSD of response factors, the correlation coefficient of linear regression or other appropriate means (i.e. quadratic fit). RTI employs computer data systems and software packages that allow for various determination and evaluations of linearity. All initial calibration curves must meet method/SOP specifications. Any exceptions must be reviewed and approved by the Laboratory or QA Manager.

7.2.3 The calibration curve defines the quantification range for the analysis. The lowest standard establishes the minimum reporting limit (LOQ or PQL) for the analyte. Results below reporting limits but greater than the DL (MDL) are considered estimated. Concentrations measured above the highest calibration standard require dilution into the calibration range or flagging as estimated values. Refer also to Section 9 and method SOPs.

7.2.4 Immediately following any calibration event the established calibration curve must be verified by a second source verification standard. The standard is prepared from a source independent from the calibration source. The second

source may be obtained from a different vendor (preferable) or from a different lot from the same vendor. In cases where a second source may not be available the verification must be prepared independently from the calibration standards by a second analyst or procedures approved by the Laboratory or QA Manager that ensure the independent nature of the calibration verification.

7.2.5 The continuing validity and adequacy of all calibration activities must be evaluated according to established criteria and specified frequency. Procedures for continuing calibration must be included in the applicable SOP.

7.2.6 All calibration and calibration verification procedures must conform to method guidelines, project requirements, accreditation standards and RTI policies.

7.3 Procedures performed must be assessed for potential interferences and environmental conditions that could impact the data generated.

7.3.1 Reagent, method and/or media blanks are analyzed to ensure that interferences arising from reagents, glassware, apparatus, etc., do not pose a problem.

Method blanks must be processed though all steps in the procedure. When additional actions are taken for any sample beyond the standard preparation process the same action must be applied to the method blank. For example: when a sample may require additional filtration post preparation, the method blank must undergo the same filtration and the analysis of the method blank performed on the filtered method blank.

Method and manufacturer's references are reviewed for additional sources of information on potential interferences.

7.3.2 Test methods or procedures performed during testing that are affected by conditions within the facility will be monitored to ensure that data generated is not adversely affected. Individual SOPs will address specific requirements and the monitoring to be performed and recorded. Examples:

7.3.2.1 Temperatures will be monitored and recorded for tests that need to be conducted within a specified range (TCLP extractions, BOD, etc.)
7.3.2.2 Analysts will verify that balances are not subject to vibrations during weighing.
7.3.2.3 Sterility checks on media and apparatus will be conducted and recorded for microbiological assays.
7.3.2.4 The laboratory environment must be maintained in a state that reduces dust and maintains a clean work environment. Analysts are responsible for cleaning all work areas and maintaining the work areas in a proper condition.

7.3.2.5 Segregation of areas to prevent problems related to contamination – volatile organic analyses are performed in an area separated from the rest of the laboratory, analytical balance will be located in a dedicated room and trace metals analyses are performed in a dedicated area of the laboratory. Daily monitoring of blanks and other QC samples will assess the effectiveness of contamination prevention.

7.3.2.6 Any condition that arises that results in the inability to maintain proper conditions or in cases where unexpected or uncontrolled interference is encountered will immediately be brought to the attention of Laboratory Management for investigation and corrective action.

7.4 Following method review, analysis of reference standards, development of the initial calibration and evaluation of potential interference the Laboratory must demonstrate the ability to perform the method through an Initial Demonstration of Capability (IDC – also referred to as IDP or IDMP) with an assessment of accuracy and precision. Continuing demonstration of capability will be performed and assessed annually.

7.4.1 Initial accuracy and precision is demonstrated through analysis of multiple measurements of spiked (4-5) laboratory control samples. All steps in the analytical procedure and all personnel involved in the method are assessed through the IDC. The IDC is performed and evaluated for suitability prior to analysis of client samples.

Accuracy is evaluated by the mean recovery of the measurements. Recovery limits are established for each analyte and the calculated mean must be within the limits for an acceptable IDC. Limits are based on method cited ranges where available, limits published in agency documents (ex. DoD QSM), target limits established in this document or limits established by the QA Manager (as necessary). It is understood that procedures involving a significant number of analytes may not be able to meet the limits for all analytes and include analytes cited in the reference method or through laboratory experience as refractory by standard procedures. The presence of such occurrences does not indicate an inability to adequately perform the method and will not necessarily invalidate the IDC. The QA Manager will determine the efficacy of the data from the IDC and render a status assessment.

Precision is evaluated by the percent relative standard deviation (RSD) of the measurements. Precision limits are established for each analyte and the RSD must be within the limits for an acceptable IDC. Limits are based on method cited ranges where available, limits published in agency documents (ex. DoD QSM), target limits established in this document or limits established by the QA Manager (as necessary). It is understood that procedures involving a significant number of analytes may not be able to meet the limits for all analytes and include analytes cited in the reference method or through laboratory experience as refractory by standard procedures. The presence of such occurrences does not indicate an inability to adequately perform the method and will not necessarily invalidate the IDC. The QA Manager will

determine the efficacy of the data from the IDC and render a status assessment.

7.4.2 Records of the IDC will be maintained by the QC Department and when used to demonstrate an individual is sufficiently trained and can be approved for performing a method a copy will be included in the applicable training file.

7.4.3 The IDC must be performed on initial method set up or whenever there is a new instrument installed or significant changes or maintenance to an instrument, changes in personnel or changes to the method or matrix.

7.4.4 Continuing demonstration is assessed through annual accuracy and bias determination at the LOQ, quarterly LOD/LOQ verifications and routine assessment of QC data (LCS, Method blanks).

7.4.4.1 During the first quarter of each calendar year in conjunction with the required quarterly LOD/LOQ verification four LOQ samples will be analyzed and assessed for continuing method accuracy and precision. This will serve to evaluate accuracy and precision at the LOQ and as the annual analyst continuing demonstration of capability. Results for the continuing demonstration will be included in the associated analyst training file.

7.4.4.2 Continuing demonstration is additionally verified by successful analyses of PT samples.

7.5 Method sensitivity and the ability to quantify analytes at required levels of concern will be determined by establishing minimum detection limits and verified limits of detection and quantification.

DL (detection limit) and MDL (minimum detection limit) are synonymous terms and are determined according to the MDL procedure specified below. LOD refers to the Limit of Detection and is established as specified below. LOQ (limit of quantification), PQL (practical quantification limit) are interchangeable terms and define the lower quantifiable concentration. The RL (reporting limit) is the project reporting limit. This can be set at the MDL, LOD or LOQ on reports, depending on the client DQOs and/or the project reporting limit. The Omega LIMS also provides a client requested MDL. LOD or LOQ to be used, provided they are greater that the laboratory established limit.

7.5.1 DL/MDL Determination

7.5.1.1 RTI uses both MDL and DL interchangeably. In this section, the MDL designation is used exclusively for clarity and to most consistently match the referenced procedure. MDLs are determined at method initiation and as required by the applicable method. MDL determinations must be re-established when the LOD fails to meet the requirements stipulated in the section below or when significant changes occur. Significant changes include:

7.5.1.1.1 Personnel
7.5.1.1.2 Instrumentation/technology
7.5.1.1.3 Test Method
7.5.1.1.4 Sample Matrix
7.5.1.1.5 Significant Component Changes (detectors, columns, sample introduction technique, etc.)

7.5.1.2 MDLs must be generated for all applicable matrices using a matrix free of the analyte(s) of interest (for example - laboratory reagent water, clean sand or other clean solid material).

7.5.1.3 MDLs must be generated for all preparatory and cleanup methods used for sample analysis. For methods requiring dual column analysis MDLs must be performed and evaluated for both columns.

7.5.1.4 For new technology or methods, the first requirement is to estimate an MDL. This can be achieved through historical data or by analyzing seven replicates containing all of the analytes of interest at a concentration level of 1-5 times the estimated MDL and calculating the standard deviation. The Student's T Value for the 7 replicates (3.143) is multiplied by the standard deviation of the analyte to calculate the initial *estimated* MDL. This *estimated* MDL can then be used in the initial and ongoing MDL determinations.

7.5.1.5 For MDLs performed on multiple instruments with identical configurations the MDL is blended using the MDL_b and MDL_s below.

7.5.1.6 The MDL is statistically defined at the 99% confidence level according to the protocol in 40 CFR Part 136. The method detection limit (MDL) is defined by the EPA document “Definition and Procedure for the Determination of the Method Detection Limit, Revision 2”, EPA 821-R-16-006, December 2016, and referenced in 40 CFR Part 136. To determine the initial MDL, seven (7) replicates containing all of the analytes of interest at a concentration level of 1 - 5 times the estimated detection limit, along with seven method blanks are prepared in 3 different batches over three days. The typical process will be one batch containing 2 blanks and 2 spiked samples on day 1,

3 blanks and 3 spiked samples on day 2, and 2 blanks and 2 spiked samples on day 3. These samples must be analyzed on three separate day are analyzed and the standard deviation is calculated. The student's T value for the seven (7) replicates (3.143) is multiplied by the standard deviation to calculate the MDL.

Compute the MDL_s (the MDL based on spiked samples) as follows:

$$MDL_s = t_{(n-1,\ 1-\alpha=0.99)}\ S_s$$

Where:

MDL = the method detection limit based in spiked samples

$t_{(n-1,\ 1-\alpha=99)}$ = The Student's t-value appropriate for a sample-tailed 99th percentile t statistic and a standard deviation estimate with n-1 degrees of freedom.

S_s = sample standard deviation of the replicate spiked sample analyses

Compute the MDL_b (the MDL based on method blanks) as follows:

1. If none of the method blanks give numerical results for an individual analyte, the MDL_b does not apply. A numerical result includes both positive and negative results, including results below the current MDL, but not results of "ND" (not detected) commonly observed when a peak is not present in chromatographic analysis.
2. If some (but not all) of the method blanks for an individual analyte give numerical results, set the MDL_b to the level that is no less than the 99th percentile of the method blank results. For "n" method blanks where n ≥ 100, sort the method blanks in rank order. The (n*0.99) ranked method blank result (round to the nearest whole number) is the MDL_b. For example, to find MDL_b from a set of 164 method blanks where the highest rankded method blank results are…1.5, 1.7, 1.9. 5.0, and 10, then 164 x 0.99 = 162.36 which rounds to the 162nd method blank result. Therefore, MDL_b is 1.9 for n=164 (10 is the 164th result, 5.0 is the 163rd result, and 1.9 is the 162nd result). Alternatively, you may use spreadsheet algorithms to calculate the 99th percentile to interpolate between the ranks more precisely.
3. If all of the method blanks for an individual analyte give numerical results, then calculate the MDL_b as:

$$MDL_b = \overline{X} + t_{(n-1,\ 1-\alpha=0.99)}S_b$$

Where:

MDL_b = the MDL based on method blanks

$\overline{X}$ = mean of the method blank results (use zero in place of the mean if the mean is negative)

$T_{(n-1, 1-\alpha=0.99)}$ = the Student's t-value appropriate for a single-tailed 99th percentile t statistic and a standard deviation estimate with n-1 degrees of freedom.

S_b = sample standard deviation of the replicate method blank sample analyses

4. Select the greater of MDL_s or MDL_b as the initial MDL

7.5.1.7 Ongoing MDL data collection

1. During any quarter in which samples are being analyzed, prepare and analyze a minimum of two spiked samples on each instrument, in separate batches, using the same spiking concentrations used to determine the initial MDL. If any analytes are repeatedly not detected in the quarterly spiked sample analyses, or do not meet the qualitative identification criteria or the method, then this is an indication that the spiking level is not high enough and should be adjusted upward. Note that is is not necessary to analyze additional method blanks together with the spiked sampled, the method blank population should include all of the routine method blanks analyzed with each batch during the course of sample analysis.

2. Ensure that at least seven spiked samples and seven method blanks are completed for the annual verification. If only one instrument is in use, a minimum of seven spikes are still required, but they may be drawn from the last two years of data collection.

3. At least once per year, re-evaluate the spiking level. If more than 5% of the spiked samples do not return positive numerical results that meet all method qualitative identification criteria, then the spike level must be increased and the initial MDL re-determined.

4. If the method is altered in a way that can be reasonably expected to change its sensitivity, then re-determine the MDL and restart the ongoing data collection.

5 If a new instrument is added to a group of instruments whose data are being pooled to create a single MDL, analyze a minimum of two spiked replicates and two method blank replicates on the new instrument. If both method blank results are below the existing MDL, then the existing MDL_b is validated. Combine the new spiked sample results to the existing spiked sample results and recalculate the MDL_S. If the recalculated MDL_S does

not vary by more than the factor specified in Section XXX, then the existing MDL_s is validated. Of either of these two conditions is not met, then calculate a new MDL.

7.5.1.8 Ongoing annual verification of MDLs.

1. At least once every thirteen months, re-calculate the MDL_s and MDL_b from the collected samples and method blank results.

2. Include data generated within the last 24 months, but only data with the same spiking level. Only documented instances of gross failures (e.g. instrument malfunctions, mislabeled samples, cracked vials) may be excluded from the calculations. The rationale for removal of specific outliers must be documented and maintained on file with the results of the MDL determination. If the laboratory believes the sensitivity of the method has changed significantly, then the most recent data available may be used, maintaining compliance with the requirement for at least seven replicates in three separate batches on three separate days.

3. Include the initial MDL spiked samples, if the data were generated within 24 months

4. Only use data associated with acceptable calibrations and batch QC. Include all routine data, with the exception of batches that are rejected and the associated samples reanalyzed. If the method has been altered in a way that can be reasonably expected to change its sensitivity, then use only data collected after the change.

5. Ideally, use all method blank results from the last 24 months for the MDL_b calculation. The laboratory has the option to use only the last six months of method blank data or the fifty most recent method blanks, whichever yields the greater number of method blanks.

6. The verified MDL is the greater of the MDL_s or MDL_b. If the verified MDL is within 0.5 to 2.0 times the existing MDL, and fewer than 3% of the method blank results (for the individual analyte) have numerical results above the existing MDL, then the existing MDL may optionally be left unchanged. Otherwise, adjust the MDL to the new verification MDL. The range of 0.5 to 2.0 approximates the 95^{th} percentile confidence interval for the initial MDL determination with six degrees of freedom.

7.5.1.9 Spiking levels for MDL studies will initially correspond to the LOQ concentration. This will tend to generate values that can be accurately determined and produce more reliable a statistical calculation of the DL. Following evaluation of the initial MDL data spiking levels may be adjusted. Spiking below the LOQ will inherently add variability to the results since quantification of the values will be

outside of the calibration range. Variation in data generated tends to be greater at and especially below the low end of the calibration curve.

7.5.1.10 MDL values are considered acceptable if the following criteria are met. Acceptable MDL results are entered into the applicable Omega Test Code following review and approval by the QA Manager.

7.5.1.10.1 The MDL is less than the required concentration that will be reported. This includes project requirements, State specified target detection limits (TDL), contract required quantification limits (CRQL), method specified detection limits, program requirements or client specified reporting limits.

7.5.1.10.2 The calculated MDL must not be greater than the MDL spike concentration.

7.5.1.10.3 The analyte must be detected in all replicates.

7.5.1.11 In cases where the MDL procedure above is not practical for determination of the detection limit (i.e. BOD, balance measurements, microbiological procedures, pH, etc.) the MDL will be based on the sensitivity of the instrument or method or will correspond to the lowest calibration standard in the working calibration curve. In these instances the MDL, LOD and LOQ/PQL values are entered in the LIMS Test Code with the same number.

Infrequently performed tests or analytes, special requests or poor performing analytes may not warrant MDL studies as described above. In cases where a DL is not established sample results will not be reported below the lowest calibration standard. The MDL, LOD and LOQ values in the Omega test code will correspond to the level of the low calibration standard.

7.5.2 LOD Determination

7.5.2.1 Immediately following the MDL study a LOD is determined by spiking the same type of matrix used for establishing the DL at 2-4 times the DL.

7.5.2.2 LODs must be generated for all preparatory and cleanup methods used for sample analysis. For methods requiring dual column analysis LODs must be performed and evaluated for both columns.

7.5.2.3 LODs must be performed on all instruments used for the applicable method.

7.5.2.4 The spiking concentration establishes the LOD provided that all analytes are detected at a 3:1 signal to noise ratio or 3 times the background level measured in the associated method blank and must meet the method requirements for qualitative identification of the analyte (ion abundance, confirmation on a second column, pattern matching, etc.).

7.5.2.5 LODs must be verified quarterly. In cases where the LOD data does not comply with the criteria in Sec. 7.5.2.4 a new MDL determination must be performed at a higher concentration and subsequently demonstrate two successful LOD verifications.

7.5.2.6 Successful LOD results are entered into the Omega LIMS test code field (LOD). For procedures specified above for which a MDL determination is not applicable the LOD filed is left blank or contains the same value as the MDL and LOQ.

7.5.3 LOQ (PQL) Determination

7.5.3.1 Following MDL entry into the Test Code and successful LOD determination the LOQ (PQL field in the LIMS test code) values are entered. The PQL data in Omega will represent the standard laboratory reporting limit that will be included on the final analytical report under the report heading LOQ or RL.

7.5.3.2 The RL can be established at any value at or above the MDL.

7.5.3.3 Default reporting limits are routinely established at levels corresponding to the lowest calibration standard.

7.5.3.4 Within the Omega LIMS reporting limits can be specified individually for clients, quotations or projects provided the criteria in Section 7.5.3.2 is met and the limits set are not below the default LOQ. Reporting limits required below the standard LIMS Test Code LOQ must be approved by a Director.

7.5.3.5 The LOQ is verified by spiking the same type of matrix used for establishing the DL at the LOQ.

7.5.3.6 LOQ values must be generated for all preparatory and cleanup methods used for sample analysis. For methods requiring dual column analysis LOQs must be performed and evaluated for both columns.

7.5.3.7 LOQ determinations must be performed on all instruments used for the applicable method.

7.5.3.8 Based on the specific method percent recovery for the analyte in the LOQ must be within 70-130%, within the control limits cited in the DOD QSM or laboratory established limits approved by the QA Manager.

7.5.3.9 LOQs must be verified quarterly. In cases where the LOQ data does not comply with the criteria in Sec. 7.5.3.8 a new LOQ determination must be performed at a higher concentration until a successful LOQ is attained and the LIMS PQL/LOQ must be adjusted to reflect the new LOQ.

It is understood that procedures involving a significant number of analytes may not be able to meet the limits for all analytes and include analytes cited in the reference method or through laboratory experience as refractory by standard procedures. The presence of such occurrences does not indicate an inability to adequately perform the method and will not necessarily invalidate the IDC. The QA Manager will determine the efficacy of the data from the IDC and render a status assessment.

7.5.3.10 Accuracy and bias at the LOQ must be established on initial LOQ determination, ongoing quarterly determinations and annually by preparing four LOQ samples. The mean recovery must be within the limits specified above and the %RSD of the four results must be <15%. Section 7.5.3.9 second paragraph also applies to this section.

7.6 After a method has been validated and incorporated into use continuing capability is assessed through routine quality control sample analyses and the procedure in 7.4.4. In the event of a significant change or failure to achieve quality control standards a demonstration of capability is performed as in Section 7.4.1 and 7.4.2. All personnel involved in the analytical process will participate in the demonstration to the extent of their involvement in the method. Significant changes include:

7.6.1 Personnel
7.6.2 Instrumentation
7.6.3 Test Method
7.6.4 Sample Matrix
7.6.5 Significant Component Changes (detectors, columns, sample introduction technique, etc.)

7.7 Method specified parameters such as inter-element correction factors, IDLs and linear ranges for ICP/ICPMS will be assessed during method validation and updated as specified in the method SOP.++

7.8 Assessment of Quality Control Samples

7.8.1 Calibration check standards must be within the guidelines specified in the associated SOP, Tables found in Section 6.0 or according to method specifications (if a discrepancy exists the method specifications will apply).

7.8.2 If a calibration check standard exceeds the applicable limits the standard is re-analyzed twice and if the results are within the required limits analyses can proceed. If the either of the repeat analyses fail to yield acceptable results the analysis is stopped and appropriate corrective actions are instituted prior to re-commencing analysis.

7.8.1 For analyses conducted under CLP protocols an unacceptable calibration check standard necessitates halting the analyses for the affected constituent, correcting the problem and re-analyzing the samples for the failed parameter(s). The only exception is the CRQL standard, which may be re-analyzed once, and if acceptable the analytical sequence can proceed.

7.8.2 Assessment of batch and method QC samples (i.e. Method Blanks, LCS samples, Matrix Spikes, Duplicates, etc) is addressed in Section 13 of the applicable SOP.

7.9 Deviations from SOPs

7.9.1 Unapproved deviations are not allowed.

7.9.2 When a deviation from a SOP is required the reason for the deviation must be documented and approved by the Laboratory Director or QA Manager, and accepted by the customer.

7.10 Specific LOD/LOQ policies

7.10.1 Guidelines for State of Wisconsin

7.10.1.1 MDL concentrations will be determined using the procedure specified in 40 CFR Part 136, and will be designated as the Limit of Detection (LOD).

7.10.1.2 From the statistically determined LOD a LOQ will be established that is mathematically related to the LOD. The standard relation will be LOQ equal to 10/3 times the LOD. Based on evaluation of the LOQ and in relation to the lowest calibration standard the multiplier may be adjusted up to 5 times the LOD.

7.10.1.3 The LOQ concentration will be at a level near the lowest standard in the associated calibration.

7.10.1.4 LOQ values will be verified quarterly.

7.10.1.5 Sample concentrations will be reported to the LOD.

7.10.1.6 LOD and LOQ values will be included in analytical reports.

Figure 7-1

RTI SOP# XXXX
STATUS: ACTIVE

DATE: June 4, 2012
Revision 0

STANDARD OPERATING PROCEDURE

SOP# XXXX

TABLE OF CONTENTS

Table 7-1

Summary of Organic Analytical Procedures

ANALYTE GROUP	LAB SOP NO.	EQUIVALENT METHOD NUMBER
Matrix: Water/Soil		
Volatile Organics	8260C_XXXXXX_RX 524_2_XXXXXX_RX	EPA SW-846/5030B/5035/8260C/624 EPA 524
Herbicides	8151A_XXXXXX_RX 515_1_XXXXXX_RX	EPA SW-846/8151A EPA 515.1
Semi-Volatile Organics (GC/MS)	8270D_XXXXXX_RX 525_2_XXXXXX_RX	EPA SW-846/8270D/625 EPA 525.2
Pesticides/PCB	8081B_XXXXXX_RX 8082A_XXXXXX_RX 508_XXXXXX_RX	EPA SW-846/8081B/8082A EPA-608 EPA 508
Polynuclear Aromatic Hydrocarbons	8310 (R)	EPA SW-846/8310 EPA/610
Gasoline Range Organics (GRO)	8015D_XXXXXX_RX	EPA SW-846/8015D
Diesel Range Organics (DRO)	8015D_XXXXXX_RX	EPA SW-846/8015D
Aldehydes	8315A (IP)	EPA SW-846/8315A
Total Petroleum Hydrocarbons	1664A_XXXXXX_RX 9071B_XXXXXX_RX	EPA 1664A SW-846/9071B
Sonication Extractions Soxhlet Extractions Pressurized Fluid Extraction	3550C_XXXXXX_RX 3540 (IP) 3546_XXXXXX_RX	EPA SW-846/3550C EPA SW-846/3540 EPA SW-846/3546
Liquid-Liquid Extractions-separatory funnel	3510C_XXXXXX_RX	EPA SW-846/3510C
Haloacetic acids	552_2_XXXXXX_RX	EPA 552.2
EDB/DBCP	504_1_XXXXXX_RX	EPA 504.1
Explosives	8330B_XXXXXX_RX	EPA 8330B
Nitrogen/Phosphorus Pesticides	507_XXXXXX_RX 8141B_XXXXXX_RX	EPA 507 EPA 8141B

Table 7-1 (cont'd)

Summary of Organic Analytical Procedures

ANALYTE GROUP	LAB SOP NO.	EQUIVALENT METHOD NUMBER
Matrix: Ambient Air		
Volatile Organics	(R)	EPA TO-17
Volatile Organics	TO15_XXXXXX_RX	EPA TO-15
Aldehydes and Ketones	(R)	EPA TO-5
Pesticides/PCB's	TO-4_XXXXXX_RX2	EPA TO-4 EPA TO-10
Phenols and Methyl phenols	(R)	EPA TO-8
Polynuclear Aromatic Hydrocarbons	(R)	EPA TO-13
Formaldehyde	(R)	EPA TO-11
Matrix: Industrial Hygiene Air		
Organic Solvents	(R)	NIOSH Various OSHA Various
Polynuclear Aromatic Hydrocarbons	(R)	NIOSH 5506/5515
Polychlorinated Biphenyls	(R)	NIOSH 5503
Formaldehyde	(R)	NIOSH 2541
Aldehydes	(R)	OSHA DHPH (64 et al)
Isocyanates	(R)	OSHA 42/47
Miscellaneous	(R)	NIOSH / OSHA Various

Table 7-2

Summary of Analytical Procedures - Metals

ANALYTE GROUP	LAB SOP NO.	EQUIVALENT METHOD NUMBER
Matrix: Water		
Metals	6020A_XXXXXX_RX	EPA 6020A/200.8
Prep-Dissolved and Total Recoverable	3010A_XXXXXX_RX	EPA 3005A/3010A
Prep-Totals	3020A_XXXXXX_RX	EPA 3020A
Metals	6010C_XXXXXX_RX	EPA 6010C/200.7
Mercury	245.1_XXXXXX_RX 7470A_7471B_XXXXXX_RX 1631E_XXXXXX_RX	EPA 245.1 EPA 7470A/7471B EPA 1631E
Matrix – Soil		
Metals	6020_XXXXXX_RX	EPA 6020A
Prep - Totals	3050B_XXXXXX_RX 3052_XXXXXX_RX	EPA SW-846/3050B EPA SW-846/3052
Metals	6010C_XXXXXX_RX	EPA 6010C
Mercury	7470A_7471A_XXXXXX_RX 1631_XXXXXX_RX	EPA 7471B EPA 1631E
ANALYTE GROUP	**LAB SOP NO.**	**EQUIVALENT METHOD NUMBER**
Matrix: Ambient Air		
Metals	ICP/MS – Reserved	EPA 40CFR Part 50 App. J
Lead	PB_TSP.AA(R)	EPA 40CFR Part 50 App. G
Matrix: Industrial Hygiene Air		
Metals	(R)	NIOSH 7300/OSHA ID121
Metals	(R)	NIOSH 7000 Series Various
Mercury	HG6009.AA	NIOSH 6009
Prep - MCE Filters	P_METIH	NIOSH / OSHA Various

Table 7-3
Summary of Inorganic and Miscellaneous Analytical Procedures

ANALYTE GROUP	LAB SOP NO.	EQUIVALENT METHOD NUMBER
Matrix: Water		
BOD	5210B_XXXXXX_RX	SM 5210B
Anions	300.0_XXXXXX_RX	EPA 300.0
Nitrite	300.0_XXXXXX_RX	EPA 300.0
Nitrate	300.0_XXXXXX_RX	EPA 300.0
Phosphorus, Total	4500-P-F_XXXXXX_RX4	SM 45000 P-F
Ortho-Phosphate	4500-P-F_XXXXXX_RX 300.0_XXXXXX_R_X	SM 4500 P-F EPA 300.0
Phenolics	420_1_XXXXXX_RX	EPA 420.1
Residual (Solids)	2540C_XXXXXX_RX 2540D_XXXXXX_RX 2540B_XXXXXX_RX	SM 2540C SM 2540D SM 2540B
PH	4500-H-B_XXXXXX_RX	SM 4500 H-B
Oil & Grease/SGT-HEM	1664A_XXXXXX_RX	EPA 1664A
Specific Conductance	120.1_XXXXXX_RX	EPA 120.1
Cyanide	4500-CN-E_XXXXXX_RX	SM 4500-CN E
Hexavalent Chromium	7196A_XXXXXX_RX	SW 846/7196A, SM 3500-Cr B
EDTA	EDTA_XXXXXX_RX	NEM
Alkalinity	2320B_XXXXXX_RX	SM 2320B
TKN	4500 Norg-B_XXXXXX_RX 4500-NH3-D_XXXXXX_RX (IP) (IP)	SM 4500 Norg-B SM 4500-NH3 D SM 4500-NH3 C SM 4500-NH3 F
Chemical Oxygen Demand	410_4_XXXXXX_RX	EPA 410.4
Chlorine, Residual	4500-Cl-I_052907_R0	SM 4500-Cl I
Ammonia	4500-NH3-D_XXXXXX_RX	SM 4500-NH3 D
Organic Carbon	5310B_XXXXXX_RX	SM 5310B
Turbidity	180_1_XXXXXX_RX	EPA 180.1

Matrix: Ambient Air & Stationary Source		
TSP	(R)	EPA 40CFR, Part 50, App. B
PM10	(R)	EPA 40CFR, Part 50, App. J
Nitrogen Oxides	(R)	EPA Method 7
Sulfur Dioxide	(R)	EPA Method 8
Hydrogen Sulfide	(R)	EPA Method 11
Halides	(R)	EPA Method 26
Matrix: Various -- Lead (HUD, Environmental Lead, Biological)		
Lead - Paint	(R)	EPA SW-846 6010
Lead - Wipe	(R)	NIOSH 9100 / OSHA ID121
Lead – Soil	(R)	EPA SW-846 6010
Matrix: Waste Characterization		
TCLP Extraction	1311_XXXXXX_RX	EPA SW-846 1311
TCLP ZHE Extraction	1311ZHE_XXXXXX_RX	EPA SW-846 1311
Ignitibility	1010_XXXXXX_RX	EPA SW-846 1010A
Paint Filter Test	9095B_XXXXXX_RX	EPA SW-846 9095B
Bomb Preparation	5050_XXXXXX_RX	EPA SW-846 5050

SOPs are listed above with a generic designation for the SOP#. The current SOP is posted in the LIMS as …_XXXXXX(date)_RX(revision)

(IP) SOP currently in progress.
(R) Reserved for future document development or SOP based on currently used agency reference method.
(NEM) No equivalent method.

SOPs for the Materials Sciences Division are maintained by the Technical Director.

8.0 INTERNAL QUALITY CONTROL CHECKS

8.1 As specified in Section 7.0 analytical procedures are documented in written SOPs. These SOPs include a section specifying the minimum QC requirement, frequency and the acceptance criteria for the QC samples. In lieu of a written SOP the minimum QC requirements will be adopted from the published method or target limits specified in Section 3 of this QAP.

Assessment, evaluation and reporting of Quality Control Checks are addressed further in Sections 9 and 12 of this document.

8.2 Internal Quality Control checks vary slightly with the procedure or analyte but in general include:

8.2.1 Field/Trip Blanks (when submitted). Used to assess contamination during the sampling process and evaluated by the sample submitter.

8.2.2 Method Blanks. Used for assessing the cleanliness of the sample preparation and analytical procedures. Method blanks are evaluated according to the specifications in the individual SOP (Section 13). Standard criteria are values less than the reporting limits, less than ½ the LOQ for QSM samples or less than the LOD for Wisconsin samples. Blank results that exceed acceptance criteria require investigation into the cause and may initiate a corrective action report. Samples associated with a method blank greater than the criteria noted above are flagged with a B on the analytical report. Unless explicitly required by client or project correcting or altering sample results for the amount found in a Method Blank sample is not permitted.

8.2.3 Reagent/Preparation Blanks. Used to evaluate the cleanliness of the reagents for sample analysis and the process for preparing samples; and in some inorganic procedures may be used for zeroing an instrument. There blanks are evaluated according to the specifications in the individual SOP (Section 13). Standard acceptance criteria are values less than the MDL or LOD.

8.2.4 Instrument Blanks (Initial and Continuing Calibration Blanks). Used for assessing the cleanliness of the analytical system. ICB and CCB results are evaluated according to the specifications in the individual SOP (Section 13). Standard acceptance criteria are values less than the MDL or LOD.

8.2.5 Media Blanks. Unexposed air sampling media analyzed with associated samples to asses contribution of the sampling media to measured sample concentrations. The mass of analyte determined in a media blank may be subtracted from samples results for reporting the final concentration.

8.2.6 Calibration Check Standards (Initial and Continuing). Assess the calibration status of the instrument. These standards are analyzed following initial calibration procedures and at the method and/or SOP specified frequency. Calibration Check Standards must be prepared at a concentration between the mid point of the calibration standard and the lowest level calibration standard. Sample results generally cannot be reported if these standards do not meet the requirements of the SOP (Section 8 and 13) or method specifications. In instances where an analyte must be reported that has an associated unacceptable Calibration Check Standard the data user will be informed. Results exceeding control limits are flagged with an S or Q on the analytical report and narrated if necessary and associated analytes may be flagged with a Z (ICV) or Y (CCV).

8.2.7 Matrix Spikes/Matrix Spikes Duplicates (media spikes for air analyses). These QC samples are used to assess matrix affects on the constituents being analyzed and accuracy and precision of the analytical method. MS/MSD evaluation is addressed in Section 12 of this document and Section 13 for the applicable SOP. Results that exceed control limits are S/Q and/or R flagged on the QC Summary reports supplied with the analytical report.

8.2.8 Surrogates (chromatography). Used to assess the efficiency of the sample preparation procedures employed for the appropriate method. Results are evaluated against established control limits and required actions are specified in Section 13 of the applicable SOP. Results exceeding control limits are flagged with an S or Q on the analytical report and narrated if necessary.

8.2.9 Post Digestion Spikes/Serial Dilutions (GFAA, FLAA, ICP/OES and ICP/MS). Assess matrix interferences on elements analyzed by the techniques above. Evaluation of results is addressed in the associated SOP (Section 13).

8.2.10 Interference Checks (ICP/ICPMS). These checks are used to assess inter-element interference for ICP/OES and ICP/MS techniques by the analysis of check solutions.

8.2.11 Laboratory Duplicates. Used for the assessment of method precision. Duplicate evaluation is addressed in Section 12 of this document and Section 13 for the applicable SOP. Duplicate results that exceed control limits are flagged with an R on the QC Summary reports supplied with the analytical report.

8.2.12 Laboratory Control Samples/Laboratory Control Sample Duplicates. Used for assessing method accuracy. LCS/LCSD evaluation is addressed in Section 12 of this document and Section 13 for the applicable SOP. Results that exceed control limits are S/Q and/or R flagged on the QC Summary reports supplied with the analytical report.

8.2.13 Internal Standard Areas (GC, ICP/MS). Added to all samples and monitored to ensure the consistency of instrument response. Evaluation is specified in Section 13 of the individual SOP. Samples associated with IS failures require re-analysis prior to reporting.

8.2.14 Mass Tuning (GC/MS, ICP/MS). Used to assed the condition of the instrument prior to beginning the analytical process. Successful tuning is required before commencing calibration or analysis.

8.2.15 Method specific quality control checks must be included in the analytical protocol and RTI SOP where required (for example grinding blanks and triplicate analyses as specified in method 8330B).

9.0 DATA REDUCTION, VALIDATION AND REPORTING

9.1 DATA REDUCTION

9.1.1 Whenever possible instruments are calibrated to display results in applicable concentration units.

9.1.2 Omega is capable of direct downloading of instrument data into the LIMS for several analytical instruments. In these instances all data reduction is performed by the LIMS.

9.1.3 Where direct interface with Omega is not possible the data export/import features of the LIMS are used. This involves exporting the samples for a specified test code into an Excel spreadsheet. The information exported will include the following fields:

9.1.3.1 Sample numbers (automatically exported)
9.1.3.2 Sample type (Samp, MS. MSD. LCS, CCV, MBLK, etc.) – automatically exported.
9.1.3.3 File number (automatically exported)
9.1.3.4 Dilution factors (default value = 1). Changed by analyst as required.
9.1.3.5 Raw Data (default value = 0 –non-detect). Actual instrument readings to be entered by the analyst.
9.1.3.6 Analysis date and time.

When instrument output cannot be directly imported or bench sheets are used to record the results of the analysis the analysts will enter the raw data readings and analysis date and time in the designated column. Following completion of data entry the Excel spreadsheet is saved to a specified file. The completed spreadsheet must be peer reviewed to ensure accurate transcription of data from the instrument print out or bench sheet. This file is then imported into Omega.

9.1.4 Excel bench sheets have been developed that automatically capture balance readings that are imported into a template file. This file is saved with the applicable new name and uploaded into the LIMS.

9.1.5 All information pertaining to the calculation of the final reported result is entered and stored in Omega.

9.1.5.1 For samples requiring reporting in dry weight the percent moisture value is automatically associated with the respective samples and the calculation to dry weight is performed automatically. This is verified by a change in units from – for example – µg/Kg to µg/Kg-dry.

9.1.5.2 All sample preparation information (weight, volumes, factors, etc.) is entered into the applicable prep table. This information automatically associates with the respective sample and is included in the calculation of the final result.

9.1.5.3 In cases where a dilution is required at the instrument level, this factor is noted in the instrument data system or logged on the instrument print out. If data is directly downloaded to Omega this factor will import with the data. If an Excel file is used for importing to Omega this factor is included in the spreadsheet, imported and incorporated into the final result.

9.1.6 All calculations producing final sample results, surrogate percent recoveries and QC sample percent recoveries and RPDs are performed by the LIMS.

9.1.7 RTI strives to maximize the use of direct electronic transfer of data. Whenever possible instrument data will be directly uploaded either to the LIMS or an electronic file that is imported directly into the LIMS. Most instruments and procedures have been configured to eliminate human transfer of data and as such are free of transcription errors. In cases where data is required to be transcribed by an analyst, that data will be reviewed by a second individual to ensure accurate data transcription. It is the goal and intent of RTI to completely eliminate transcription errors and to identify and correct all transcription mistakes prior to reporting.

9.1.8 Air volume data is logged for each sample when this information is supplied at the time of sample log in.

9.1.9 Tables within Omega contain the sampling rates for diffusive samplers and the molecular weights for analytes reported in ppm or ppb air.

9.1.10 Air sample results are provided in total mass units, mass per unit volume and ppm or ppb (where applicable) with the calculations being performed automatically by the LIMS on report generation.

9.1.11 The LIMS Administrator or a Director verifies all calculations performed by the LIMS prior to general use.

9.1.12 Instrument print out data that is not used will have a line drawn through that particular sample and a notation of “data not used” and an explanation will be provided when applicable.

9.1.13 For special projects that require data handling outside of the routine LIMS functions various computer programs are available to assist in data reduction. These include:

9.1.13.1 Excel spreadsheets with associated mathematical and statistics functions.
9.1.13.2 BOD Calculator
9.1.13.3 Grain Size Software

9.1.13.4 These commercial software products used within the designed applications are considered sufficiently validated (Refer also to next section).

9.1.14 Software designed for automated data reduction processes will be verified on installation of new or updated software versions or whenever programming code is modified. Verification will include:

9.1.14.1 Data systems in use have been verified through:

9.1.14.1.1 Manual calculations performed by various staff.
9.1.14.1.2 Third party data validation packages submitted
9.1.14.1.3 Comparison to LIMS functions (i.e. CLP module).

9.1.14.2 New, updated or re-programmed systems will undergo verification by using a sample data set to verify all data operations. These calculations will be performed outside of the instrument data system using Excel or equivalent programs. Results of the verifications will be stored electronically in a designated folder.

9.1.15 Any formulas used in Excel or equivalent program for data reduction must be protected from alteration. The protection of the cells containing the formulas is ensured through passwords available only to authorized personnel (i.e. QA Department staff). Users of the spreadsheets will not be able to access or modify formulas but may view the formulas to ensure accuracy. Any necessary modification to a formula will be performed by authorized personnel and immediately protected from further revision. Only QA Department staff will have access to the passwords required to unprotect spreadsheets.

9.2 DATA VALIDATION AND REVIEW

Initial Calibration/Initial Calibration Verification

9.2.1 Analysts are responsible for evaluating the results of the initial calibration to ensure compliance with SOP requirements and items in Section 9.2.7. Sections 8 and 13 of each SOP contain the specifications for acceptable ICAL criteria and measures to be taken when these criteria are not met.

9.2.2 Analysts are responsible for ensuring that the results of all calibration verifications are within the acceptable limits specified in the SOP and assessing all items in Section 9.2.8

9.2.3 No sample data can be reported until both the ICAL results and calibration verification (CCV, ICV) results meet the criteria specified in the method SOP and/or any problems are addressed according to Section 9.2.10 below.

9.2.4 All calibration and initial calibration verification data including raw data files are imported into the LIMS.

9.2.4.1 ICAL data, including raw data files, is imported in an individual analytical sequence with a designated run number. Sample and QC data are associated with the appropriate ICAL by entering the ICAL run number in the designated field in the analytical sequence.

9.2.4.2 Methods requiring daily calibration will have the associated ICAL information imported into the sequence containing the sample/QC data.

9.2.4.3 In all instances the sample/QC data imported into the LIMS will be able to be tracked to the ICAL used to generate the data.

9.2.5 All ICAL and ICV data will undergo a second review by the Laboratory Director, QA Manager or designated data review personnel –collectively designated as Data Reviewer(s) in subsequent Sections - for compliance with method requirements (Sec. 9.2.7 and 9.2.8). Any problems noted will be immediately brought to the attention of the responsible analyst and resolved before reporting sample data. Where this data exists in an individual sequence the reviewer will acknowledge the sequence producing a check mark in the ACK field. This person and the date of acknowledgement will appear in the analytical sequence.

9.2.6 ICAL and ICV data that have been reviewed as above and are acceptable for use will have the analytical sequence validated by checking the QA field. Only individuals possessing QA passwords will be able to perform this function.

9.2.7 Prior to validation ICAL data must be reviewed during the steps above for:

9.2.7.1 Procedures requiring instrument tuning – acceptable tune results prior to ICAL analysis.

9.2.7.2 Correct identification of all analytes.

9.2.7.3 Lowest standard is at or below the LOQ (RL/PQL).

9.2.7.4 Only contiguous data points are used.

9.2.7.5 Correct number of standards included in the ICAL. Must comply with the minimum number cited in the method and include the minimum number of points for the calibration model (e.g. 6 levels required for quadratic)

9.2.7.6 Percent RSD or correlation coefficient meets SOP requirements (or requirements of the method, technique or manufacturer are met) and where applicable minimum response factor criteria are met.

9.2.7.7 Major deviations in response from previous ICAL which would necessitate investigation.

9.2.7.8 All applicable raw data files including calibration curves when applicable are correctly imported into Omega.

9.2.7.9 ICAL standards logged into applicable analytical sequence.

9.2.7.10 Any notes or comments from the analysts or Data Reviewers.

9.2.8 Prior to validation ICV data must be reviewed during the process above for:

9.2.8.1 Acceptable instrument tune results (where applicable).

9.2.8.2 ICV is at or below the mid point of the calibration standards.

9.2.8.3 Percent difference, drift or recovery meets requirements.

9.2.8.4 Correct evaluation of the above is applied for the curve type used. %D is used for evaluations based on average response factors. Percent drift or recovery is used for other calibration models.

9.2.8.5 Minimum response factor criteria are met (where applicable).

9.2.8.6 Internal standard responses and compound retention times are within method requirements (where applicable)

9.2.8.7 Correct identification of analytes (where applicable).

9.2.8.8 ICV meets program requirements (see below).

9.2.9 ICAL and ICV data are further evaluated during Level IV data package review for completion, acceptability and conformance to SOP requirements. Any problems noted will be immediately brought to the attention of the analyst (and when necessary the Laboratory and/or QA Manager) producing the data and will be resolved prior to reporting sample results. If the review identifies problems that have impacted previously reported results, revisions to the affected data will be generated and all involved clients will be notified. Client

notifications will occur through clearly identified revised reports and through direct contact as necessary. Project managers or Laboratory Directors will be responsible for client notifications.

9.2.10 It is imperative that ICAL, ICV and CCV data be assessed according to the program under which sample data will be reported. Some methods assess continuing calibration by evaluating a subset or percentage of the compound list while specific programs require all target compounds meet designated criteria. In some instances compound lists may contain analytes that are poor performing or consistently fail to meet requirements. In these instances the following procedures are required:

9.2.10.1 Calibration ranges and verification levels can be adjusted to concentrations suitable for specific analytes provided the lower range corresponds to the required project LOQ or authorization is provided to raise the project LOQ.

9.2.10.2 Consistently problematic analytes can be designated as such and included as a variance to program requirements in project proposals.

9.2.10.3 Compounds that do not meet calibration or verification criteria can be communicated to the client project manager for authorization to proceed, with narration on the final report.

9.2.10.4 Efforts are made to identify the critical compounds for a project and to ensure that all calibration data for those compounds complies with the project/method requirements. Re-analysis is required when analytes critical to a project fail to meet specifications unless otherwise approved by the client. Any inability to meet acceptance criteria for critical analytes must be communicated to the data user.

9.2.10.5 Analytes that may not be considered critical to a project may be evaluated in conjunction with project time frames, holding times, laboratory capacity or other factors. In any instance communication with the client must occur and any results that do not meet project specifications must be narrated and communicated to the client.

9.2.11 It is the intent of RTI to report all sample data under conditions of acceptable ICAL/calibration verification. The above procedures (Sec. 9.2.10) are applied to instances of holding time considerations, project deadlines and chronic problematic analytes that have been identified as such through laboratory investigations or method citations.

In cases where calibration verification data (ICV/CCV) produces results for individual compounds exceeding limits with a high bias and that compound is not detected in samples the non-detect results may be reported without further action. The exceeding compounds will be noted in the report narrative.

It is understood that unique situations may be encountered and that not every possible variation in the analytical process can be addressed in this document. In all cases extraordinary analytical events will be brought to the attention of a Director. Communication between the laboratory, management, project managers and the data users is critical

9.2.12 The model used for initial calibration must conform to the options cited in the reference methods (e.g. EPA Method 8000D or individual methods), program criteria (e.g. DoD QSM) or when not specified instrument manufacturer options. Calibrations may follow the external standard, internal standard or isotope dilution (rarely used by RTI) approach. Calibration models include:

9.2.12.1 Linear calibration using average calibration or response factors (CF or RF/RRF).

9.2.12.2 Linear calibration using least squares regression – weighted or non-weighted. RTI adopts the procedure in EPA Method 8000D which allows the use of the instrument force through zero option for unweighted regression curves. RTI does not allow true forcing through zero by including a zero/zero point in the regression. As stated in Method 8000C this approach pivots the regression line and compensates for unequal weighting of the high standards. This approach will not be used when specifically prohibited by program or contract.

The instrument response is treated as the dependent (y) variable and the standard concentration (x) as the independent variable.

9.2.12.3 Non-linear calibration – quadratic (second order). When using this option the calibration curve must be continuous, continuously differentiable and monotonic over the calibration range. Weighting and forcing through the origin (as described above) may be used. A minimum of six calibration levels must be used.

The instrument response is treated as the dependent (y) variable and the standard concentration (x) as the independent variable.

RTI will use non-linear calibration models when the linear approaches do not meet acceptance criteria or when instrument responses do not follow a linear model over a sufficiently wide calibration range.

RTI does not allow use of non-linear calibration for compensation of detector saturation or in lieu of proper instrument maintenance.

9.2.13 The entire review process (Section 9.2.1 – 9.2.12) must be completed and any necessary comments included prior to reporting any sample data.

Analytical Data Review

9.2.14 On completion of an analytical event the data imported into the LIMS as described in Section 9.1 will be thoroughly reviewed by the analyst responsible for performing the testing. This initial review will encompass the following:

9.2.14.1 Verification that all samples in the analytical batch including calibration verification and QC samples are present in the LIMS analytical sequence.

9.2.14.2 Verification that all associated raw data files are correctly linked with the applicable file type in the LIMS analytical sequence. In addition to the sample associated raw files, verification that batch files (run logs, calibration evaluations, degradation checks, second column RPD reports and others as required) are correctly linked to the sequence.

9.2.14.3 Analysts will verify that all LIMS references (Blank, Spike, RPD, CCV, Second column) have the correct LIMS designated sequence number.

9.2.14.4 Confirm that the correct LIMS prep batch number is linked to the sample for methods having an associated sample preparation step.

9.2.14.5 Ensure the sample preparation factors where applicable are present and correct.

9.2.14.6 Verify that dilution factors (when required) are present and correct.

9.2.14.7 Verification that continuing calibration samples are present in the correct frequency, correctly bracket samples where required and that analysis occurs within method time frames where stipulated.

9.2.14.8 After ensuring that the sequence is complete the analyst will calculate the sequence. This will result in all required calculations being performed and will change the status of the samples to complete.

9.2.14.9 The analyst will review the calculated results for obvious anomalies (dilution factor errors, incorrect units, etc.) and for results exceeding the upper calibration range (E flagged). The results for compounds exceeding the upper calibration range will be un-checked to report and repeated at a dilution unless there is insufficient volume for additional analysis. In this case a comment will be placed in the appropriate sample field for inclusion in the case narrative.

9.2.14.10 Acceptable continuing calibration results are required to proceed with sample reporting. If continuing calibration data is not acceptable the analyst will repeat the analytical batch or those samples affected (within the associated bracket where applicable for the method), consult with a Director on the proper course of action or inform the project manager for client contact. Analysts will review continuing calibration data for:

9.2.14.10.1 Acceptable instrument tune results (where applicable).

9.2.14.10.2 CCV is at or below the mid point of the calibration standards.

9.2.14.10.3 Percent difference, drift or recovery meets requirements.

9.2.14.10.4 Correct evaluation of the above is applied for the curve type used. %D is used for evaluations based on average response factors. Percent drift or recovery is used for other calibration models.

9.2.14.10.5 Minimum response factor criteria are met (where applicable).

9.2.14.10.6 Internal standard responses and retention times are within method requirements (where applicable).

9.2.14.10.7 Correct identification of analytes (where applicable).

9.2.14.10.8 CCV meets program requirements (refer to Section 9.2.10).

9.2.14.11 Standard RTI procedure requires the analysis of a standard at the LOQ. These samples are designated as CRQL or RLVS and are evaluated for continuing sensitivity at the reporting limit and to assess the effect of regression models used for calibration. This approach improves quantification of results at the low end of the calibration range. Except where required by method to assess linear regression data, CRQL/RLVS results are evaluated against method control or default limits in the test code and are not used to strictly assess method control since it is expected that results at this level will exhibit more variability. The judgment of the analyst, Data Reviewer and QA department will determine when action needs to be taken on results exceeding specified limits. Single analyte and metals analyses require results to be within limits before sample data can be reported. Multi-analyte procedures are evaluated for general suitability of data without strict guidelines

except as noted above for linear regression evaluation. The judgment and experience of the reviewer with the method and compounds determines if action is required.

9.2.14.12 Method blanks will be reviewed for positive results. An acceptable method blank will contain no results greater than the reporting limit (RL/LOQ/PQL), ½ the LOQ (for DoD QSM projects) or greater than the LOD as defined by the program for State of Wisconsin projects. Results exceeding the applicable criteria above will be qualified in the analytical report case narrative. Qualifiers (B flags) will be assigned to the associated analyte(s). Obvious contamination present in a method blank requires re-extraction/re-digestion of the batch if sufficient volume is available. If insufficient sample remains the data must be appropriately qualified and narrated. In cases where results are slightly above the blank acceptance criteria the analyst will consult with a Project Manager or Data Reviewer on actions to be taken. Method blanks will also be assessed in relation to the concentrations observed in the associated samples. Method blank concentrations may be acceptable if the level is < 1/10 of the amount detected in all associated samples.

9.2.14.13 Analysts will evaluate the LCS for acceptability. The results of the LCS must be within the test code specifications. LCS control limits are based on DoD QSM limits where available, method required limits when specified or laboratory generated limits (refer also to QAP Sections 3 and 12). Results exceeding control limits will be flagged with an S or Q.

The analyst will perform an initial overall review of the LCS and when obvious problems exist with the data (i.e. unacceptable results for single analyte tests or metals, significant number or degree of unacceptable data points) may initiate re-analysis of the sample batch provided other considerations as described below do not preclude the re-analysis.

Analysts may defer further evaluation of the LCS to the Data Reviewer when questions regarding the suitability of the LCS arise.

Unacceptable LCS results require re-extraction/re-digestion and re-analysis unless there is insufficient sample volume for repeat analysis, holding time considerations or other affecting factors. If no reanalysis occurs the data must be appropriately flagged and narrated.

Multi-analyte tests are evaluated according to the following guidelines or according to program (DoD QSM) or project specifications when required. The number of compounds exceeding control limits in a LCS must conform to the following for acceptability.

Compounds	Exceedances
>90	5
71-90	4
51-70	3
31-50	2
11-30	1
<11	0

Exceedances are defined as results exceeding the LIMS test code limits for a compound since the limits are based on DoD QSM values and not statistically derived numbers. Evaluation of the marginality of an exceeding result can be determined though comparison to the LIMS generated control limits – results >3 standard deviations but <4 standard deviations are generally considered as marginal exceedances.

A compound that exceeds control limits in consecutive LCS samples or in two of the last three consecutive LCS samples is considered to be an indication of a problem requiring investigation and possible corrective actions.

It is the intent of RTI to report sample data under conditions of acceptable LCS results. However in analyses involving extensive lists of compounds and/or containing known poor performing analytes situations may arise that prevent strict application of the above criteria. LCS results will be evaluated in relation to the impact on project objectives and the relationship between the LCS results and the sample data (e.g. Elevated LCS recoveries for non-detect sample results)

Efforts are made to identify the critical compounds for a project and to ensure that all LCS data for those compounds complies with the project/method requirements. Re-analysis is required when analytes critical to a project fail to meet specifications unless otherwise approved by the client. Any inability to meet acceptance criteria for critical analytes must be communicated to the data user.

Analytes that may not be considered critical to a project may be evaluated in conjunction with project time frames, holding times, laboratory capacity or other factors. In any instance communication with the client must occur and any results that do not meet project specifications must be narrated and communicated to the client.

9.2.14.14 Analysts will review Matrix Spikes (MS), Matrix Spike Duplicates (MSD) and sample Duplicates (DUP) against control limits incorporated in the associated test code. Results exceeding control limits for spikes will be flagged with an S or Q; results exceeding control limits for duplicates will be flagged with an R. QC data exceeding control limits will be assessed for possible matrix affects, spiking errors, analyte concentration in the parent sample or other situations that may impact these QC sample results. Significant failure of QC samples that cannot be directly attributed to sample matrix, dilution or spiking will be brought to the attention of the Laboratory or QA Manager for determination of additional actions.

9.2.14.15 Evaluate surrogate recoveries for applicable methods. Recoveries that exceed control limits will be flagged with an S or Q and must be assessed for possible matrix effects, spiking errors, dilution effects or other factors that may impact surrogate results. Actions taken or narrative comments will conform to SOP guidelines or be determined by the Laboratory or QA Manager.

9.2.14.16 Analysts will check to ensure that no holding time flags are present for samples analyzed in the sequence. Samples that are H flagged will require investigation to assess if the holding time has been exceeded. Samples determined to have been prepared or analyzed beyond the holding time will be brought to the attention of the Project Manager for communication to the client and any necessary action.

9.2.14.17 Verify the acceptability of internal standard responses and re-analysis for unacceptable internal standard results.

9.2.14.18 The analysts will verify that the analytical sequence has met the requirements of the method SOP.

9.2.14.19 For methods that may require manual integration the analyst will ensure that all linked raw data contains the before and after integrations, reason for the manual integration and the initials of the analyst.

9.2.15 Following review by the analyst a second review will be performed by a Data Reviewer. All of the steps in Section 9.2.14 will be performed during the review.

9.2.16 The Data Reviewer will then review the analytical sequence to ensure and/or evaluate:

9.2.16.1 Verification that all ICAL, ICV and CCV results conform to method/program requirements and if necessary ensure that procedures specified in Section 9.2.10 have been followed.

9.2.16.2 Ascertain that the correct types and frequency of QC samples have been analyzed with the batch and all references are correct.

9.2.16.3 Ensure that all raw data files are linked correctly.

9.2.16.4 Review raw data for completeness and assess manual integrations where applicable.

9.2.16.5 Ensure that sequences entered contain the sample preparation information where required, date and time of analysis and the analyst performing the tests.

9.2.16.6 Check for QC data flags. QC sample results are automatically calculated by the LIMS and if values are outside of the established limits flagged as follows:

9.2.16.6.1 Q – Quality control sample result exceeds control limits (QSM DoD reporting).
9.2.16.6.2 R – RPD value exceeds control limit.
9.2.16.6.3 B – Analyte found in associated method blank.
9.2.16.6.4 J – Estimated result, analyte detected below PQL.
9.2.16.6.5 U – Undetected at the limit of detection.
9.2.16.6.6 E – Estimated result, value exceeds UQL.
9.2.16.6.7 S - Quality control sample result exceeds control limits.
9.2.16.6.8 N – Non-target analyte (GCMS Tentatively Identified Compound).
9.2.16.6.9 P – Second column RPD exceeds 40%.
9.2.16.6.10 */X – Sample result exceeds the Maximum Contaminant Level (Permit or Regulatory Limit).

The Test Code database within Omega contains sections for entering applicable QC specifications including the known value of the standard or spike, the upper and lower control limits and the RPD for duplicate measurements.

9.2.16.7 The Data Reviewer will evaluate the data set for any flags associated with either the sample or QC results. Q/S flags associated with calibration verification standards or LCS samples require assessment according to the guideline in Sections 9.2.10, 9.2.11 and 9.2.14.13 and may result in rejection of the data, re-analysis of the affected samples or actions taken according to guidelines above. Flags appearing on matrix spikes, duplicates or other non-calibration verification QC samples will be investigated to the extent necessary (in accordance with Method and SOP specifications) and applicable comments will be noted for that sample. These comments will be automatically transferred to the Case Narrative for that particular Work Order. Batch QC data that does not meet the minimum requirements for acceptance as specified in the SOP or reference method will require rejection of the data or narration of the problems if re-analysis cannot be performed.. The Rpt check mark in the view/edit data section will be removed. This disables reporting of data for that analyte in the sample and requires re-preparation and/or re-analysis of the sample batch. Similarly, individual samples with unacceptable surrogate recoveries may be rejected as above and require re-analysis. For instances in which QC results are unacceptable and there is insufficient sample for re-analysis, the appropriate notation will be made on the case narrative for that report.

9.2.16.8 Ensure that all required comments and narrations are present, appropriate for the data and are correctly presented.

9.2.16.9 Verify that the data in the analytical sequence meets the requirements of the SOP and project data quality objectives.

9.2.16.10 During review the Data Reviewer will evaluate sample results for possible anomalies, missing data (PMOIST results, prep information, etc.) and any other factors affecting data quality.

9.2.16.11 Ensure that the Cal Stds, Reagents/Chemicals and Equipment tabs have the required information.

9.2.16.12 When the Data Reviewer determines that the data set meets the required objectives the sequence will be toggled to an acknowledged status and a check mark will be placed in the ACK field of the sequence.

9.2.17 Analytical data entered into Omega requires the review and validation process specified above prior to reporting. Any data that has not been toggled as validated will result in the report being automatically flagged by the LIMS as preliminary. Acknowledged analytical data is validated by the Data Reviewer. Individuals with authority to validate data within Omega have a unique password that allows validation of sequences. When the Reviewer has determined that the data set meets the required objectives, the data can be toggled to a validated status by entering the appropriate password and selecting QA sequence. This review consists of an overall review of the data set for completeness, adequate addressing of any QC issues noted and may incorporate any or all of the review steps noted above. At a minimum 10% of all data will be audited by performing a complete review of the data set during preparation of Level IV data packages.

The Level IV data process encompasses:

9.2.17.1 Gathering and compilation of all work order reports, sample receiving documents and raw data for all testing performed.

9.2.17.2 Review of project data for completeness, adherence to project specifications and compliance with all method/program requirements.

9.2.17.3 Review by QA Department.

9.2.18 Only the designated individuals have the required passwords to validate sample data and are separate from the passwords required to log onto the system. These passwords are also required to make any changes in data that has been previously validated. Once a sample or data set has been completed and validated only an individual possessing the authority can make changes. These require an explanation of the reason for the change that is automatically mandated by the LIMS.

9.3 DATA REPORTING

9.3.1 When all tests have been validated in a Work Order the Work Order will be updated within Omega to validated status. A final report will then be generated and reviewed by a Project Manager. Assigned individuals in the QA Department or a Director can also issue reports. These individuals have been assigned electronic signatures and are designated as the approved signatories for final reports. The responsible individual will evaluate the report for the following and if acceptable validate the report and either make it available to the client via web based access (Flashpoint) or issue an electronic version.

9.3.1.1 Comparison to historical data (when available) and general credibility.
9.3.1.2 Analyte correlation or other relationships.
9.3.1.3 Completeness and adherence to sample request and project objectives.
9.3.1.4 Review of case narrative to ensure comments are clear and concise. Review comments that require client notification and verify that issues have been adequately resolved or communicated. Assess comments for correct spelling and grammar.

It is understood that unique situations may be encountered and that not every possible variation in the analytical process can be addressed in this document. In all cases extraordinary analytical events will be brought to the attention of a Director. Communication between the laboratory, management, project managers and the data users is critical

9.3.2 Sample data is entered into and reported from the LIMS system. Reports are provided as electronic pdf documents by Flashpoint, e-mail or fax. Hard copy paper reports can be provided on request. The RTI LIMS can export data into several formats (Excel, Access, etc.) and can be customized to include the information required by the client. The individuals noted above are authorized to validate the report and electronic data deliverable (EDD) in the work order. Electronic transmission of the work order cannot occur within the LIMS unless it has been validated. The above individuals must generate and review the initial report prior to validation.

9.3.2.1 It is the standard practice of RTI Laboratories Inc. to issue reports without advertising logos or reference to certifying or accrediting bodies. References to currently held accreditations such as A2LA, NELAC or others do not appear on standard RTI reports and as such include tests and analytes within the RTI scope of services without reference to accreditation status. All test procedures are performed in accordance with current accreditation standards; however RTI does not maintain accreditation for every test procedure that is reported. RTI publicly maintains its accreditation information and certificates issued by the accrediting body listing the scope on its web site. Accreditation status is readily available to all clients through the RTI web site. When required tests are reported that are not included in an applicable scope the test is noted in the report case narrative.

9.3.2.2 Standard test reports are issued according to the formats described below and are based on ISO 17025, DoD QSM or other specifications.

9.3.2.3 In instances where a program or client mandates that reports comply with the applicable accreditation, RTI will issue compliant data deliverables. These reports will clearly identify the accreditation status of all test procedures and will contain flags to indicate tests or analytes reported that are not included in the scope of accreditation. The report will identify the accrediting body and the RTI certification number. The report will also include any specific reporting requirements for the applicable standard. The logo of the accrediting agency generally will not be included on the report but when required will comply with the advertising policies of the accrediting body.

9.3.3 Data is reported in RTI format corresponding to Level I, II, III or IV depending on the project requirements. These reporting levels are integrated into the LIMS and are specified at sample login depending on client/project specifications.

9.3.4 A Level I standard laboratory report contains the items listed below. All reports are automatically page numbered in the format Page X of X from the first page to the end of the report:

9.3.4.1 Cover page including client name and address, client designated individual receiving the report, laboratory name and address, project name/number, laboratory order #, date received, date reported, number of samples received, notes applicable to the types of samples, and signature and title of reviewer.
9.3.4.2 Title and Laboratory Order #
9.3.4.3 Sample Identification (Lab ID and Client ID)
9.3.4.4 Date and Time of Collection
9.3.4.5 Matrix
9.3.4.6 Air Volume Information – where applicable
9.3.4.7 Test Name
9.3.4.8 Method References
9.3.4.9 Analytes Reported
9.3.4.10 Final Results including surrogate recoveries and control limits – where applicable.
9.3.4.11 Detection Limits – LOQ/RL and LOD and DL when required.
9.3.4.12 Reporting Units
9.3.4.13 Date and Time Analyzed
9.3.4.14 Analyst
9.3.4.15 Dilution Factor
9.3.4.16 Qualifier Flags
9.3.4.17 Page Numbers
9.3.4.18 Sample Summary (optional) – when requested
9.3.4.19 Dates Report (optional) – when requested. Includes preparation, extraction and analysis dates for holding time verification.
9.3.4.20 Chain of Custody Record
9.3.4.21 Case Narrative

9.3.4.22 Definitions
9.3.4.23 Sample Receipt Checklist (optional)

9.3.5 A Level II report contains all of the information included in Section 9.3.4 plus:

9.3.5.1 Quality Control summary that includes, where applicable, the results and control limits for:

9.3.5.1.1 Method blanks
9.3.5.1.2 Laboratory control sample
9.3.5.1.3 Matrix spike/Matrix spike duplicate
9.3.5.1.4 Duplicate sample –where applicable
9.3.5.1.5 Other QC samples as specified by project requirements (ICV, CCV, ICB, CCB, PSD, Serial Dilution, etc.)

9.3.6 A level III reports contain in addition to the material in Sections 9.3.4 and 9.3.5 client specified information beyond the Level II report but not including raw data. This report is generally specific to client/project requirements without containing the full data package information in a Level IV report. Information that may be included in a Level III report:

9.3.6.1 Instrument calibration and continuing calibration summaries.
9.3.6.2 Sample receipt checklists.
9.3.6.3 Other information as required by client or contract.

9.3.7 Level IV reports contain the following components and include all of the information provided in Level I and II reports:

9.3.7.1 Cover page signed by the person responsible for the report.
9.3.7.2 Table of Contents
9.3.7.3 Case Narrative
9.3.7.4 Definitions and Acronyms Report
9.3.7.5 Project receiving documents including chain of custody forms, shipping labels and information and sample receipt checklists.
9.3.7.6 Sample summary report.
9.3.7.7 Dates report.
9.3.7.8 Analytical report summary.
9.3.7.9 Quality control summary.
9.3.7.10 Forms and raw data for each analytical method – non-CLP forms.

9.3.7.10.1 Sample preparation logs (where applicable)
9.3.7.10.2 LIMS Run Log
9.3.7.10.3 LIMS Analytical Run Summary
9.3.7.10.4 LIMS Surrogates Report (where applicable)
9.3.7.10.5 LIMS Spikes Report
9.3.7.10.6 LIMS Method Blank Report
9.3.7.10.7 Raw data including as applicable to the method - injection/run logs, tune reports, CCV evaluations,

chromatograms/instrument printouts, detailed compound spectra reports, library search reports, instrument calibration evaluations and associated raw data, internal standard reports, degradation reports, manual integration reports, second column RPD reports all sample, QC sample and calibration raw data.

9.3.7.10.8 Reports utilizing CLP equivalent forms will in place of items 9.3.7.9.2 – 9.3.7.9.6 use standard CLP forms 1 –10 for organics and forms 1 –15 for inorganics.

9.3.7.10.9 Other forms and data as may be required by the project.

9.3.8 A Level IV report following the reporting format of the EPA Contract Laboratory Program (CLP) current SOW (Statement of Work) and is available on request. The LIMS contains the CLP deliverables forms that comply in equivalent format with the SOW under which analyses are performed and the cited Exhibits and Appendices for that SOW and will include:

9.3.8.1 Instrument Calibration Data
9.3.8.2 Instrument Data Printouts
9.3.8.3 Chromatograms
9.3.8.4 GC/MS Tuning Results
9.3.8.5 Preparation and Analysis Logs

9.3.8.6 A designated individual and alternate will be responsible for the preparation of the SDG (Sample Delivery Group) files to be submitted.

9.3.8.7 All documents pertaining to the SDG file as required by the SOW will be compiled, maintained in a secure location and all copies will be made in a manner that ensure legibility and completeness.

9.3.8.8 Documents pertaining to more than one SDG will be stored with the lowest SDG number and subsequent files will be stamped with the location of the copies.

9.3.8.9 All complete SDG files will be paginated with sequential numbers on each page and accompanied by a complete Form DC-2.

9.3.8.10 Completed SDG files will be reviewed by the QA Manager or designated individual prior to submittal and will include review for completeness, compliance with SOW requirements, legibility of documents and delivery requirements.

9.3.8.11 Shipping of the files will be documented with what was sent, to whom, the date and the manner of shipping (i.e. carrier used). Data packages will get affixed with custody seals signed and dated.

9.4 RECORD RETENTION

9.4.1 Paper copies of the original Chain of Custody and sample log sheet (where applicable) are maintained in Laboratory files for no less than twelve (12) years unless otherwise stipulated by contract.

9.4.2 LIMS data is stored electronically for a period of no less than twelve (12) years unless otherwise stipulated by contract.

9.4.3 Electronic instrument data, bench sheets, calculation spread sheets and other forms of computer generated and storable data are stored electronically for no less than twelve (12) years unless otherwise stipulated by contract. Required paper copies of laboratory raw data, bench sheets and instrument printouts are stored for at least twelve (12) years unless otherwise stipulated by contract.

9.4.4 All records either electronic or hard copy will be considered confidential to the client and maintained in a secure manner.

9.4.5 All records involved in the analytical process and required to reproduce the analytical activities associated with data produced will be maintained.

9.5 ELECTRONIC DATA SECURITY

9.5.1 Data integrity is ensured through daily backups, multi-level security and off-site storage. Access to the specific user privileges can be individually controlled.

9.5.2 Each user has a unique user name and password that allows certain privileges.

9.5.2.1 All individual LIMS passwords must be changed at least annually

9.5.2.2 The QC and IT Departments will maintain a record of all LIMS password changes to ensure the annual requirement is being met.

9.5.3 The LIMS Administrator is responsible for maintaining the security of the RTI server and ensuring that external sources cannot compromise the integrity of laboratory data.

9.5.4 All employees are provided computer security awareness training annually.

9.5.5 A computer usage policy is incorporated in Section 17.

9.5.6 The IT manager is responsible for the proper operation of all hardware systems and for ensuring compatibility with software, data system and instrument requirements.

10.0 PERFORMANCE AND SYSTEM AUDITS

10.1 Internal Laboratory Audits

10.1.1 Internal Performance Audits – Proficiency Testing Plan

RTI participates in programs whereby samples of unknown concentration are submitted for analysis. These single blind performance audits follow the plan below.

Table 1
Environmental Sciences PT Plan

Parameter	ERA WP	ERA Soil	ERA WS	ERA AE
Metals 6020/200.8	Twice per year	Twice per year	Twice per year – 200.8	
Nutrients – EPA and Standard Methods	Twice per year	Twice per year	Twice per year – 300.0	
Demand – EPA and Standard Methods	Twice per year	Twice per year		
Wet Chemistry – EPA and Standard Methods	Twice per year	Twice per year	Twice per year – Cyanide	
Organics – EPA 600/8000 Methods	Twice per year	Twice per year		
Organics – EPA 500 Methods			Twice per year when certified.	
Organics – EPA TO4, TO10 and TO15				Twice per year when certified.
Waste Parameters		Twice per year		

Accredited test methods with no available PT samples:

White Phosphorus
Chemical Agent Degradation Compounds

Proficiency monitored through LCS samples prepared for each batch, quarterly LOD/LOQ studies and annual demonstration of accuracy and precision at the LOQ.

The following Test Matrix describes the proficiency testing (both inter and intra-laboratory) for the period of 2011 and beyond. The matrix utilizes all commercial testing providers where available.

Table 2
Materials Sciences PT Plan 2016 – 2019 (A2LA Scopes)

Parameter	**2016 Provider**	**2017 Provider**	**2018 Provider**	**2019 Provider**
Tension	CTS - Twice	CTS – Twice	CTS - Twice	CTS Twice
Rockwell Hardness	CTS – Twice	CTS – Twice	CTS - Twice	CTS Twice
Brinell Hardness	CTS – Twice	CTS – Twice	CTS - Twice	CTS - Twice
Microhardness	CTS – Twice	CTS – Twice	CTS – Twice	CTS – Twice
Alloy chemistry	CTS-Twice	CTS-Twice	CTS-Twice	CTS-Twice
Charpy Impact	None – NIST verification annual	None – NIST verification annual	None – NIST verification annual	None – NIST verification annual
Coating Thickness	None – no commercial vendors	None – no commercial vendors	None – no commercial vendors	None – no commercial vendors
Plating Adherence	None – no commercial vendors	None – no commercial vendors	None – no commercial vendors	None – no commercial vendors
Coating Weight	None – no commercial vendors	None – no commercial vendors	None – no commercial vendors	None – no commercial vendors
Olsen Cup	None – no commercial vendors	None – no commercial vendors	None – no commercial vendors	None – no commercial vendors
Bend Test	None – no commercial vendors	None – no commercial vendors	None – no commercial vendors	None – no commercial vendors
Metallographic analysis (banding, decarb, inclusion, grain size, case, microstructure, cast iron)	CTS Pilot study - twice	CTS Pilot study - twice	CTS Pilot study - twice	CTS Pilot study - twice

SEM/EDS	None	None-qualitative	None-qualitative	None-qualitative
Salt Spray	None	Round robin – twice with 2 local labs	None – twice with 2 local labs	None – twice with 2 local labs
Failure Analysis	None	None-qualitative	None-qualitative	None-qualitative
ICP OES and MS	ERA WP (twice), ERA Soil (twice)	ERA WP (twice), ERA Soil (twice)	ERA WP (twice), ERA Soil (twice)	ERA WP (twice), ERA Soil (twice)
Ion chromatography	ERA WP (twice), ERA Soil (twice)	ERA WP (twice), ERA Soil (twice)	ERA WP (twice), ERA Soil (twice)	ERA WP (twice), ERA Soil (twice)
Phenols	ERA WP (twice)	ERA WP (twice)	ERA WP (twice)	ERA WP (twice)
PCB	ERA WP (twice), ERA Soil (twice)	ERA WP (twice), ERA Soil (twice)	ERA WP (twice), ERA Soil (twice)	ERA WP (twice), ERA Soil (twice)
Water Content	None	None	None	ASTM – Oil program – 3 times
Viscosity	None	None	None	ASTM – Oil program – 3 times
Hexavalent Chromium	ERA WP (twice), ERA Soil (twice)	ERA WP (twice), ERA Soil (twice)	ERA WP (twice), ERA Soil (twice)	ERA WP (twice), ERA Soil (twice)

10.1.1.1 All performance evaluation samples are analyzed in a manner consistent with routine sample analysis. Every attempt is made to integrate these performance evaluation samples into normal workload. Treatment of PT (performance testing) samples in a manner that would not be used for client samples is prohibited. This includes multiple analyses that would not routinely be performed, averaging of results, eliminating or adding any steps in the sample preparation or analytical process, sub-contracting of PT samples or consultation with outside organizations during open studies and any other means designed to apply special treatment to these samples.

10.1.1.2 Results of PT studies are submitted to primary accrediting bodies (A2LA, State of Utah – NELAC, State of Michigan – Drinking Water), for secondary State certifications where requested and ACIL.

10.1.1.2.1 ERA graded results are submitted directly to A2LA, applicable States and ACIL.

10.1.1.2.2 CTS results are forwarded by RTI to A2LA within 7 days of receipt of the graded results.

10.1.1.2.3 Corrective actions for unacceptable PT data are submitted to primary accrediting bodies within 30 days of receipt of the graded results.

10.1.1.3 PT samples are a single blind program and as such are not meant to completely mimic routine samples. These samples arrive in a manner that is not consistent with client samples, contain specific preparation and reporting instructions and in containers clearly marked as PT samples that are not consistent with normal sample containers. PT samples are received and distributed by the QA department PT coordinator. PT samples are logged in the LIMS and a report generated for use in PT data submittal. PT results are reported through the LIMS by generation of a csv file and direct upload to the ERA web site. PT samples are tracked by the Laboratory Director and analysts in a manner consistent with routine samples according to the assigned due date.

10.1.1.4 The QA Manager evaluates the results of these studies. Corrective Action procedures as specified in Section 13.0 are undertaken to resolve deficiencies.

10.1.1.5 As part of the effort to identify and resolve deficiencies or as an additional check on Laboratory performance the QA Manager or Laboratory Director may obtain additional PT samples, performance check samples from another commercial source or prepare samples internally. These samples are evaluated against the acceptance levels or laboratory control limits and corrective actions taken as necessary.

10.1.1.6 The laboratory may receive client audit or blind QC samples. These samples will be analyzed as routine samples or according to client specified procedures. Any provided feedback from the results of these samples will be used to assess laboratory performance and institute any necessary corrective actions.

10.1.2 Internal Systems/Technical Audits.

10.1.2.1 Audits will assess Laboratory compliance with the QAP, certification policy requirements and technical method requirements. Annually the QA Manager will schedule an internal Laboratory system and technical audits. The audit will be conducted based on and documented using 'Audit Form.doc'. The form used is the A2LA combined ISO/IEC 17025 and DOD checklist for laboratory site assessment and includes the requirements of the ISO Standard and DoD QSM requirements.

10.1.2.1.1 The systems audit will be conducted by the QA Manager and Laboratory Director during the second calendar quarter of each year (April – June).

10.1.2.1.2 Technical audits will commence in 4th quarter of each year and be completed by the 1st quarter of the next year and will include evaluation of each method performed by the laboratory.

10.1.2.2 The system audit encompasses Laboratory documentation on sample receiving, sample log in, sample storage, chain of custody procedures, sample preparation and analysis, sample tracking, report generation and any other pertinent facet of the Laboratory operation required to demonstrate compliance with QAP and accreditation/certification requirements. Records included in the review include:

10.1.2.2.1 QAP and SOPs for status of current review.
10.1.2.2.2 Training records for completeness.
10.1.2.2.3 LIMS records for compliance with QAP/SOP procedures.
10.1.2.2.4 Non-LIMS laboratory logs.

10.1.2.3 Systems audits are conducted and documented on the audit form each year by the QA Manager and Laboratory Director.

10.1.2.4 Any deficiencies noted during the audits will require investigation and corrective action implementation. Findings will be discussed with applicable personnel. If required by the finding periodic reviews will be conducted to assess completed resolution. Subsequent audits will assess the effectiveness of the corrective actions.

10.1.2.5 The QA Manager and Laboratory Director are independent of the activities being audited with respect to the basic operational activities of the laboratory. While both individuals participate in data review, report generation and compilation of data packages the ability to effectively assess these areas is not compromised since these activities incorporate data assessment of the analytical process with the end result of generating quality data. Data package compilation represents a form of data auditing whereby the QA Manager and QA staff review raw data and assess compliance with method and program requirements. The packages generated are evaluated by an outside party for compliance. Both individuals may generate routine analytical reports but are also able to assess the process from an independent perspective and participate in LIMS system assessments to continually improve the accuracy and quality of laboratory reports.

10.1.2.6 Level IV data packages (Refer to Sec. 9) are routinely produced by the QA Manager, QA department staff or Project Management Department. These data packages include a review of all raw data, instrument printouts, laboratory reports and chain of custody/sample receipt for compliance with laboratory, method, client and program requirements and enable a data audit of select projects.

10.1.2.7 Technical audits are performed by the QA Manager, QA department staff or the Laboratory Director to assess compliance with method specific requirements to ensure quality of data generated by the related technical activities. These procedures involve evaluation of all aspects of individual test methods and are documented on the technical audit form located in the applicable audit folder. QA department staff has been trained by the QA Manager on process and details for performing technical audits. Training documents are maintained on file.

Technical audits may also be performed by senior staff chemists provided the method audited is not being performed by that individual. The assigned individual will be trained by the QA Manager or Laboratory Director in the required aspects of the auditing process.

All trained individuals will be instructed to:

10.1.2.7.1 Assess the assigned method according to the Laboratory SOP.

10.1.2.7.2 Review the laboratory SOP to the method reference for compliance of required specifications or acceptability of modifications.

10.1.2.7.3 Audit current practices for compliance with the SOP and assess actions related to the generation of data.

10.1.2.8 All individuals involved in the auditing process will work under the direction of the QA Manager.

10.1.2.9 Audit checklists used by other accrediting programs (A2LA, Client, etc.) may be used to ascertain compliance with the program policies. These checklists will supplement internal system audit documentation.

10.1.2.10 Following completion of the system audit any findings that represent instances of non-compliance will be investigated as to the cause and corrective actions implemented (Refer to Sec. 13 for addition information regarding corrective action procedures).

10.1.2.11 Any deficiencies noted during the technical audits will be immediately brought to the attention of the QA Manager for investigation and corrective action implementation. Subsequent audits will assess the effectiveness of the corrective actions.

10.1.2.12 Any deficiencies noted that may have impacted the validity of reported results require notification to affected clients.

10.1.2.12.1 Clients will be notified immediately (within 24 hours) of any finding that would cause a significant change in the test results reported. Corrections to the data set will be made and a revised report issued within one to five days of notification depending on the magnitude of the change and the complexity of the report. Significant changes are defined as those that would cause a reported result to be re-evaluated with respect to a regulatory limit or represent false positive or false negative situations with regard to critical project analytes.

10.1.2.12.2 The above notification requirements would also apply to findings that identify major deviations from the SOP/Method that would invalidate the

data (wrong reagents, incorrect volumes, inadequate or malfunctioning equipment) or quality control results that would render the data unusable.

10.1.2.12.3 Clients will be notified within 30 days of any finding that would result in minor changes to the data reported

10.2 EXTERNAL LABORATORY AUDITS

10.2.1 RTI willingly participates in any client or government agency audit whether project specific or required by the client or agency.

10.2.2 The Laboratory has had numerous project related audits and maintains accreditations that require periodic audits, these include.

10.2.2.1 A2LA - Every 2 years
10.2.2.2 UT NELAC – Every 2 years
10.2.2.3 Michigan DEQ drinking water – Every 3 years

11.0 PREVENTATIVE MAINTENANCE

11.1 Maintenance Activities

11.1.1 RTI maintains analytical instruments based on the manufacturer's recommendation and/or the requirements of the reference method.

11.1.2 The laboratory is committed to maintaining instruments in proper working order and will perform preventative maintenance to ensure optimum operation.

11.1.3 Section 15 of each SOP details specific preventative maintenance activities associated with the analytical method.

11.1.4 The instrument section of the LIMS contains a table for each instrument/instrument type that specifies routine maintenance for each instrument.

11.1.5 All instruments are logged in the Omega LIMS and contain instrument description, manufacturer, serial number, date purchased and service agreement information where applicable or when available.

11.1.6 A maintenance log is associated with each instrument in the LIMS. All instrument maintenance is recorded in these logs.

11.1.7 Maintenance activities include any action taken on an instrument that involves replacement or modification of instrument components (e.g. septa, tubing, columns, etc.) either routine or non-routine and is not associated with the electronic instrument settings (e.g. flow, temperature, etc.)

11.2 Contingency Plans

11.2.1 The Laboratory is equipped with multiple instruments that serve the same or similar purpose allowing for back up capabilities in most areas. Alternate accepted techniques are also available for sample analysis. The techniques can be used provided the required reporting limits can be achieved and are acceptable to the data user.

11.2.2. If samples cannot be analyzed due to capacity or down time, within the holding time requirement or other factors stipulated by the project, RTI will, in consultation with the client, attempt to arrange for analysis by another Laboratory. Projects with accreditation stipulations require that the subcontracted laboratory have the requisite certification. Analyses that will be performed under accreditation standards (e.g. NELAP, DoD ELAP) must be sent to a laboratory holding that accreditation unless approved by the client.

12.0 ROUTINE PROCEDURES USED TO ASSESS DATA ACCURACY, PRECISION AND COMPLETENESS

12.1 Accuracy Assessment – Matrix/Media Spikes (MS/MSA) Matrix/Media Spike Duplicate (MSD/MSDA)

12.1.1 The accuracy of analytical procedures is monitored by spiking random samples of the same matrix or type at a frequency of 5% (one (1) per batch of twenty (20) or as stipulated by the method or project) with the analyte(s) of interest and processing through the same procedures as the samples. Spikes are prepared at a level near the middle of the calibration range. For air sample analyses media spikes are employed whereby a known amount of analyte is added to blank sample collection media (unless calibration is performed by fortifying and desorbing/eluting certain media). The amount recovered is a function of the concentration measured in the spiked sample minus any sample level of analyte and is expressed as percent recovery. The calculation follows the formula:

$$\%\ R = (C_{MS} - C_S)/A \times 100 \qquad \text{Eq. 12-1}$$

Where:

% R	= Present Recovery
C_{MS}	= Concentration of Matrix Spike
C_S	= Sample Concentration
A	= Amount Spiked

12.1.2 For most analytical procedures a MSD is required. This QC sample is used to verify MS accuracy as above and to assess precision (See Section 12.4). Routinely both the MS and MSD are used to assess the accuracy of the associated analytical event and statistically can be used to assess the overall accuracy of the method. In specific instances when both a MS and MSD are analyzed the %R used for accuracy assessment may be calculated as the average of the %R MS and %R MSD. Air sampling procedures require routine assessment of a MSA and MSDA.

12.1.3 Recovery data is complied in Omega and used to generate control charts. Warning and control limits are based on the calculated mean recovery with two (2) and three (3) standard deviations respectfully. The following formulas are used to determine these limits:

$$X_m = \frac{\sum x}{n} \qquad \text{Eq. 12-2}$$

$$sd = \text{sqrt} \quad \frac{\sum x^2 - \sum (x)^2}{n-1} \qquad \text{Eq. 12-3}$$

$$UWL = Xm + 2\,sd \qquad \text{Eq. 12-4}$$
$$LWL = Xm - 2\,sd \qquad \text{Eq. 12-5}$$
$$UCL = Xm + 3\,sd \qquad \text{Eq. 12-6}$$
$$LCL = Xm - 3\,sd \qquad \text{Eq. 12-7}$$

Where:

X_m = Mean Recovery
$\sum x$ = Sum of the values
n = Number of data points
UWL = Upper Warning Limit
LWL = Lower Warning Limit
UCL = Upper Control Limit
LCL = Lower Control Limit

Control limits should not exceed agency ranges where available and should approach the target range of 75 - 125%R. The QA Manager will evaluate the data for adherence to method specifications or general acceptability.

When agency/project specific control ranges are provided the QA Manager will compare the laboratory statistically calculated ranges to those provided for consistency between the two sets of values. If the laboratory range exceeds the specified range the individual data points will be compared to the range and if the results fall within the range the control limits can be adopted for used. In cases where the laboratory range exceeds the project required range and the above is not met, the client will be contacted to determine if the laboratory ranges are acceptable or the laboratory will perform corrective action procedures to bring the method control limits within the project specifications.

The laboratory currently uses the control limits published in the most recent version of the DoD QSM as the default limits in the LIMS. Laboratory data has been assessed with regard to those limits. In cases where QSM limits are not available the laboratory will use method limits for MS/MSD samples.

12.1.4 For frequently performed test procedures the warning and control limits are based on forty (40) data points and the control charts are updated with the calculated values. In instances where a particular method specifies an acceptable %R range (i.e. 75-125%R) the LIMS test code will incorporate those limits. MS/MSD data can be subject to sample matrix effects that render some individual data points unusable. The LIMS control charting module incorporates the Grubbs

outlier test and allows values that exceed the limit (5% Risk) to be excluded from the calculations of the control limits. The QA Manager can further eliminate obvious anomalous data points from data sets for calculating control limits. It is not the intent of RTI Laboratories to produce excessively wide control limits for assessing data quality. Measures will be taken to ensure control limits are not broadened by matrix affected data. The QA Manager maintains the authority to set reasonable control limits in cases where extreme variation exists in specific methods or for individual poor performing analytes.

12.1.5 In the case of infrequent analyses, the control limits are based on a minimum of seven (7) data points, default values of 75-125% (LCL & UCL) or agency ranges when available. The QA Manager will determine the appropriate method for establishing the control limits on an analyte specific basis.

12.1.6 Control charts can be used to evaluate to ensure a test is in control. Conditions that may represent an out of control situation and may warrant corrective action before proceeding with sample analysis include:

12.1.6.1 Mean accuracy value exceeding specified control limits.
12.1.6.2 Two (2) or more data points in a set of twenty (20) exceeding the control limits.
12.1.6.3 Five (5) consecutive data points exhibiting a trend
12.1.6.4 Five (5) consecutive data points exhibiting a shift

12.1.7 In cases where the sample concentration of analyte is high and was unknown at the time of spiking, the MS/MSD may be lost due to excessive dilutions or analyte concentration. This also applies to interferences present which may obscure the recognition and quantification of the analyte. When this occurs, the recovery is assessed by evaluation of a laboratory control sample.

12.2 Accuracy Assessment – Laboratory Control Sample (LCS)

12.2.1 A LCS is prepared near the mid range of the calibration curve at a frequency of one (1) per batch, by adding a known amount of analyte(s) to a known blank sample matrix (e.g. laboratory reagent water or clean solid matrix) and processing it through the same procedures as the samples. Optionally, reference samples may be purchased that have established acceptable ranges. The recovery of the LCS is calculated by:

$$\%R = A_R / A_A \times 100 \qquad \text{Eq. 12-8}$$

Where:

%R = Percent Recovery
A_R = Amount Recovered
A_A = Amount Added

12.2.2 Control charts are generated in Omega using equations 12-1 through 12-7. When a reference sample is used as the LCS, the control charts are constructed with the upper and lower control limits based on the acceptable range. For frequently performed test procedures, the warning and control limits are based on forty (40) data points and the control charts are updated with the calculated values. In instances where a particular method specifies an acceptable %R range (i.e. 80-120%R) the LIMS test code will incorporate those limits. Laboratory procedures may result in unusable data due to spiking or preparation errors. The LIMS control charting module incorporates the Grubbs outlier test and allows values that exceed the limit (5% Risk) to be excluded from the calculations of the control limits. The QA Manager can further eliminate obvious anomalous data points from data sets for calculating control limits. It is not the intent of RTI Laboratories to produce excessively wide control limits for assessing data quality and measures will be taken to ensure control limits are not broadened by laboratory errors. The QA Manager maintains the authority to set reasonable control limits in cases where extreme variation exists in specific methods or for individual poor performing analytes.

When agency/project specific control ranges are provided the QA Manager will compare the laboratory statistically calculated ranges to those provided for consistency between the two sets of values. If the laboratory range exceeds the specified range the individual data points will be compared to the range and if the results fall within the range the control limits can be adopted for use. In cases where the laboratory range exceeds the project required range and the above is not met, the client will be contacted to determine if the laboratory ranges are acceptable or the laboratory will perform corrective action procedures to bring the method control limits within the project specifications.

The laboratory currently uses the control limits published in the most recent version of the DoD QSM as the default limits in the LIMS. Laboratory data has been assessed with regard to those limits. In cases where QSM limits are not available the laboratory will use method limits for LCS samples.

12.2.3 In the case of infrequent analyses, the control limits are based on a minimum of seven (7) data points, default values of 80-120% (LCL & UCL) or agency ranges when available. The QA Manager will determine the appropriate method for establishing the control limits on an analyte specific basis.

12.2.4 Control charts are evaluated to ensure the system remains in control. Conditions that represent an out of control situation and warrant corrective action before proceeding with sample analysis include:

12.2.4.1 Mean accuracy value exceeding control limits
12.2.4.2 Two (2) or more data points in a set of twenty (20) exceeding the control limits
12.2.4.3 Five (5) consecutive data points exhibiting a trend
12.2.4.4 Five (5) consecutive data points exhibiting a shift

12.2.5 Each quarter the QA Manager will generate and review LCS control charts for continued acceptable performance. The generated charts will be stored in a folder and available for additional review if necessary. Instances demonstrating degradation in performance or indications of potential out of control situations will be investigated and corrective actions take as needed. The QA Manager is responsible for determining the suitability of the control charts and will evaluate the data according to the guidelines in Section 12.2.4 and experience and knowledge of the procedures and analytes.

12.3 Precision Assessment - Duplicates - MS/MSD – LCS/LCSD

12.3.1 Assessing precision is accomplished through evaluation of the relative percent difference (RPD) of duplicate measurements. Depending on the method, this may be in the form of a duplicate (second aliquot) sample analysis, duplicate spikes (MS/MSD or LCS/LCSD) or duplicate media spikes. All steps in the sample process are applied to the duplicates and are analyzed at a frequency of 5% or 10% depending on the method. The RPD of the two (2) measurements is calculated as follows:

$$RPD = \frac{|D_1 - D_2|}{(D_1 + D_2)/2} \times 100 \qquad \text{Eq. 12-9}$$

Where:

RPD = Relative Percent Difference
D_1 = First Measurement Value
D_2 = Second Measurement Value

12.3.2 Precision data is compiled in Omega and can be used to generate control charts with the exception that the LWL and LCL are not applicable.

12.3.3 In the case of infrequent analyses, the control limits are based on a minimum of seven (7) data points, default values of 40% (UCL) or agency ranges when available. The QA Manager will determine the appropriate method for establishing the control limits on an analyte specific basis. Data will be assessed and adopted consistent with the procedures in Sec. 12.2.2 above.

12.3.4 Control charts are evaluated to ensure the system remains in control. Conditions that represent an out of control situation and warrant corrective action before proceeding with sample analysis include:

12.3.4.1 Method precision value exceeding control limits
12.3.4.2 Two (2) or more data points in a set of twenty (20) exceeding the control limits
12.3.4.3 Five (5) consecutive data points exhibiting a trend
12.3.4.4 Five (5) consecutive data points exhibiting a shift

12.3 Accuracy Assessment – Method Blanks

12.3.1 Accuracy of analytical data is predicated upon the absence of contamination or interference that can produce positive or negative bias in the data. A Method Blank is analyzed with each sample batch. All steps in the sample process are applied to the method blanks which are analyzed at a minimum frequency of 5% or 10% depending on the method.

12.3.2 Method blank results should be less than the LOD but must be less than the reporting limit for acceptability. Analyses conducted under DoD QSM protocols require method blank results to be less than one half of the LOQ. Some State or agency programs required method blank results to be less than the DL or LOD.

12.3.3 Method blank data is assessed according to the project requirements. Blank results that exceed specifications (and in cases where re-analysis of the batch is not possible) are qualified through narration and B flagging sample data where applicable.

12.3.4 Individual method SOPs contain procedures for method blank evaluation and corrective action procedures for unacceptable blank results.

12.4 Completeness Assessment

12.4.1 Completeness can be assessed on an individual project basis, batch basis, per matrix analyzed or analytical method. In all the above instances, completeness will be the ratio of the number of useful measurements to the total number of measurements performed and is calculated by:

$$\%C = N_U / N_T \times 100 \qquad \text{Eq. 12-10}$$

Where:

- %C = Percent Complete
- N_U = Number of useful values
- N_T = Total values obtained

12.4.2 Assessment of completeness is typically the responsibility of the data user. Only the end user can adequately asses the usability of the data with respect to the project objectives.

12.4.3 Laboratory assessment of completeness can be performed at the discretion of the Laboratory Director or Project Manager to assess specific projects or overall laboratory performance. This assessment will only evaluate laboratory completeness from the perspective of the number of results reported to the number of results that could not be reported due to laboratory accident, matrix interference that cannot be mitigated through normal laboratory procedures or other factors that render reporting of sample data impossible. This assessment cannot account for the usability of the data from the perspective of the data user. Historically the number of non-reported sample data points is minimal. Completeness of reported in ratio to non-reported results is generally significantly greater than 99%. As such this assessment will be rarely performed or necessary.

12.4.4 Completeness can also be assessed through client feedback on specific projects or overall performance.

12.4.5 Completeness assessment when required or performed will be discussed during weekly scheduled staff meetings.

13.0 CORRECTIVE ACTION

13.1 The need for corrective action can arise from a myriad of sources. These include, but are not limited to, client inquiries, review of sample or QC data by management, problems encountered or noted by technical staff, instrument malfunctions, supplies and laboratory apparatus or due to the need to meet sample or method specifications.

13.2 Corrective Action Policy

13.2.1 When any situation arises that could result in the potential for compromising data quality or integrity or affects the standards of the operation, the QA Manager, Laboratory Director or assigned supervisory level individual will assume the responsibility and authority for instituting the appropriate measures necessary to resolve the issue. All personnel can at any time recommend corrective actions to improve operations and/or act as preventative measures.

13.2.2 Documentation of the problem, cause and solution is required and an assessment of the significance and magnitude of the nonconformance is made by the Laboratory Director, QA Manager or assigned individual. Significant problems include:

13.2.2.1 Problems that affect the accuracy of sample results.
13.2.2.2 Conditions that impact the integrity of laboratory data.
13.2.2.3 Deviations from method procedures or laboratory policies.
13.2.2.4 Quality control results that indicate a noncompliant situation.
13.2.2.5 Unethical actions by laboratory personnel.

13.2.3 In cases where procedures are deemed to be in nonconformance with essential components of the method or laboratory policies all associated work will cease until the problem is corrected. Affected laboratory data will not be issued and if results have already been submitted the client will be notified of the situation and advised to disregard the affected results and that a pending revision will be issued.

13.2.4 Corrective actions instituted will be designed not only to resolve the particular problem but also to prevent any reoccurrence.

13.2.5 Required changes to laboratory operations will be immediately implemented and monitored.

13.2.6 The laboratory shall continuously engage its activities toward a preventative approach designed to preclude the necessity for corrective actions through diligent monitoring and adherence to QAP policies.

13.3 Corrective Action Procedure

13.3.1 An investigation into the cause of the problem will commence immediately on identification of a problem. The root cause investigation is the most important aspect of the procedure and may either be obvious or seemingly intractable. Problems that will necessitate initiation of the corrective action procedure include the following; however Laboratory Management may at any time require initiation of a corrective action procedure at their discretion.

13.3.1.1 Unacceptable proficiency testing data.
13.3.1.2 Incorrectly reported sample results.
13.3.1.3 Unacceptable quality control data not immediately corrected.
13.3.1.4 Analyses performed under noncompliant conditions.
13.3.1.5 Calibration/calibration verification issues.
13.3.1.6 Inadequate review and comments for QC data.
13.3.1.7 Unapproved deviations from an SOP.
13.3.1.8 Problems with data sets that propagate to final reporting.
13.3.1.9 Unresolved problems with sample receiving.
13.3.1.10 Systematic or organizational problems resulting in the inability to consistently meet holding time or project deadline requirements.
13.3.1.11 Failures in proper documentation requirements, lack of proper instrument maintenance or inadequate data backup.
13.3.1.12 Conditions resulting in failure to maintain proper sample storage.
13.3.1.13 LIMS functions that result in reporting problems.
13.3.1.14 Noncompliance with QAP policies or accreditation standards.
13.3.1.15 Applicable internal/external audit findings.

13.3.2 Once the cause is identified, steps will be instituted to identify the necessary corrective actions and implement the measures required to correct the problem and prevent a reoccurrence.

13.3.3 For actions prior to sample analysis RTI has procedures for identifying, documenting and resolving problems with samples submitted. The laboratory staff will assist samplers in formulating any necessary corrective actions (Sections 4.0 and 5.0).

13.3.4 Each SOP contains a section specifying acceptance criteria for QC samples and the corrective action required.

13.3.5 Problems that are resolved by repeating the appropriate QC sample(s) and sample re-analyses (if necessary) with acceptable results do not require further corrective actions. All QC failures and sample re-analyses if required are documented in the appropriate section within Omega and/or analyst logs.

13.3.6 Problems that cannot be readily resolved or QC failures that require investigation will be documented in the Corrective Action section of the Omega LIMS. The type of information recorded is provided in Figure 13-1. Sample results are not reported until all necessary corrective actions are taken and approved by the QA Manager and/or the Laboratory Director. The QA Verify check box will close and lock the corrective action report. Subsequent changes can only be made by individuals with the assigned authority to unlock the form.

13.3.7 Identification of problems during data validation or assessment will require an inquiry into the nature of the problem and sample re-analysis if practical (holding time, volume etc.). If samples cannot be repeated the client is notified and actions including re-sampling, data qualifying, non-reporting of data or other necessary steps are undertaken.

13.3.8 If necessary an internal audit will be performed to ensure continued compliance with corrective actions and verification of resolution.

13.4 RTI has developed procedures and a form for documenting and addressing client complaints. Any corrective actions resulting from a client complaint/inquiry are documented (Refer also to Section 5.0).

13.5 Performance audit nonconformance is investigated and documented on the form presented in Figure 13-2. Following investigation into the cause of an unacceptable performance testing (PT) result and the corrective actions implemented, the QA Manager will provide this information to the Laboratory Director.

13.6 The QA Manager will maintain and review a log of PT related corrective action forms that have been initiated will include the following information:

13.6.1 Reason for action
13.6.2 Person responsible for returning response
13.6.3 Date initiated
13.6.4 Date of expected completion
13.6.5 Date of actual completion

13.7 LIMS corrective actions are maintained in a table that is reviewed by the QA Manager to assess completion of corrective actions and reviewed for repeat or continuing problems that would indicate inadequate resolutions for the problems.

13.8 Preventative Action

13.8.1 RTI Laboratories maintains a proactive approach toward improving the operations and reducing the likelihood of instances that would result in the necessity for instituting corrective actions. Management seeks to prevent nonconformance problems from arising through:

13.8.1.1 Frequent staff meetings to discuss areas for improvement.
13.8.1.2 Staff training in ethical practices and data integrity.
13.8.1.3 Integrated LIMS control charts to monitor QC data.
13.8.1.4 LIMS performance reports.

13.8.2 Identified preventative actions are implemented through document (i.e. SOP) revision or generation and are monitored for effectiveness through QC monitoring and performance reports.

13.8.3 Implemented preventative actions become integrated into laboratory operations and are subject to the control and review processes incorporated in this and other applicable documents.

Figure 13-1

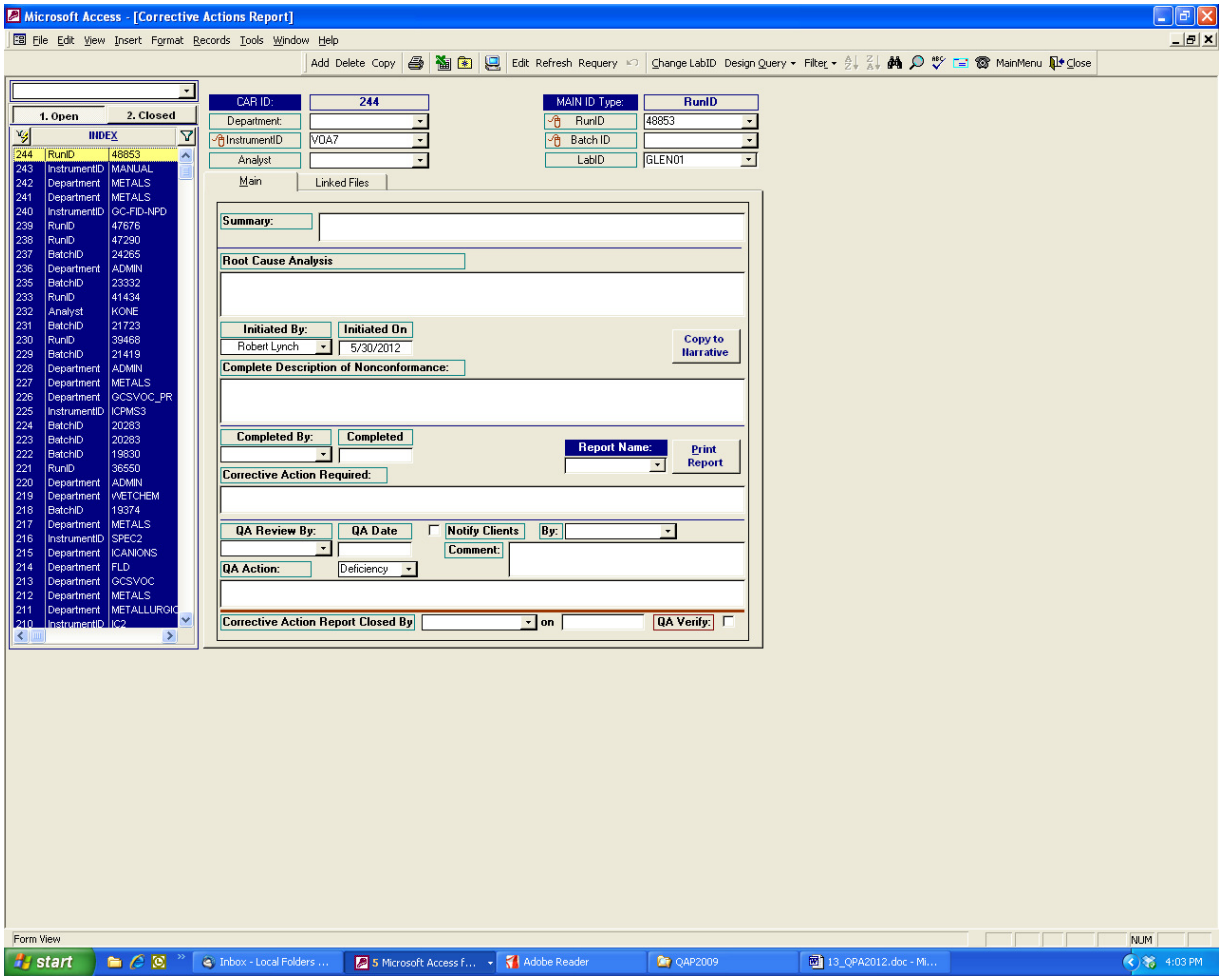
Microsoft Access - [Corrective Actions Report]
File Edit View Insert Format Records Tools Window Help
Add Delete Copy Edit Refresh Requery Change LabID Design Query Filter MainMenu Close
1. Open
2. Closed
INDEX
CAR ID:
244
Department:
InstrumentID
VOA7
Analyst
MAIN ID Type:
RunID
48853
Batch ID
LabID
GLEN01
Main
Linked Files
Summary:
Root Cause Analysis
Initiated By:
Initiated On
Robert Lynch
5/30/2012
Copy to Narrative
Complete Description of Nonconformance:
Completed By:
Completed
Report Name:
Print Report
Corrective Action Required:
QA Review By:
QA Date
Notify Clients
By:
Comment:
QA Action:
Deficiency
Corrective Action Report Closed By
on
QA Verify:
Form View
NUM
start
Inbox - Local Folders ...
5 Microsoft Access F...
Adobe Reader
QAP2009
13_QPA2012.doc - Mi...
4:03 PM

Figure 13-2

RTI PERFORMANCE AUDIT CORRECTIVE ACTION FORM

DATE: DATE DUE:

PT Study:

Analyte/Category:

Result Reported:
Target Value:
Acceptance Range:

Analyst:

Reason for Error:

Root Cause Investigation:

Corrective Action:

Analyst: Date:

Approved: Date:

14.0 MANAGEMENT REVIEW

14.1 Management reviews are conducted weekly during scheduled meetings attended by the following:

14.1.1 Environmental Sciences Division – Production Meeting

Director, Environmental Sciences
Quality Assurance Manager
Wet Chemistry Group Lead
Metals Group Lead
SVOC/VOC Group Lead
GC/HPLC/IC Group Lead

14.1.2 Environmental Sciences Division – Project Manager Meeting

Director, Environmental Sciences
Director, Federal Programs (monthly or as needed)
Project Managers and Assistants

14.1.3 Environmental Sciences Division – General Manager Meeting

Director, Environmental Sciences
Technical Director

14.1.4 Environmental Sciences Division – General Manager Meeting

Director, Federal Programs

14.1.5 Materials Testing Division

General Manager
Director, Materials Testing
Metallurgical Engineer

When required other individuals may be requested to attend the meeting at the discretion or approval of the Environmental Sciences Director or Material Testing Director.

14.2 Each individual attending the Production or Project Manager meeting prepares a report that is given to the Director at the end of the meeting. The basic format for the report may include:

14.2.1 Equipment activities
14.2.2 Backlog review

14.2.3 Status
14.2.4 Personnel, Training & Vacations
14.2.5 QC Discussion items
14.2.6 To do list
14.2.7 Issues/Problem Solving
14.2.8 Incoming work
14.2.9 New business/contracts

Personnel who are unable to attend the meeting will be identified on the agenda page and whether a report has been submitted by the absentee person.

Each report represents a review of the area of responsibility of the individual Director and may include findings that necessitate action. These findings and subsequent actions are recorded in the individual reports with any required corrective actions or resolutions. In some instances the issues may be transferred to the action item report as described in Section 14.6.

14.3 Subjects reviewed and discussed at the General Manager meeting may include all or some the following topics:

14.3.1 Corrective actions arising from performance or system audit results or due to significant quality assurance problems.
14.3.2 Performance evaluation results
14.3.3 External audit evaluations.
14.3.4 New SOP's generated or revisions to SOP's.
14.3.5 Method validation studies when applicable.
14.3.6 Items related to quality control
14.3.7 Client communications and complaints.
14.3.8 Problems that directly affect data quality.
14.3.9 Review and/or revisions to the QAP and SOPs for suitability of policies and procedures.
14.3.10 Assessment of laboratory performance and areas of concern.
14.3.11 Instrumentation status, problems and corrective actions.
14.3.12 Resource assessment – staff and equipment
14.3.13 Workload backlog.
14.3.14 Reporting status and areas of concern.
14.3.15 Client project status.
14.3.16 Financial status.
14.3.17 Projection of projects expected including scope, volume and assessment of the ability of the laboratory to perform.
14.3.18 Assessment of ability to meet client expectations and method requirements.
14.3.19 Status of new methods or equipment under development.
14.3.20 Overall assessment of the organization.
14.3.21 Status of significant corrective action items.
14.3.22 Preventative actions required or actions implemented and the effectiveness of the action.

14.3.23 Staff training – subjects and schedules.
14.3.24 Areas for improvement.
14.3.25 Reports provided by others as required.
14.3.26 Other topics as relevant.

14.4 The goal is to meet on a weekly basis however due to availability of attendees, laboratory activities, holiday/vacation time or other pressing factors meetings may not be held on all weeks.

While not every point in Section 14.3 is discussed at every meeting, through the course of the year each topic is addressed as applicable. However many of the subjects are routinely included in the weekly reports from the individual Directors.

All items presented in the individual reports are open for additional discussion. The General Manager maintains the authority to add any subject or item that may not be addressed in the individual reports to the meeting topics and may limit discussion as necessary.

14.5 Management review reports are compiled and distributed to the attendees and a copy of each consolidated report is maintained electronically.

14.6 In addition to the Director reports an action item report is maintained for the weekly meetings. This report will include issues that have been identified as requiring attention and monitoring. The General Manager or Directors with the approval of the General Manager will designate issues as action items. The report will contain:

14.6.1 The identified responsible individual.
14.6.2 Date Initiated.
14.6.3 Date due for resolution.
14.6.4 Action item description.
14.6.5 Status and progress.

Once an action item has been completed to the satisfaction of the General Manager and Directors it will be removed from the report. The effectiveness of any action taken will then be assessed through routine procedures for review and evaluation of laboratory operations. Actions deemed to be inadequate for continued resolution will be placed back on the action item report for further evaluation.

15.0 DOCUMENT CONTROL

15.1 The functions of the Document Control Officer (DCO) are currently assumed by the QA Manager and performed by the QA Department.

15.2 Quality system documents (QAP, SOP's, etc) are stored electronically in a manner by which only authorized personnel (QA Manager, DCO, Technical Director) have access to and can make changes to the editable files. Final documents available to laboratory personnel are posted electronically in a form that does not allow changes to these documents.

15.2.1 These documents are identified uniquely with a document number that will correspond to the electronic file name.

15.2.2 Documents will contain the revision number and the date of review and approval for use. All documents must be reviewed and approved by Laboratory Management prior to posting for use.

15.2.3 Individuals responsible for approving the documents will be identified and an approved signature log will be maintained.

15.2.4 Documents will be posted in the appropriate section of the LIMS (Documents and SOPs) that serves as the log for these documents.

15.2.5 The electronic posted version of the document is the current form in use and is considered as the only acceptable version. Hard copies, including hand written amended versions, are not permitted in the laboratory.

15.2.6 When documents are revised the obsolete version is immediately removed from the LIMS log and archived in a location that is not accessible to general staff. The archive directory can only be accessed by Laboratory Management with the assigned rights.

15.2.7 Archived documents are maintained for at least twelve (12) years from the date of removal or as stipulated by contract.

15.2.8 Electronic files are backed up daily. Restored files will maintain the same protection from access or editing.

15.2.9 The current in use quality system documents will be reviewed at least once per year and revised as necessary.

15.2.10 The QA Manager is responsible for notifying appropriate personnel when revised SOPs are posted in the LIMS. This can occur verbally or via e-mail. It is the responsibility of the analytical staff to ensure they are familiar with and using the correct version of a SOP.

15.2.11 Personnel are notified of changes or revisions to the QAP through a signature form that notes the electronic location of the document. Personnel will sign the form attesting to the notification and that the employees affirm that they will read and become familiar with the contents of the document and abide by the policies in the QAP. The form will be placed in the staff training file.

15.3 When procedural documents require review or revision by analytical staff an editable file will be provided in the accessible SOP-Documents Revisions folder. Changes will be clearly designated (e.g. changes in red) and the QA Manager will review the file. Until the new document is posted in the LIMS the prior document remains the official version. The QA Manager will transfer the editable file to the secure location, approve changes or maintain the file in the folder for additional revisions. When all changes have been approved and accepted the editable file will be stored in a secure location, removed from the revisions folder and the prior file transferred to the archive folder. The approved document will be posted in the LIMS in a form that does not allow changes.

15.4 Forms used in the laboratory are maintained by the QA Department in electronic form not accessible to the staff. Each form includes the form designation, date of issue and revision designation. Forms are supplied as needed to the user by request to the QA Department. Obsolete forms reside in electronic locations inaccessible to the general staff and are stored for no less than twelve (12) years.

15.5 Individual record keeping forms are submitted to the QA Department upon completion. The completed forms are scanned and saved in electronic format and stored in a designated folder on the RTI server for no less than twelve (12) years. The original forms are destroyed after the electronic copy has been stored.

15.6 Prior to use of any document approval by the QA Department is required.

15.7 Spreadsheets or electronic files used for data capture and/or result calculations are approved by the QA Department prior to use. Any calculations preformed are verified for accuracy and all cells containing formulas are protected from alteration. Passwords for unprotecting and revising protected worksheets are controlled by the QA Department. Only personnel with designated authority have access to passwords required to unprotect data spreadsheets.

15.8 Procedures that require the use of spreadsheets will have a blank template created that has undergone the verification and protection process described in Section 15.7. With each use the file will be saved with a unique name and stored in the designated server folder. On completion of the analytical event the spreadsheet will be immediately saved in pdf format with the same file name and stored in the same location. The pdf file serves as the official unalterable record of the data and is electronically linked to the associated analytical sequence in Omega.

15.9 Hardcopy Laboratory records are maintained in logbooks for recording information that is not stored electronically in the LIMS.

15.9.1 RTI strives to minimize the use of hardcopy logbooks. These logs are used only when electronic recording is not practical or unavailable.

15.9.2 Logbooks will contain the name of the logbook, the date initiated and the end date of the last entry. Logbook entries will comply with the specification in Section 15.10 below.

15.9.3 Completed logbooks will be forwarded to the QA Department and a new logbook issued by the QA Department.

15.9.4 Changes to the format of the logbooks will be made by the QA Department and will contain the appropriate form designation indicating the revision. Obsolete logs or formats will be removed from use.

15.9.5 Logbooks will be maintained by the analyst while in use. Following completion the logbook will be submitted to the QA Department and archived in the posted and restricted records retention area of the facility for a minimum of twelve (12) years. Access to archived records is restricted to QA Department personnel. Requests for archived records must be submitted to the QA Department. QA Department personnel will retrieve the records and have the individual sign for receipt. The records log will contain the person receiving the document, the identification of the record, data and time of transfer, date and time of return and initial of the QA Department individual transferring and receiving the record. Records will be required to be returned within one week and are not allowed to be removed from the facility.

15.10 When any changes to logbooks or forms are required or when mistakes need to be corrected the procedure below must be followed:

15.10.1 Any corrections to recorded information must be made by a single line through the error and the correction dated and initialed by the individual making the change. Use of white-out or non-permanent writing devices is strictly prohibited.

15.10.2 Unused portions of the form must be ‘Z’d’ out.

15.11 Forms must contain complete information including the individual completing the form, date and information appropriate to and required for the form.

15.12 The QA Department will periodically review laboratory data forms to ensure compliance with correct record keeping procedures. Any discrepancies will be discussed with the individual using the form.

15.13 Contingency Plan for Record Retention

15.13.1 In the event of a transfer of ownership of the laboratory all records will be maintained under the new ownership arrangement. Unless instructed otherwise by a client, records will become the responsibility of the new owner and maintained under the guidelines of that organization provided these are consistent with prior arrangements agreed to with the client. Client records will be transferred to that specific client upon request.

15.13.2 Should RTI decide to cease all company operations, provisions will be made for laboratory records as below.

15.13.3 Client records will be transferred to that client or according to specific instructions provided by the client.

15.13.4 The Company General Manager/President will make arrangements for storage of records and will provide clients with the information required for record retrieval and the intended date of permanent disposal of records.

15.14 External Documents.

15.14.1 These comprise reference materials that are not issued to personnel and are used for reference purposes only with no intent to replace or otherwise supercede laboratory controlled documents used in the quality system. To ensure that only the most recent version is available the documents will only be accessed though on-line services. Links are established by RTI to ensure that the user is directed to the correct site location to access the pertinent information.

15.14.2 Master list of current reference sites/documents.

15.14.2.1 SW-846 Test Methods:
http://www.epa.gov/epawaste/hazard/testmethods/index.htm

15.14.2.2 EPA.gov Safe water analytical methods:
http://water.epa.gov/scitech/methods/cwa/methods_index.cfm

15.14.2.3 Standard Methods on-line. Login required. Account information (username and password) maintained by Laboratory Management.

15.14.2.4 A2LA.org – Relevant Documents Section. Links for applicable A2LA documents are listed below. The required documents for include P102a-Reference Material Traceability for Life Sciences Testing Laboratories, P113-Measurement

Traceability for Life Sciences Testing Laboratories, P103-Policy on Measurement Uncertainty, P103b-Annex: Policy on Estimating Measurement Uncertainty for Life Sciences Testing Laboratories, R103-PT Requirements, R103a-PT Requirements Annex and R105- Requirements When Making Reference to A2LA Accreditation Status.

https://www.a2la.org/policies/A2LA_P102a.pdf

https://www.a2la.org/policies/A2LA_P113.pdf

https://www.a2la.org/policies/A2LA_P103.pdf

https://www.a2la.org/policies/A2LA_P103b.pdf

https://www.a2la.org/requirements/R103_2013.pdf

https://www.a2la.org/requirements/Annex_to_the_A2LA_General_Requirements_for_Proficiency_Testing.pdf

https://www.a2la.org/policies/A2LA_R105.pdf

Checklists and Materials required for application renewal and other publications as required for reference are available from the A2LA web site.

15.14.3 These sites contain the most recent version of specific methods and ensure RTI references will be maintained in conjunction with the most recent version.

15.14.4 Archived versions of the required documents will be maintained in a specified directory on the RTI server as pdf files, as hard copy maintained in the QC Department office as needed or obtained when required from the agency archives.

15.14.5 A2LA Advertising Policy.

15.14.5.1 The current document (R105 – Requirements When Making Reference to A2LA Accreditation Status) will be downloaded from the A2LA web site and stored on the RTI server in the marketing directory. The RTI individual assigned to maintaining and overseeing the use of A2LA approved logos and symbols will ensure that the most current version of the policy is maintained in the current directory. Previous versions will be stored in the archived directory.

15.15 All documents whether electronic or hardcopy will be maintained for no less than twelve (12) years unless as otherwise stipulated by contract.

15.16 Electronic Signatures

15.16.1 All electronic signatures are maintained in the Omega LIMS.

15.16.2 All employees are provided an Omega User Configuration in the System Administration/System Configuration. Upon hiring, employees will provide the LIMS Administrator with a unique signature for electronic incorporation into Omega. The User Configuration will contain the electronic signature for the employee which will be a unique signature applicable to only that employee. This signature will be attached to the user configuration profile by the LIMS Administrator.

15.16.3 Employees will have access to only their established user configuration for the specific user logged on to the LIMS. Electronic signatures once established cannot be altered. Alterations will require authorization by the LIMS Administrator.

15.16.4 Several Omega documents will automatically attach the signature of the RTI employee logged on to the specific computer work station. This signature will appear in the formatted location for that document.

15.16.5 Documents requiring signature that do not have an automated signature field or are generated outside of the Omega system will be electronically signed by the employee through copying the Omega signature field into the appropriate section of the document.

15.16.6 Electronic signatures will be placed on analytical reports, quotations, contracts, invoices and any other documents requiring signature when submitted in electronic format.

15.16.7 Only the employee generating a document requiring signature will be allowed to place their signature on the document. An exception to this would be, project managers giving permission to report generators to use their signature for reports only. Employees are expressly forbidden from attempting to or placing the signature of another employee on any document generated. Procedures incorporated in the LIMS are designed to prevent such occurrences.

15.16.8 The RTI LIMS Administrator is responsible for maintaining the integrity of the electronic signature system and ensuring that electronic documents are properly signed.

16.0 DEFINITIONS

16.1 Acceptance Criteria - specified limits placed on characteristics of an item, process or service defined in required documents.

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

16.3 Analyst - the designated individual who performs the “hands-on” analytical methods and associated techniques and who is the one responsible for applying required laboratory practices and other pertinent quality controls to meet the required level of quality.

16.4 Batch - samples that are prepared and/or analyzed together with the same process (method, technique, etc.), using the same lot(s) of reagents and applicable apparatus. A preparation batch is composed of one to twenty samples of the same matrix processed during an analytical shift (12 hours). An analytical batch is composed of prepared environmental samples (extract, digestate or concentrate), which are analyzed together as a group. An analytical batch can include prepared samples originating from various environmental matrices and can exceed 20 samples. However, for analytical processes that do not include separate preparation, QC samples (MB, LCS, MS, MSD, DUP) must be prepared for each batch of 20 or less samples.

16.5 Blank, Trip - a sample that has not been exposed to the analyzed sample stream in order to monitor contamination during sample transport, storage or analysis. The blank is subject to the usual analytical and measurement process and is used to assess potential contamination issues with the associated samples.

16.6 Field Blank - blank prepared in the field by filling a clean container with pure de-ionized water and appropriate preservative, if any, for the specific sampling activity being undertaken.

16.7 Method Blank - a sample of matrix similar to the batch of associated samples (when available) that is free from the analytes of interest and is processed simultaneously with and under the same conditions as samples through all steps of the analytical procedure to assess the extent to which target analytes or interferences are present at concentrations that impact the analytical results for sample analyses.

16.8 Calibration (Initial Calibration – ICAL) - to determine, by measurement or comparison with a standard, the correct value of each scale on a meter, instrument or other device. The levels of the applied calibration must bracket the range of planned or expected sample measurements.

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

16.10 Calibration Standard - a substance or reference material used to calibrate an instrument.

16.11 Certified Reference Material (CRM) - a reference material one or more of whose property values are certified by a technically valid procedure, accompanied by a NIST traceable certificate or other documentation which is issued by a certifying body.

16.12 CLP – Contract Laboratory Program.

16.13 Corrective Action - the action taken to eliminate the cause of an existing nonconformity, defect or other undesirable situation in order to prevent reoccurrence.

16.14 CRQL – Contract Required Quantification Limit. A standard analyzed at the LOQ/RL/PQL to verify acceptable quantification at the lowest standard in the calibration curve that corresponds to the current or project reporting limit.

16.15 Demonstration of Capability (Initial Demonstration of Method Performance - IDMP)- a procedure to establish the ability of the analyst to generate acceptable accuracy.

16.16 Detection Limit (DL, MDL) - the lowest concentration or amount of the target analyte that can be identified, measured, and reported with confidence that the analyte concentration is not a false positive value.

16.17 Dry weight - actual weight of a solid sample minus free moisture as driven off at 105°C.

16.18 Holding Times (Maximum Allowable Holding Times) - the maximum time samples may be held prior to analysis and still be considered valid or not compromised.

16.19 Internal Standard (IS) - a known amount of standard added to a test portion of a sample as reference for evaluating and controlling the precision and bias of the applied analytical method.

16.20 Laboratory Control Sample (LCS) - a sample matrix, free from the analytes of interest, spiked with verified known amounts of analytes or a material containing known and verified amounts of analytes. It is generally used to establish intra-laboratory or analyst specific precision and bias or to assess the performance of all or a portion of the measurement system.

16.21 Laboratory Duplicate - aliquots of a sample taken from the same container under laboratory conditions and processed and analyzed independently.

16.22 Matrix - the component or substrate that contains the analytes of interest. For purposes of batch and QC required determinations, the following matrix distinctions shall be used:

16.22.1 Aqueous - any aqueous sample excluded from the Drinking Water matrix or Saline/Estuarine source. Includes surface water, groundwater, effluents, and TCLP or other extracts.

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

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

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

16.22.5 Solids - includes soils, sediments, sludge and other matrices with >15% settleable solids.

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

16.23 Limit of Detection (LOD) - The minimum concentration of an analyte greater than or equal to the DL in a given matrix, analyzed by a specified method, on an individual instrument that can be detected at 3 or more times the noise level. The LOD verification is performed quarterly on a sample prepared in a clean matrix and processed through all steps in the procedure.

16.24 Limit of Quantification (LOQ/RL/PQL) - The minimum reporting limit of an analyte can be accurately quantified and corresponds to a level within the calibration range. The LOQ value cannot be less than the lowest calibration standard. The LOQ verification is performed quarterly on a sample prepared in a clean matrix and processed through all steps in the procedure. The value of the LOQ verification must be within the control limits of the method.

16.25 Matrix Spike (MS, spiked sample or fortified sample) - a sample prepared by adding a known amount of target analyte(s) to a specified amount of sample. Matrix spikes are used to determine the effect of the matrix on method recovery efficiency.

16.26 LIMS – Laboratory Information Management System

16.27 Matrix Spike Duplicate (MSD, spiked sample or fortified sample duplicate) - a second replicate matrix spike prepared in the laboratory and analyzed to obtain a measure of the precision.

16.28 Method Detection Limit - the minimum concentration of a substance (an analyte) that can be measured and reported with 99% confidence that the analyte concentration is greater than zero and is determined from analysis of a sample in a given matrix containing the analyte.

16.29 ml - milliliter or 10^{-3} liters.

16.30 mg - milligram or 10^{-3} gram.

16.31 ng - nanogram or 10^{-9} grams.

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

16.33 Preservation - refrigeration and/or reagents added at the time of sample collection (or later) to maintain the chemical and/or biological integrity of the sample.

16.34 Post Digestion Spike (PDS)- A know amount of analyte added to the digestion or extraction solution following sample preparation. Used to evaluate matrix interference.

16.35 QAP - Quality Assurance Plan

16.36 Quality Control - the overall system of technical activities whose purpose is to measure and control the quality of a product or service so it meets the needs of the users.

16.37 Quality Control Sample - an uncontaminated sample matrix spiked with known amounts of analytes from a source independent from the calibration standards. It is generally used to establish intra-laboratory or analyst specific precision and bias or to assess the performance of all or a portion of the measurement system.

16.38 Quantification Limits - levels, concentrations or quantities of a target variable (e.g., target analyte) that can be reported at a specified degree of confidence.

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

16.40 Records – The output of implementing and following management system documents (i.e., test data in electronic or hand written forms, files and logbooks).

16.41 Reference Material - a material or substance that one or more properties of which are sufficiently well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.

16.42 Reference Method - a method of known and documented accuracy and precision issued by an organization recognized as competent to do so.

16.43 Reference Standard - a standard, generally of the highest metrological quality available at a given location, from which measurements made at that location are derived. For all applicable procedures a standard from a vendor certified by an accrediting body to ISO Guide 34 for that standard must be obtained when available.

16.44 Replicate Analysis - the measurements of the variable of interest performed identically on two or more sub-samples of the same sample within a short time interval.

16.45 Reporting Limit (RL) - refer to Limit of Quantification (LOQ)

16.46 Sample - any material that is prepared and analyzed according to the procedures outlined within a SOP or reference method. Includes, but not limited to calibration standards, laboratory control samples, blanks, matrix spikes, and client samples.

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

16.48 Serial Dilution (SD) - An incremental dilution of a sample extract or digestion solution, typically at 5-fold. Used to assess matrix interference.

16.49 SOP - Standard Operating Procedure.

16.50 SOW - Statement of Work. The current CLP SOW with Exhibits and Appendices or the statement of work as presented in project documents.

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

16.52 Standardized Reference Material (SRM) - a certified reference material produced by the U.S. National Institute of Standards and Technology or other equivalent organization and characterized for absolute content, independent of analytical method.

16.53 Stock Standard Solution - a concentrated solution containing one or more method analytes prepared in the laboratory using assayed reference materials or purchased from a reputable commercial source.

16.54 Surrogate - a substance with properties that mimic the analyte of interest. It is unlikely to be found in environmental samples and is added to them for quality control purposes.

16.55 Traceability - the property of a result of a measurement whereby it can be related to appropriate standards, generally international or national standards, through an unbroken chain of comparisons. Also the ability to track method events to the various component sources.

16.56 µg - microgram or 10^{-6} grams.

16.57 µL- microliter or 10^{-6} liters.

17.0 COMPUTER USAGE POLICY

17.1 Employees in several job categories will be required to use a computer and applicable software in the course of their duties. Individuals will be assigned a computer station or instructed in the computers that are available for their use. All computers are set up in a manner that requires individuals to log on to the system and enter a valid password. Various rights within the Omega LIMS and access to certain server files are assigned on system log in. Restrictions placed on employee computer accounts are designed to prevent inadvertent or deliberate alterations to laboratory data or operating software while allowing that individual the ability to perform the required job functions. Deliberate alterations to laboratory data or restricted server files will result in disciplinary actions up to and including termination of employment.

17.2 Unauthorized use of computers by employees is strictly prohibited. Employees found to be using computers for which they are not authorized will be subject to disciplinary actions. Sharing of passwords or using a system logged under another user is not acceptable. Individuals that will be away from a logged on computer for an appreciable length of time should log off of the system during their absence or lock the station.

17.3 Modifications to computer operating systems, instrument data/operating systems or Laboratory Information Management Systems (LIMS) are restricted to IT and Laboratory Management Personnel.

17.4 It is explicitly prohibited for employees to use or attempt to use a computer station assigned to IT or Laboratory Management Staff, except under supervised use.

17.5 Unauthorized electronic transmission of Laboratory/Client data, company files or documents to locations or individuals outside of the facility is prohibited. The confidentiality and integrity of client data is an essential component of the RTI Quality Assurance Program.

17.6 The copying of any company software for personal use outside of the facility is forbidden. Unauthorized, copying, deleting or removal and re-location outside the facility of company data or files are prohibited.

17.7 RTI understands that employees may use the Internet during work hours; however, abuse of this privilege, including email and shopping is prohibited. To enforce these restrictions, and to protect RTI information systems, employees are advised that RTI may monitor, filter, analyze, track, document and investigate the use of any RTI computer, software, database, internet access or other information system (RTI Systems). The employee should understand, therefore, that there is no expectation

of privacy in the use of the RTI Systems whether the same is being used for business or personal purposes.

17.8 Employees engaging in any prohibited action noted above will be subject to appropriate disciplinary actions. Employees noting or observing any instance of a prohibited action are encouraged to report this immediately to their supervisor.

17.9 All employees must have training on computer security awareness. This training is provided on initial hire during orientation and through annual refresher training conducted by the QA Department IT staff.

18.0 Revisions

18.1 Revision 13.

18.1.1 This revision to the Quality Assurance Plan includes extensive changes in all Sections. The majority of the revisions involve modification of text for clarification purposes. Additions and deletions from the prior version are also contained in this revision.

Due to extensiveness of the changes to this document a listing of the revisions is not included in this Section. The previous version of the QAP is available for comparative review.

18.2 Revision 13.1

18.2.1 Section 9: Revised record storage time from 10 years to 12 years.

18.2.2 Section 15: Revision 15.15 from 10 years to 12 years.

18.2.3 Section 16: 16.40 definition of Records.

18.3 Revision 13.2

18.3.1 Section 7: Section was changed to update MDL, LOQ, LOQ, RL procedures.

18.3.2 Section 14.1 Management reviews sections were updated.

18.4 Revision 13.3

18.4.1 Section 1.2: Replaced Director with Quality Manager.

18.4.2 Section 1.6.5: Added ISO 17025-2017 and DOD QSM Version 5.1.1 2018.

18.4.3 Section 1.9: Changed Director, Quality Management to Quality Manager.

18.4.4 Section 2.1.2/2.1.2.1/2.5.1/2.5.2.4: Changed from Director, Quality Management to Quality Manager.

18.4.5 Section 3.0: Replace QA Director to QA Manager.

18.4.6 Section 5.4.6: Changed log-in review sop to LOGREV-032318_R1.1.

18.4.7 Added Section 5.4.8

18.4.8 Section 6: Changed QA Director to QA Manager.

18.4.9 Added Section 6.1.12 information regarding reference materials. Adjusted following numbers to accommodate additional section.

18.4.10 Section 7: Changed QA Director to QA Manager.

18.4.11 Section 7.1.5: Last sentence added information regarding RTI recording results, procedure for validation and a statement regarding if method is fit for intended use.

18.4.12 Section 7.9.2: Added “and accepted by the customer”.

18.4.13 Section 9: Changed QA Director to QA Manager.

18.4.14 Section 10: Changed QA Director to QA Manager.

18.4.15 Section 10.1.2.6: Added Project Management Department.

18.4.16 Section 12: Changed QA Director to QA Manager.

18.4.17 Section 13: Changed QA Director to QA Manager.

18.4.18 Section 15: Changed QA Director to QA Manager.

18.4.19 Table 1 (section 10.0): Edited ERA AE Organics – EPA T04. T010 and T015 to “Twice per year when certified” from “Twice per year”.

18.5 Revision 13.4

18.5.1 Section 4 – Table 4-1 changed Cyanide pH >10 to pH >12

18.6 Revision 13.5

18.6.1 Section 1.11 Added

18.6.2 Section 2.6 Added

18.6.3 Section 15.16 Added

18.6.4 Added Steve Suchar’s Name to cover Page