QUALITY ASSURANCE MANUAL

for

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Annual review of this QAM has been performed and the QAM still reflects current practice.

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3.0 INTRODUCTION AND COMPANY QUALITY ASSURANCE POLICY

Columbia Analytical Services, Inc. (CAS/SIMI) in Simi Valley, California is a professional consulting laboratory which performs chemical analyses on a wide variety of sample air matrices, including indoor and outdoor ambient air, stationary source emissions, landfill gas, soil vapor, process gas, industrial hygiene samples, and product emissions. In addition, both chemical and physical analyses are conducted on a number of matrices, including drinking water, groundwater, surface water, wastewater, soil, sediment, sludge, industrial and hazardous waste, and other materials.

The quality policy statement is under the issuance of top management and includes the purpose of the quality system and management's commitment to comply with and to continually improve the effectiveness of the system. To assure the quality of the environmental test results, the laboratory has the responsibility and commitment to carry out its testing in such as way as to meet the requirements of all applicable standards (as specified herein) and to satisfy the needs of the customer, the regulatory authorities or organizations providing recognition and their applicable standards and requirements. The purpose of the CAS/SIMI quality management system and quality policy is that there will be sufficient Quality Assurance (QA) activities conducted in the laboratory to ensure that all analytical data generated and processed will be scientifically sound, legally defensible, of known and documented quality, and will accurately reflect the material being tested. In addition, avoidance of involvement in any activity that would diminish confidence in its competence, impartiality, judgment, operational integrity, or integrity of the data provided and the services rendered is a strict policy. This goal is achieved by ensuring that adequate Quality Control (QC) procedures are used throughout the monitoring process, and by establishing a means to assess performance of Quality Control and other QA activities.

The laboratory continually improves the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review. The scope of laboratory quality assurance is reflected in our Statement of Core Values as specified in the most recent Columbia Analytical Services Employee Handbook. Top management ensures that the integrity of the management system is maintained when changes to the management system are planned and implemented.

Management has implemented a standard of service which includes, but is not limited to, maintaining good client communication regarding any delays or method deviations, affording clients or the client's representative cooperation to clarify requests and/or the ability to monitor the laboratory's performance associated with any work performed (while maintaining the confidentiality of other clients as stated in this document). The laboratory seeks feedback, both positive and negative, from its customers and the feedback is used and analyzed to improve the management system and testing activities, as well as customer service.

It is recognized by management that quality assurance requires a commitment to quality by everyone in the organization - individually, within each operating unit, and throughout the entire laboratory. Management ensures that there are appropriate communication processes within the laboratory whereby

personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the quality system and the effectiveness of the management system. In addition, the importance of meeting customer requirements as well as statutory and regulatory requirements is communicated to personnel through the use of laboratory meetings and training sessions. CAS/SIMI including all management personnel is committed to ensuring that all laboratory personnel have read, understood and agree to implement and uphold accepted laboratory policies, practices and the quality of testing services described in this document.

CAS/SIMI conducts all reportable business in accordance with the appropriate procedures, policies and guidelines in this Quality Assurance Manual and other corresponding documents. The laboratory management including the Quality Assurance Program Manager has established, implemented and maintains a quality system, based on the required elements for NELAC Chapter 5, which is appropriate to the type, range and volume of environmental testing activities it undertakes. The laboratory is committed to complying with and ensuring that all documents and practices comply with the National Environmental Laboratory Accreditation Conference (NELAC) Standards, N.J.A.C. 7:18, American Industrial Hygiene Association (AIHA) LQAP Policy Document (Effective April 1, 2005), ISO/IEC 17025:2005(E), Arizona Department of Health Services (Department) pursuant to A.R.S. § 36-495.01 et. seq. and A.A.C. R9-14-601 et seq., and the Department of Defense Quality Systems Manual for Environmental Laboratories (Final Version 3, January 2006), as well as referenced method requirements in order to maintain and uphold the degree of data quality for which these are intended. The frequency with which the laboratory will perform the procedures listed pursuant to the requirements as listed above is specified in this document and/or associated CAS/SIMI procedures and documents.

The information in this document has been organized according to the format described in National Environmental Laboratory Accreditation Conference (NELAC) Quality Systems Standards, June 5, 2003, ISO/IEC 17025:2005(E), *EPA Requirements for Quality Management Plans*, EPA QA/R-2, EPA/240/B-01/002, March 2001, and *Guidance on Preparation of Laboratory Quality Assurance Plans*, USEPA, Revision, 1 October 9, 1992. This document is controlled under the requirements specified in the *Standard Operating Procedure for Document Control.*

4.0 PROGRAM DESCRIPTION

The concept of Quality Assurance can be extended, and is expressed in the mission statement of CAS/SIMI:

"The mission of Columbia Analytical Services is to provide high quality, cost-effective, and timely professional testing services to our customers. We recognize that our success as a company is based on our ability to maintain customer satisfaction. To do this requires constant attention to customer needs, maintenance of state-of-the-art testing capabilities and successful management of our most important asset - our people - in a way that encourages professional growth, personal development and company commitment."

In support of this mission, our QA program addresses all aspects of laboratory operations, including laboratory organization and personnel, sample management, document storage, archival and disposal, critical documents and records including standard operating procedures, sample and quality control data, calibration data, standards traceability, equipment maintenance records, method proficiency data (such as method detection limit studies and control charts), and laboratory personnel training records as well as client communications such as contracts, complaints and confidentiality.

4.1 Quality System Documentation

The quality system is the organizational structure, the policies, processes and procedures necessary to ensure that the overall intentions and direction of an organization as it regards quality are met and that the quality of the laboratory's services are assured. The quality assurance manual, related quality documentation and all policies and operational procedures described therein were established in order to meet requirements as described in NELAC, state, and other agency standard(s) referenced in Section 3.0 of this document. As part of the document control procedure, all written procedures are reviewed at least annually and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements.

4.1.1 Quality Assurance Manual

The documentation of the quality system begins with this document, which contains, describes or provides reference to all of the policies and requirements needed to comply with applicable State, Federal and other governing body standards, policies and requirements.

The quality assurance (QA) manual is applicable to all activities conducted at both the main laboratory located at 2655 Park Center Drive, Suite A, Simi Valley, California and the off-site extraction facility at 8030 Remmet Avenue in Canoga Park, California. This document provides the main platform for technical and administrative operations, as well as laboratory organization and responsibilities, equipment and facilities, and procedures and policies by which the laboratory operates. The laboratory QA manual is one of many tools, including systems and analytical standard operating procedures, available to assist analytical and administrative staff in the uniform implementation of the quality system. For references to all supporting procedures of the laboratory's quality system and this document refer to Appendix C.

The contents of the manual are reviewed, revised (as needed) and approved annually by the Quality Assurance Program Manager (QAPM), Laboratory Manager and Team Leaders to ensure that it continuously reflects current policies and practices.

4.1.2 Standard Operating Procedures

Standard operating procedures (SOPs) are the tools through which the policies and procedures, as expressed in the QA manual, are implemented. They form the next tier in the documentation of the quality system. CAS/SIMI maintains SOPs for use in both technical and administrative functions, which accurately reflect all phases of laboratory activities such as data integrity, corrective actions, customer complaints, and all test methods. Each SOP generated in the laboratory has been reviewed and approved by at least the Laboratory Manager and the Quality Assurance Program Manager (QAPM). Standard operating procedures may be internally written documents or copies of published methods with any changes or selected options clearly documented. In addition, certain administrative standard operating procedures are distributed by the corporate Chief Quality Officer for local implementation. These SOPs are implemented wherever and whenever necessary based on the requirements. However, any exceptions and/or additions to the requirements of these procedures are clearly detailed in the appropriate SOPs. Refer to Appendix C for a list of the laboratory's standard operating procedures.

4.1.3 Analytical Methods

In addition to SOPs, the laboratory maintains a copy of all referenced promulgated and non-promulgated methodology used at CAS/SIMI to perform analyses as well as those methods and/or procedures referenced in a specific test method. These methods and procedures are accessible to all laboratory staff regardless of discipline in the corresponding method manual. Refer to Section 18.0 for a list of references and Appendix C for methods and standard operating procedures. This list includes both routine and non-routine methods performed at CAS/SIMI.

4.1.4 Laboratory Notebooks and Records

The third tier of the quality system can be considered to be all records generated by the quality system as described in Section 8.0. Laboratory logbook entries have been standardized following the guidelines in the *Standard Operating Procedure for Making Entries into Logbooks and onto Benchsheets*. The logbook entries are reviewed (approximately 10%) quarterly by either the QAPM or Laboratory Manager (however named), or the appropriate supervisor. All logbook review deficiencies shall be discussed and documented. Logbooks are retained on file for a period of five years from the date of the last entry. A master list or log of all logbooks shall be maintained and must include at a minimum the logbook identification, type, start and end dates and archival date.

4.2 Measurement Traceability

Traceability is defined as the property of a measurement result or value of a standard which can be related to stated references through an unbroken chain, each with stated uncertainties and is documented for all material used to perform calibrations. The documentation, a certificate of analysis containing, at a minimum, the manufacturer, address, accreditation number (where applicable), how traceability was achieved, the traceable values, their associated uncertainty, and the unique serial or laboratory identification number of the equipment or standard reference material (SRM) shall serve as initial point in the chain of traceability. The unique serial number or laboratory identification number is used throughout the laboratory to trace equipment and materials back to the original certificate of analysis.

All metrology equipment (with unique serial numbers) including analytical balances and weights, thermometers and digital pressure/vacuum gauges are calibrated annually using SRMs traceable to the National Institute of Standards and Technology (NIST). All calibration information for this equipment is kept on file by the laboratory. Refer to Section 11.1 on the evaluation and approval of suppliers of critical services.

Consumable SRMs routinely purchased by the laboratory (e.g. primary stock standards) are purchased from nationally recognized, reputable vendors. Most vendors have fulfilled the requirements for ISO 9000 series certification and/or are accredited by American Association of Laboratory Accreditation (A_2LA). Certificates of Analysis and Statements of Accuracy provided by the vendors of reference materials are retained. Traceability for consumable SRMs as well as the procedure for approval of vendors of critical consumables and supplies is accomplished by following the requirements set forth in the corresponding *Standard Operating Procedure for Handling Consumable Materials*. Nevertheless, the procedure requires that each standard reference material, upon receipt, is given a unique identification code and this number is utilized throughout the standard preparation, analytical, reporting, and disposal processes. This is performed to ensure that all analytical data is traceable to the standard and/or standards information involved in producing the data including standard preparation, storage, expiration date, and vendor. It may be noted that atmospheric air is a natural standard and is used with the same confidence as traceable standards. If particular traceable standards do not exist, then the laboratory uses certified reference materials provided by a competent supplier otherwise able to provide reliable chemical characterizations of materials.

4.3 Operational Assessments

There are a number of methods used to assess the laboratory and its daily operations. In addition to the routine quality control (QC) measurements used by a laboratory to measure quality, the senior laboratory management staff at CAS/SIMI examines a number of other indicators to more accurately assess the overall ability of the laboratory to successfully perform those analyses

requested by clients. These indicators include the ability of the laboratory to carry out analyses with regards to available equipment and personnel. This assessment is carried out through an annual management review of instrumentation, personnel and sample load. In addition, the management review includes a list of analytes for which the laboratory offers analyses versus those additional analytes requested and analyzed over the previous year. At the discretion of management, analyte or analytes may be added to the routine list(s) offered. This decision is based in part to the number of requests received, the costs of standards and suitability of adding the analyte to the existing standard.

A frequent, routine assessment must also be made of the laboratory's facilities and resources in anticipation of accepting an additional or increased workload. CAS/SIMI utilizes a number of different methods to insure that adequate resources are available in anticipation of the demand for service. Regularly scheduled staff meetings, tracking of outstanding proposals and an accurate, current synopsis of incoming work all assist the senior staff in properly allocating resources to achieve the required results. This process is more extensively detailed in Section 4.8 of this document and in the *Standard Operating Procedure for Project Management and Business Development.*

4.4 Subcontract Laboratories

Analytical services are subcontracted when CAS/SIMI needs to balance workload and/or when the laboratory does not perform the requested analyses. Subcontracting is only done with the knowledge and approval of the client and this is accomplished by following the requirements specified in the *Standard Operating Procedure for Project Management and Business Development*. Refer to Section 9.10 for additional information.

4.5 Communications (Contracts and Complaints)

Laboratory communications entail each the following areas:

4.5.1 Contracts – The policy for reviewing contracts and analysis requests ensures that the requirements, including methods to be used, for testing are adequately defined, documented and understood. In addition, the laboratory shall ensure that it has the capability and resources to meet the client's requirements and that the appropriate test method is selected to meet the clients' requirements. The review shall also cover any work that is subcontracted by the laboratory. The client shall be informed of any deviation from the contract. Records of oral discussions with the client are maintained. All amended contracts and requests are distributed to all affected personnel. The actual procedure for performing this review is detailed in the *Standard Operating Procedure for Project Management and Business Development*. Other procedures for evaluating, performing and reporting results for client requests and jobs are also specified in Sections 4.6, 4.7, 4.8, and 4.9.

4.5.2 Complaints – Where a complaint or inquiry, from a client or some other entity raises any doubt as to the laboratory's compliance with CAS/SIMI policies or procedures, or otherwise

concerning the quality of calibrations or results, the laboratory shall promptly evaluate the affected area(s). Records of the complaint and subsequent evaluation and any corrective actions and/or audits are thoroughly documented and maintained. Complaints are primarily handled by the Project Manager and Quality Assurance Program Manager according to the policy and procedures for the resolution of complaints outlined in the *Standard Operating Procedure for Dealing with Complaints.*

4.5.3 Communication – Communication between the laboratory (more specifically the Project Managers) and the client is maintained throughout the duration of a contract and/or request. In addition, whenever there is a request, clients are allowed to monitor testing activities for verification purposes and these visits are handled in such a manner as to not jeopardize other clients' confidentiality (refer to Section 8.5 for information on preserving confidentiality). Additional and more specific information regarding this matter is included in the *Standard Operating Procedure for Project Management and Business Development*.

4.6 Deviation from Standard Operating Procedures

Deviations from current standard operating procedures are handled in accordance with this document. Generally, when a customer requests a modification to a SOP (such as an addition or deletion of target analyte(s), etc.), the Project Manager (PM) handling that project discusses the proposed deviation with the Laboratory Manager and to obtain approval to accept the project. The PM is responsible for documenting the approved deviation from the standard operating procedure and providing a detailed description of the deviation to the laboratory prior to analysis.

For circumstances when a deviation or departure from company policies or procedures involving any non-technical function is found necessary, approval must be obtained from the Laboratory Manager, or other level of authority. Frequent departure from policy is not encouraged. However, if frequent departure from any policy is noted, the Laboratory Manager will address the possible need for a change in policy. The information provided in Section 4.3 entitled Operational Assessments describes in detail the process of managerial review and the criteria for implementing a change in policy or procedure.

4.7 Method Modifications

CAS/SIMI strives to perform published methods as described in the referenced documents. However, if there is a deviation from the published method, the method is cited as a "Modified" method in the analytical report. If the modification is such that the method becomes "Performance Based," client approval is obtained for the use of the method prior to the performance of the analysis.

4.8 Procedures for Accepting New Work

The specific procedures for accepting new work are dictated in this document as well as in the *Standard Operating Procedure for Project Management and Business Development*. The procedure for accepting new work takes into account the laboratories ability to complete the work in a timely fashion and the ability to actually perform the work. The requests include:

1. Normal and routine analysis utilizing existing laboratory methodologies
2. Non-routine analyte which is specified in a laboratory offered method
3. Analyte for which no method is specified by the client
4. Complete start-up of an established method
5. Analysis requested with no published method

In all cases, the current laboratory analysis backlog (which includes all in-house samples), anticipated samples from accepted jobs, sample holding times, analysts availability, requested turn around time, and number of samples requested are taken into account when making the decision to accept a proposed job. Each scenario is specified and the procedure for determining whether or not to accept the work is described in detail below. In addition, the minimum requirements for performing this work with regards to quality issues such as calibration, training, detection limits, and reporting is included in Section 11.4 of this document.

Normal and Routine Analysis Using Existing Laboratory Methodologies – This includes methods and analytes which are currently offered and routinely analyzed. If it is determined that a proposed job can be completed in a time acceptable to the client without hindering completion of any other job (previously accepted and in-house) then the new work is accepted.

Non-Routine Analyte Which is Specified in a Laboratory-Offered Method – This entails an analyte which is listed in the method but for which we do not currently offer in the analyte list for that method. These types of requests are accepted based on whether or not the proposed job can be completed in a time acceptable to the client without hindering completion of any other job (previously accepted and in-house) and the availability of the standard. In addition, the decision is largely made based on the amount of QC requested, as well as the required confidence level of the data.

New Analyte with No Specific Method Requested – The analyte(s) is researched and reviewed by the appropriate personnel for chemical nature, formula, and other related information. The Merck Index and CRC Handbook are reviewed to determine the type of compound, where necessary. After this has been determined, it is assumed, based on the information provided and the matrix that it can be analyzed by an existing method. If not, perhaps a modification of a method or the creation of a method may be attempted. The efficiency of the various approaches is compared and if no method allows for acceptable precision and accuracy then the job is not accepted.

These types of requests are also accepted based on the availability of a standard, sample backlog of the laboratory, the requested QC, and the required confidence level of the data.

Complete Start-up of an Established Method – The method is obtained and reviewed by the Project Manager and/or other appropriate personnel to determine if the laboratory believes it is worth the time and expense necessary to proceed; and if the instrumentation and reagents required by the method are available.

The issues listed above are in addition to the ones previously stated such as whether or not the job can be completed in a time acceptable to the client without hindering completion of any other job (accepted and in-house), availability of a standard and the current sample backlog of the laboratory.

Analysis Requested with No Published Method – These are usually special requests made by a client and include the analysis of a particular substrate or product. The analyte(s) or analysis is researched and reviewed by the appropriate personnel for chemical nature, formula, and other related information. The Merck Index and CRC Handbook are reviewed if necessary to determine the type of compound, where necessary. After this has been determined, it is assumed that it can be analyzed by an existing method. If not, perhaps a modification of a method or the creation of a method could be attempted, comparing the efficiency of the various approaches. The method, which allows for the best precision and accuracy, shall be used. The analysis is reviewed by the Project Manager and/or other appropriate personnel to determine: If the laboratory believes it is worth the time and expense necessary to proceed; and if the instrumentation and reagents required by the method are available.

Instrument Out of Service - The Project Manager assesses the situation for the estimated maintenance time for the instrument against the client's requirements prior to the acceptance of any job. The effect of the downtime on in-house samples is also taken into account when trying to schedule additional analyses.

4.9 Quality Assurance and Control Guidelines for Performing New Work

The purpose of this section is to describe the minimum quality guidelines for performing work (from Section 12.8) with regards to calibration, training, standard operating procedures, method detection limits, standards, and reporting. The expected confidence level of the data, aside from the precision and bias measurements, is especially vital when a primary or second source standard is not available, no standard operating procedure has been written, or no specific training records are available for review. In each of these cases the report will reflect the amount or level of confidence in an analytical result.

Normal and Routine Analysis Using Existing Laboratory Methodologies

The laboratory retains the following information on file for work of this type being performed.

- Standard operating procedure – The SOP may either be a laboratory generated document or in a few cases be the published method with any additions and/or deletions specified in an attachment.
- Training documentation – Initial or continuing demonstration of proficiency.
- Method detection limit – Statistical determination of the minimum concentration of a substance or analyte that can be measured and reported with 99% confidence that the analyte concentration is greater than zero.
- Initial calibration – Calibration standards of varying analyte concentrations (with the low standard concentration at or below the method reporting limit) used to calibrate the response of the measurement system with respect to target analyte concentration.
- Second source standard – The method SOPs include the specific criteria for this standard. A second source standard is prepared from material obtained from a source other than the source of the calibration standards and is analyzed after the measurement system is calibrated, but prior to sample analysis in order to verify the calibration of the measurement system.

Any deviation from this list will result in either declining the proposed job or a special notation made on the final report to the client.

Non-Routine Analyte Which is Specified in a Laboratory-Offered Method

The quality assurance and control information outlined above may not be fully employed in non-routine analyses (new analyte). If this is the case, results are qualified in the final report. The laboratory analyzes samples based on quantitative, semi-quantitative, or tentatively identified compound(s) reporting confidence levels. Basically, the level of confidence, aside from the precision and accuracy measurements, is established and depends on the existence of a primary standard and initial calibration curve as well as the reporting requirements of the client.

1. Quantitative result with an initial calibration curve, method detection limit study, and whenever possible a second source standard.
2. Quantitative result with an initial calibration curve, method reporting limit indicated as the low standard on the curve, and whenever possible a second source standard.
3. A semi-quantitative result includes (at a minimum) a one-point calibration with the method reporting limit reported as that concentration.
4. Tentatively identified compound(s) are reported as such when the compound of interest is not included in the standard. It is identified when the GC/MS is operated in SCAN mode and the resulting peak is compared to the mass spectra library. An estimated result is determined by assuming a response factor of one (1) for the compound and comparing the height of that compound (TIC) to the nearest internal standard.

Regardless of the confidence level, a standard operating procedure will be in place for the method being offered. However, the SOP specifies only those analytes routinely analyzed and will not be revised to include non-routine analytes. Nevertheless, based on the described procedure for operational assessments, the target analyte list is reviewed on an annual basis.

New Analyte with No Specific Method Specified

Regardless of the confidence level and in all cases where an existing method may be used to analyze the analyte(s), a standard operating procedure will be in place specifying only those analytes routinely analyzed and will not be revised prior to analysis. The laboratory shall analyze the sample using one of the following reporting confidence levels. The confidence level reported shall depend on both the existence of a standard and the required reporting information of the client.

1. Quantitative result with an initial calibration curve, method detection limit study, and whenever possible a second source standard.
2. Quantitative result with an initial calibration curve, method reporting limit reported as the low standard on the curve, and whenever possible a second source standard.
3. A semi-quantitative result includes at a minimum a one-point calibration with the method reporting limit reported as that concentration.
4. Tentatively identified compound(s) are reported as such when the compound of interest is not included in the standard. It is identified when the GC/MS is operated in SCAN mode and the resulting peak is compared to the mass spectra library. An estimated result is determined by assuming a response factor of one (1) for the compound and comparing the height of that compound (TIC) to the nearest internal standard.

Complete Start-up of an Established Method

CAS/SIMI strives to obtain all of the information listed under established and routine methods. However, depending on the required turn around time, reporting confidence and the end result of the data there may be deviations. Specific deviations with regards to calibration, method reporting limits, as well as training are specified on the final report.

Analysis Requested with No Published Method

The final report includes a summary of the method used to analyze the samples. In addition, the job file will contain sufficient information to reconstruct the analysis if necessary. Also, CAS/SIMI shall strive to obtain all of the information listed under established and routine methods. However, depending on the required turn around time, reporting confidence and the end result of the data there may be deviations. Specific deviations with regards to calibration and method reporting limits are specified on the final report.

5.0 LABORATORY ORGANIZATION AND RESPONSIBILITIES

Columbia Analytical Services, Inc. (CAS) is an employee-owned company and CAS/SIMI is one of six network laboratories operated by CAS Holdings, Inc. The resumes of all key laboratory personnel as well as the organizational and management structure (as outlined in the organization charts) are in Appendix A. The organizational arrangements are such that there are no conflicting interests, such as production, commercial marketing or financing and do not adversely influence the laboratory's compliance with the requirements of appropriate quality standards or any policies and/or procedures.

The CAS/SIMI staff consists of approximately 47 employees, including management, chemists, technicians, and support personnel. They represent diverse educational backgrounds and experience, and provide the comprehensive skills that a modern analytical laboratory requires. Minimum qualifications for each position listed below are on file in the laboratory and are available for review.

CAS/SIMI is committed to providing an environment that encourages excellence as everyone within CAS/SIMI shares responsibility for maintaining and improving the quality of our analytical services. The responsibilities of key personnel within the laboratory are described below (other staff member descriptions are on file in the laboratory) and Table 5-1 lists the experience, signatures and initials of CAS/SIMI personnel assigned to these key positions. All managerial and technical staff members who, irrespective of other responsibilities, have the authority and resources needed to perform their duties including the implementation, maintenance and improvement of the system and to identify the occurrence of departures from the quality system or from the procedures for performing environmental tests, and to initiate action to prevent or minimize such departures.

All employees are required to and are responsible for familiarizing themselves with the applicable quality documentation and implementing the policies and procedures in their work.

- The role of the **Laboratory Manager (LM)** is to provide technical, operational, and administrative supervision/leadership through planning, allocation and management of financial, personnel and equipment resources of the laboratory. This person is responsible for providing resources for implementation of the QA program and ensuring quality, overall laboratory efficiency, and financial performance of the CAS/SIMI facility. Additional duties of the Laboratory Manager (LM) include, but are not limited to, monitoring standards of performance in quality control and quality assurance; monitoring the validity of the analyses performed and data generated in the laboratory to assure reliable data. The Technical Director shall be referred to throughout all laboratory documentation, including the remainder of this document as Laboratory Manager. The LM is also required to perform direct report laboratory personnel work reviews and shall certify and document that personnel with appropriate educational and/or technical background perform all tests. The LM has the responsibility of working with the Project Managers on scheduling conflicting client projects and the Quality Assurance Program Manager to ensure compliance with all company procedures and policies as well as all standards for accreditations (i.e. NELAC Chapter 5, AIHA Policies, ISO/IEC 17025:2005(E), and other State and Federal requirements).

- The Quality Assurance (QA) program is completely independent of the laboratory and is managed in such as way as to prevent any conflict of interest. The responsibility of the **Quality Assurance Program Manager (QAPM)** is to provide an independent focus for overall quality assurance activities within the laboratory and is responsible for the oversight and/or review of quality control data and has the responsibility and authority for ensuring that the quality system is implemented and followed at all times and notify laboratory management of deficiencies in the quality system and monitor corrective action. The QAPM has direct access to the highest level of management at which decision are made on laboratory policy and resources. The QAPM is able to evaluate data objectively and perform assessments without outside (i.e., managerial) influence including hardcopy data package, electronic data audits and internal systems and method audits. This person works with individual laboratory production units to establish effective quality control and assessment plans and is also responsible for identifying and responding to QA problems, needs and requests from the technical staff and ensuring compliance with all company procedures and policies and standards for accreditation (i.e. NELAC Chapter 5, AIHA Policies and ISO/IEC 17025:2005(E)). The QAPM is a technical advisor and is responsible for arranging and conducting internal audits (in accordance with Section 14.0 of this document), summarizing and reporting overall unit performance, including round-robin programs, certification and accreditation activities, and blind and reference sample analyses, ethics and data integrity training, administering inter-laboratory QA efforts; e.g., review performance evaluation results, monitors and approves nonconformities, complaints and any corrective actions taken, conducts QA/QC training, prepares QA reports to management, and reviews and updates the QA Manual.

The Analytical Laboratory is divided into operational units or departments, based upon specific disciplines. Each department performing tests including VOA/Gas Chromatography, VOA Gas Chromatography/Mass Spectroscopy (Air), VOA Soil and Water, Semi-Volatile Organics, and General Chemistry is responsible for establishing, maintaining and documenting a quality control program based upon the unique requirements within that department. Each **Chemist/Analyst** and/or **Technician** in the laboratory has the responsibility to carry out preparation and testing according to current prescribed methods, standard operating procedures and quality control guidelines particular to the department in which he/she is working.

- The **Team Leader/Technical Manager** has the responsibility to ensure that quality control functions are carried out as planned, and to guarantee the production of high quality data. Team Leaders/Technical Managers have the responsibility to monitor the day-to-day supervision of laboratory operations for the applicable departments/analyses and reporting of results, as well as to ensure that productivity and data quality objectives are met. The Team Leader/Technical Manager's duties includes monitoring standards of performance in quality control and quality assurance; monitoring the validity of the analyses performed and data generated in the laboratory to assure reliable data. In addition, the Team Leader/Technical Manager is required to perform laboratory personnel work reviews, schedule programs such as method detection limit studies and training, review corrective action reports and implement necessary actions to prevent any reoccurrence, and coordinate sample analysis scheduling with respect to holding times and client requirements. The Team Leader is responsible for evaluating and approving team work shifts and vacation requests, monitoring in-house projects including on-time delivery and data review, ensuring that all annual

and semi-annual quality control and assurance activities are completed and approved. The team leader also has the responsibility of occasionally working with the Project Managers on scheduling conflicting client projects and the Quality Assurance Program Manager and Laboratory Manager on certain quality issues and any implementation as needed, as they directly relate to the laboratory and their department. The Team Leader/Technical Manager also ensures compliance with all company procedures and policies as well as all standards for accreditations (i.e. NELAC Chapter 5, AIHA Policies, ISO/IEC 17025:2005(E), and other State and Federal requirements). The Team Leader/Technical Manager will be referred throughout most documentation as Team Leader, Analyst or Chemist with the same job functions/responsibilities as indicated.

- The **Director of Research and Development** is required to identify and develop new markets and technologies, and manage the implementation of such endeavors through support of the **Director of Technology Development.** It is also the responsibility of the Director of R&D to manage business development and those individuals responsible for this role.
- The **Environmental Health and Safety (EH&S) Coordinator** is responsible for the administration of the laboratory health and safety policies. This includes the formulation and implementation of safety policies, the supervision of new-employee safety training, the review of accidents, incidents and prevention plans, the monitoring of hazardous waste disposal and the conducting of departmental safety inspections.
- **Information Technology (IT)** staff (**Systems Analysts**) is responsible for the administration of the laboratory support services. Other functions of the IT staff include laboratory network maintenance, education of analytical staff in the use of scientific software, custom software development and implementation, data back up, archival and integrity operations. **Data Processors** are responsible for generating and reviewing Electronic Data Deliverables (EDDs).
- The **Sample Management Personnel (Sample Custodian)** and alternates play a key role in the laboratory QA program by performing and/or assisting in the proper preparation and shipment of sampling media. In addition, the custodian or alternates are responsible for the verification of sample receipt information, performing sample acceptance and log-in and distribution of documentation per laboratory defined procedures and the initial storage of samples in the proper environment and location and either assisting or performing proper sample disposal. The custodian also monitors and records all thermal preservation equipment temperatures and calibrates associated thermometers against a NIST traceable thermometer.
- The **Project Manager (PM)** is a assigned to act as a technical liaison between the client and the laboratory. The PM is responsible for ensuring that the analyses performed by the laboratory meet all project, contract, and regulatory-specific requirements. This entails coordinating with the CAS/SIMI laboratory and administrative staff to ensure client-specific needs are understood and that the services CAS/SIMI provides are properly executed and satisfy the requirements of the client.
- The **Data Validation Coordinator** is responsible for data review, data package preparation, review and coordination, and preparation of case narratives (based on the information provided by the laboratory).

- The **Disposal Technician** is responsible for coordinating for the appropriate disposal of spent chemicals, sample extracts and other hazardous wastes. In addition, the Disposal Manager has the responsibility for the proper disposal of solids, liquids and air samples in Tedlar bags and canisters.

5.1 Nominated Deputies

When either of the key positions listed below is vacant, the deputy assigned to that position assumes the duties and responsibilities of that position during their absence.

Acting Laboratory Manager/Technical Director ....Director of Research and Development
Acting Quality Assurance Program Manager.....Team Leader (VOA GC/MS-Air)

5.2 Provision Signatures, Technical Experience and Qualifications

The undersigned (Table 5-1) are key personnel responsible for planning, implementing, maintaining and improving the Quality Assurance (QA) activities conducted within Columbia Analytical Services.

Table 5-1
Technical Staff Summary

Name / Title	Signature	Initials	Years of Experience
John Yokoyama, B.S. *Laboratory Manager*		JY	21
Lynne Nelson, B.S. *Quality Assurance Program Manager*			16
Michael Tuday, B.S. *Director of Research and Development / Project Manager*		MT	27
Ku-Jih Chen, B.S. *Director of Technology Development*		KJC	32
Wade Henton, B.S. *Team Leader (Volatiles GC - Air)*		WH	21
Chris Parnell, B.S. *Team Leader (Volatiles GC/MS – Air)*		CP	21
Madeleine Dangazyan, B.S. *Team Leader (Semi-Volatiles/ Industrial Hygiene)*		MD	12
Sue Anderson, B.S. *Project Manager / Team Leader (General Chemistry)*			17
Karen Ryan, B.S. *Project Manager / Team Leader (Volatiles - Soil and Water)*		KR	16
Rusty Bravo, B.S. *Chemist*			15
Aristotle Bragasin, B.S. *Chemist*			12
Roger Wong, B.S. *Chemist*		RW	3
Regan Lau, B.S. *Chemist*		RL	6
Zheng Wang, B.S., M.S. *Chemist*		ZW	19
Chaney Humphrey, B.S. *Chemist*		CH	3
Liliana Marghitoiu, B.S. *Chemist*		LM	3
Takashi Miyake, PhD *Chemist*		T.M	5
Simon Cao, B.S. *Chemist*			14
Kristiana Miller, B.S. *Chemist*	ON FILE		6

Name / Title	Signature	Initials	Years of Experience
Wida Ang, B.S., M.S. *Chemist*			22
Sadia Terranova, B.S. *Chemist*			7
David Castillo, B.S., M.S. *Chemist*		DC	1
Robin Gill *Data Validation Coordinator; Team Leader (Sample Management and Reporting)*	Robin Gill	RG	27
Michelle Sakamoto, B.A. *Data Validation Coordinator*	Michelle H. Sakamoto	MS	11
Kelly Horiuchi, B.A. *Project Manager*	Kelly M. Horiuchi	KMH	7
Kathleen Aguilera, B.A. *Project Manager*	ON FILE		18
Indian Tyler, B.S., M.S. *Business Development*			3
Robert De La O *Systems Analyst / IT*	ON FILE		17
Richard Adams, B.S. *Systems Analyst / IT*			30
Shreejana Singh, B.S. *Systems Analyst*		SSM	2
Manny Zamora *Sample Management Custodian*			5
Lonnie Kukita, A.A. *Sample Management Custodian*			12
Llensenia Cercado *Team Leader – Canister Cleaning and Shipping, Alternate Sample Management Custodian*		LC	7

6.0 STATEMENT OF PROFESSIONAL CONDUCT AND LABORATORY PRACTICE

One of the most important aspects of the success of CAS/SIMI is the emphasis placed on the avoidance of involvement in any activity that would diminish confidence in the laboratory's competence, impartiality, judgment, operational integrity, or integrity of the data provided and services rendered. The laboratory's success is reliant on both the professional conduct of all employees within CAS/SIMI as well as established laboratory practices. CAS has a policy entitled *CAS Commitment to Excellence in Data Quality*, requiring certain stated standards of conduct and ethical performance among our employees. This policy includes all aspects of data production, analysis, review and reporting and is required to be reviewed and signed upon hire and annually thereafter by every employee, regardless of responsibility.

The success of quality assurance requires a commitment by everyone in the organization, individually within each operating unit and throughout the entire laboratory, to ensure that CAS personnel are free from any commercial, financial, and other undue pressures, which might adversely affect the quality of the work. An ombudsman program is available to handle any conflict of interest, disagreements, and problems within any CAS laboratory as specified in Section 6.4. Additional information regarding professional conduct and laboratory practice is included in the following sections.

6.1 Professional Conduct

To promote quality, CAS/SIMI requires certain standards of conduct and ethical performance among employees. The following examples of documented CAS/SIMI policy are representative of these standards, and are not intended to be limiting or all-inclusive:

- Under no circumstances is the willful act of fraudulent manipulation of analytical data condoned. Such acts are to be reported immediately to senior management for appropriate corrective action.
- Unless specifically required in writing by a client, alteration, deviation or omission of written contractual requirements is not permitted. Such changes must be in writing and approved by senior management.
- Falsification of data in any form will not be tolerated. While much analytical data is subject to professional judgment and interpretation, outright falsification, whenever observed or discovered, will be documented, and appropriate remedies and punitive measures will be taken toward those individuals responsible.
- Unauthorized release of confidential information about the company or its clients is taken very seriously and is subject to formal disciplinary action. A corporate *Confidentiality and Conflicts of Interest Employee Agreement* is reviewed and signed upon hire and on an annual basis. Refer to Sections 8.5 and 8.6 for additional information.

6.2 Prevention and Detection of Improper, Unethical or Illegal Actions

It is the intention of CAS/SIMI to proactively prevent and/or detect any improper, unethical or illegal action conducted within the laboratory. This is performed by the implementation of a program designed for not only the detection but also prevention of such acts. Prevention consists of educating all laboratory personnel in their roles and duties as employees, company policies, inappropriate practices, and the corresponding implications as described in Section 6.3 of this document.

In addition to education, appropriate and inappropriate practices are included in SOPs such as manual integration, data review, data integrity, and specific method procedures. Other aspects of this program include electronic data tape audits, post-analysis and whenever possible single blind and/or double blind analyses. All aspects of this program is documented and retained on file according to the company policy on record retention.

6.3 Laboratory Ethics Training Plan

Laboratory ethics training (approximately 8-hours) is held annually for every new CAS employee including all full and part time personnel; however, as part of the new hire process a one hour ethics course is given which incorporates a summary of the topics listed below. This session has been incorporated as interim training to ensure that new employees are aware of the commitment of CAS/SIMI to laboratory ethics. The training session includes at a minimum the following legal and ethical topics:

- Triggers and types of unethical behavior
- CAS Employee Handbook (overview including mechanism for reporting and seeking advice on ethical decisions)
- CAS' Commitment to Excellence in Data Quality (overview including legal consequences)
- Measures taken to prevent and detect fraud
- Examples of data falsification or misrepresentation
- Acceptable and unacceptable solutions to typical laboratory problems
- Data validation
- Implications of laboratory data fraud
- Potential punishments and penalties for improper, unethical or illegal actions

It is the responsibility of the Quality Assurance Program Manager to ensure that the training plan as retained on file and briefly described in this section including content and frequency is conducted. All employees may review the mechanism for reporting and seeking advice on ethical decisions as well as the legal consequences of unethical behavior in the CAS Employee Handbook & CAS Commitment to Excellence in Data Quality Statement, both of which are available to all employees. In addition, the Excellence in Data Quality Statement is reviewed and signed on an annual basis by all laboratory personnel. Also, all employees are required to complete two ethics "refresher" training (approximately 1-hour) sessions annually. The subject and content are generally at the

discretion of the Corporate Quality Assurance Department and are retained on file in the QA Department.

6.4 Laboratory Practices Affecting Personnel

CAS/SIMI makes every attempt to ensure that employees are free from any commercial, financial, or other undue pressures that might affect their quality of work. This is accomplished by utilizing each of the following policies, programs and procedures, wherever necessary. In instances of ethical concern, laboratory management is informed of a need for further detailed investigation to ensure that complete and accurate information is obtained.

- Ombudsman Program – CAS has implemented an external ombudsman/hotline program through EthicsPoint, a phone and internet-based reporting system, to enhance communication and empower employees to promote safety, security, and ethical behavior. Employees can file a report anonymously to address issues in the workplace and to cultivate a positive work environment.
- Open Door Policy – Employees have the right and obligation for open door communications to ask questions, seek guidance, and report incorrect practices and wrong doing without fear of retribution. As described in the CAS Open Door Policy (CAS Employee Handbook), CAS believes in using the chain-of-command channels for this dialogue. However, if there is fear or a concern that using this approach is not appropriate, employees are free to take their concerns to the President, Director of Human Resources, the Chief Quality Officer, use the EthicsPoint program as listed above. Employees may do any of these options without fear of retribution.
- Project Scheduling – Jobs are scheduled (when prior notice is available) according to the *Standard Operating Procedure for Project Management and Business Development* as well as Section 11 of this Quality Assurance Manual. The scheduling is done not only to prevent missed holding times and on-time deliveries but as a way for management and analysts to be prepared for incoming samples and to utilize flexible work schedules, whenever necessary.
- Laboratory Capacity – The maximum number of samples that can be analyzed on a single instrument in a typical eight-hour day (per analysis) has been determined. This number is located in each specific method Standard Operating Procedure and is useful in informing both analysts and management of the number of samples which can typically be analyzed in an eight hour day. This is used to evaluate analysts against unethical practices, impossible work expectations as well as project scheduling.
- Flexible Work Hours – Analysts are able to work flexible work hours (with management approval). Additionally, analysts may "team" with a co-worker (again with approval) and work split shifts in order to extend the work day and increase the number of samples that can be analyzed, whenever necessary.
- Gifts and Favors (CAS Employee Handbook) – To avoid possible conflict of interest implications, employees do not receive unusual gifts or favors to, nor accept such gifts or favors from, persons outside the Company who are, or may be, in any way concerned with the projects on the Company is professionally engaged. Anything beyond an occasional

meal, an evening's entertainment, or a nominal holiday gift is considered an "unusual gift or favor".

6.5 Fraud, Waste and Abuse

6.5.1 Fraud Under no circumstances is the willful act of fraudulent manipulation or falsification of analytical data, or deviations from contractual requirements of the client is condoned. Any attempt by management or by an employee to compromise this commitment presents a case for serious disciplinary action. Actions against an employee violating this policy can ultimately lead to termination of employment.

While much analytical data is subject to professional judgment and interpretation, outright falsification, whenever observed or discovered, will be documented, and appropriate remedies and punitive measures will be taken toward those individuals responsible. It is the responsibility and right of all employees to report any situation, which may impact the final quality or integrity of data produced for our clients.

6.5.2 Waste Samples are characterized as non-hazardous or hazardous based upon the results of the analyses performed by the laboratory and other information supplied by the customer. This characterization assumes contaminants requested for analyses are the only hazardous substances contained in the sample. Procedures for sample treatment and disposal are written in the SOPs for the treatment of foreign soils and waste disposal.

6.5.3 Abuse CAS recognizes the importance of maintaining a safe work environment. The abuse of alcohol or drugs by employees, either on or off the job, can impair the ability of employees to perform their jobs or may also result in accident and/or other failures which may pose serious risks to employees, co-workers, clients, and the general public. Details of CAS' Substance Abuse Policy can be found in the appropriate section of the Employee Handbook.

6.6 Data Integrity

An integral part of the CAS/SIMI Quality System is the data integrity procedures. These procedures provide assurance that a highly ethical approach to testing is a key component of all laboratory planning, training and method implementation. There are four elements to the laboratory's procedures for data integrity. These include 1) data integrity training (conducted initially and at least annually); 2) signed data integrity documentation for every employee (*CAS Commitment to Excellence in Data Quality* agreement); 3) in-depth periodic monitoring of data integrity (QAPM electronic and hard-copy data audits); 4) data integrity procedure documentation (*Standard Operating Procedure for Ensuring Data Integrity*), which is reviewed and updated at least annually and is signed and dated by senior management and this document, as well as all associated implementation records are available for review.

The training conducted includes discussions regarding all data integrity procedures, in-depth data monitoring and data integrity procedure documentation. There is specific emphasis on the importance of proper written narration on the part of the analyst with respect to those cases where analytical data may be useful, but are in one sense or another partially deficient. A signature attendance sheet of data integrity training including their understanding of their obligations related to data integrity and as specified in the training is generated for each attendee and maintained on file for review.

CAS has a policy entitled *CAS Commitment to Excellence in Data Quality*, requiring certain stated standards of conduct, ethical performance and data integrity among our employees. This policy includes all aspects of data production, analysis, review and reporting and is required to be reviewed and signed upon hire and annually thereafter by every employee, regardless of responsibility. Laboratory procedures and requirements with respect to data integrity are completely defined in the *Standard Operating Procedure for Ensuring Data Integrity*. Refresher data integrity training will be conducted annually as part of ethics training (Section 6.3) or in addition to this training.

The QAPM is responsible for monitoring data integrity through periodic electronic data and hardcopy data audits. Internal systems and data audits are conducted periodically in addition to external agency and client audits. The data audits include a detailed in-depth review of hardcopy data and electronic data to ensure compliance with CAS Quality program (refer to Section 14.0 for additional information).

CAS Quality and Ethics Policy Statement, which is on file and maintained in the laboratory includes a commitment by CAS Corporate senior management to sponsor and support the quality and ethics program.

7.0 LABORATORY FACILITIES AND SECURITY

COLUMBIA ANALYTICAL SERVICES maintains 20,000 square feet of laboratory and office space at 2655 Park Center Drive, Suite A in Simi Valley, California. The space is divided into volatiles and semi-volatiles and general/wet chemistry laboratories, sample preparation laboratory, workshop, canister conditioning laboratory, sample receiving/sample log-in room and sample storage area and administrative areas.

Carrier, make-up, purge and detector gases are supplied to the laboratory instruments via a gas delivery system located in the warehouse portion of the facility. The gas delivery system is comprised of four (4) two-cylinder manifolds, which allow tanks to be changed without interruption to the gas supply. Gas purification devices and indicator tubes are housed in an enclosure located in close proximity to the instruments. In addition, a liquid nitrogen bulk tank is utilized to provide cryogenic cooling to specific instrumentation.

CAS/SIMI maintains a satellite extraction facility located at 8030 Remmet Avenue in Canoga Park, California. The 1300 square foot unit contains three eight-foot fume hoods and a three-ton air conditioning unit. The facility is designed with the expressed purpose of performing semi-volatile organics extraction of air, liquid and solid matrices. The extraction facility is equipped with approximately sixty-five linear feet of bench space, glassware washing equipment and materials, flammable solvent storage, sample/extract storage refrigerators and an electric kiln.

The laboratories are designed and constructed to provide safeguards against cross-contamination of samples and are arranged according to work function, which enhances the efficiency of analytical operations. In addition, the facilities are maintained in such as way as to facilitate correct performance of the environmental tests. Precautions are taken to ensure that the environmental conditions do not bring into question or invalidate the results or adversely affect the required quality of any measurement. Constant and consistent test conditions (both instrumental and environmental) where required by the test method are monitored in accordance with Sections 9.7, 12.1.1 of this document and *Standard Operating Procedures for Handling Consumable Materials* and *Laboratory Storage, Analysis and Tracking.* The segregated laboratory areas are designed for safe and efficient handling of a variety of sample types. Specialized areas and/or segregated laboratories include:

- Sample Management Office; Shipping and Receiving
- Records Archival
- Volatile Organics Laboratory (GC and GC/MS)
- Semi-Volatiles Laboratory (GC, GC/MS and HPLC)
- Ultra Low Level Volatile Organics GC/MS
- General/Wet Chemistry Laboratory
- Sample Preparation Laboratory
- Canister Conditioning and Maintenance
- Flow Controller and Critical Orifice Calibration Station

- Controlled-access (when necessary) Sample Storage Walk-in Refrigerator
- Sample, Standards and Media Storage
- Laboratory Deionized Water System
- Laboratory Management, Client Service, Report Generation and Administration
- Information Technology (IT)
- Waste Disposal

Within the designated areas for sample receiving and storage, there are refrigerated and non-refrigerated sample storage, dedicated sample container preparation, and shipping area, provided for the efficient and safe handling of samples. Figures 7-1 and 7-2 show the facility layouts of our analytical and extraction/preparation laboratories respectively.

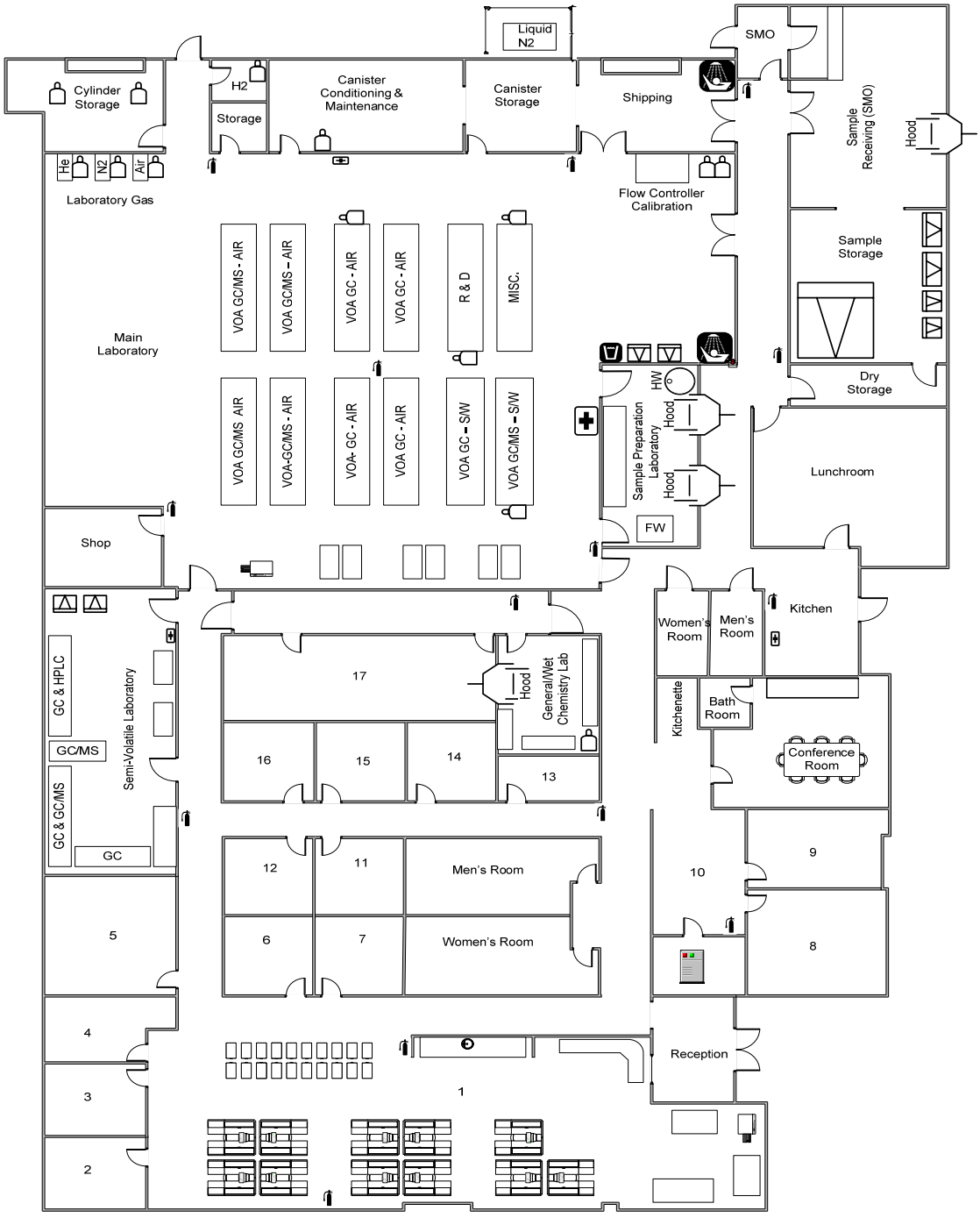
The laboratory is equipped with state-of-the-art analytical and administrative support equipment. Appendix B lists the major equipment at the analytical and extraction/preparation laboratories, illustrating the laboratory's depth and overall capabilities.

7.1 Facilities Security

Laboratory security utilizes physical and administrative controls to protect data (electronic and hardcopy), samples, digestates, and extracts from unauthorized or unnecessary access or intentional modification. Physical entry to the laboratory is limited to authorized personnel only. All visitors must sign-in at the front desk and the sample storage area is limited to authorized CAS personnel only. No visitors are allowed beyond the entry area of the building without being accompanied by a CAS employee. The laboratory is secured every night by locked gates, doors, windows, and electronic alarms.

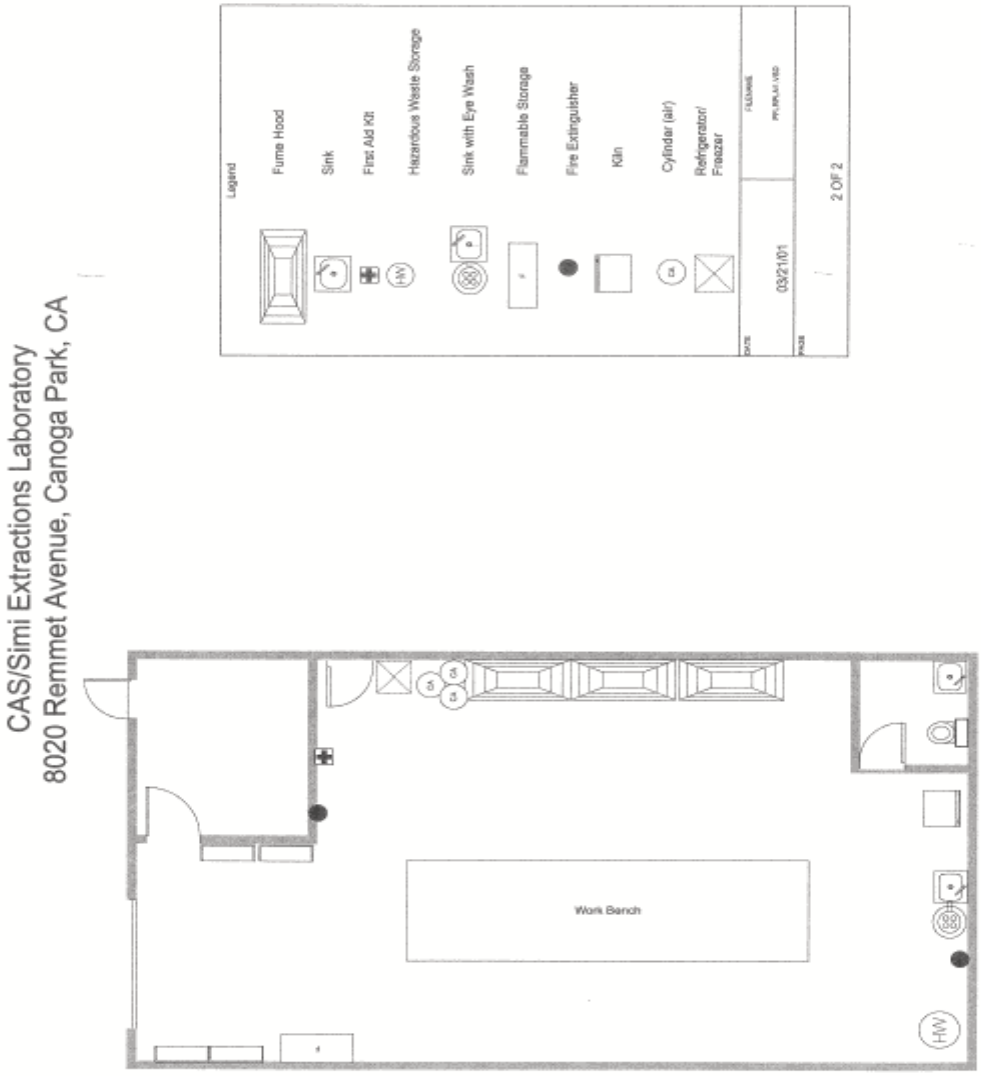
CAS/SIMI is a secure facility with laboratory access limited and controlled to protect the integrity of in-house samples. All entrances, with the exception of the front door, shall remain locked and secure during business hours. Also, the receptionist must monitor the front entrance for all incoming persons.

Figure 7-1



CAS SIMI VALLEY FLOOR PLAN		
2655 Park Center Drive, Suite A, Simi Valley, California 93065		
Rooms 1-17 -Administrative Offices	**-First Aid**	**HW -Hazardous Waste Cabinet**
-Network Server Room	**-Emergency Shower**	**FW -Flammable Waste Cabinet**
-Fire Extinguisher	**-Gas Cylinder(s)**	
-Refrigerator/Freezer	**-Deionized Water**	

Figure 7-2


CAS/Simi Extractions Laboratory
8020 Remmet Avenue, Canoga Park, CA
Legend
Fume Hood
Sink
First Aid Kit
Hazardous Waste Storage
Sink with Eye Wash
Flammable Storage
Fire Extinguisher
Kiln
Cylinder (air)
Refrigerator/ Freezer
03/21/01
2 OF 2
Work Bench
HW

8.0 DOCUMENT AND RECORD CONTROL, STORAGE AND SECURITY

This section outlines and/or references procedures for the proper control, storage and security of all documents and records which include both hardcopy and electronic versions. In addition, procedures required for protecting the electronic storage and transmission of results, and clients' confidential and proprietary rights are detailed.

8.1 Documentation

The laboratory maintains a document and records system that ensures all laboratory documents and records relevant to the work of the laboratory are retained and are made readily available to personnel, where applicable. These include quality assurance manuals, standard operating procedures, forms, result and reporting templates, software and any external source documents such as reference methods, equipment manuals, raw data, reports, supporting records, instructions, and reference data are. All equipment manuals regarding the use and operation of all relevant equipment are maintained and are readily available to personnel regardless of discipline.

The necessary certifications and approvals administered by external agencies (refer to Attachment E), as well as, all records required to document the existence of and compliance with CAS/SIMI policies and procedures including both internal and external audit reports and managerial reviews are maintained.

Procedures for the control and maintenance of documents that form part and are required to maintain an effective quality system are described in *Standard Operating Procedure for Document Control* and includes distribution, tracking and filing procedures. The requirements of the SOP apply to all logbooks, standard operating procedures, quality assurance manuals, and other controlled CAS documents including forms and reference tables. All records and documents reference the date or dates for which the document and/or record was in force, where applicable.

In addition, a master list of all documents (manuals, forms, procedures, etc.) is maintained and includes information (dependent on type of document) such as title, revision and location. Each list is revised in order to ensure that the most recent authorized document is retained and is being utilized. Authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed. In addition, this manual and all standard operating procedures are reviewed at least annually and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements. Changes may be made to SOPs prior to revision and distribution as long as the changes are noted on all copies including the original and are approved (initialed and dated) by at least two signatories including the QAPM for local documents and the QAPM and Laboratory Manager for corporate QA issued documents.

8.2 Documentation and Data Storage

All related quality documentation such as the quality manual, standard operating procedures, temperature, and balance records, maintenance logs, etc. are controlled and retained by the laboratory for 5-10 years depending upon the program (refer to the *Standard Operating Procedure for Document Control).* Analysis data is retained for 5 years from the report date unless contractual terms specify a longer retention time and include the final reports/data packages sent to the client, chain-of-custody records and associated sample receipt documentation logs, extraction logs, standard and reagent preparation logs, analytical logs, data system printouts, corrective action reports, data review documentation, and instrument maintenance logs. Hard copies are filed in the most logical manner usually be document type and date or job number. Hard copies of all other documents, which are batch-specific (i.e. QC data), are indexed by dates, instrument and/or method. All physical records are stored onsite for at least one year, after which they are moved and stored offsite for the remainder of the storage period. Once archived, an access log is used to document access.

8.3 Records Maintenance (Security, Storage, Archival, Access, and Retention)

This section describes both specific and general procedures for the identification, collection, indexing, access, filing, storage, maintenance, retention, archival and disposal of quality and technical records. A record is any documentary material, regardless of physical form or characteristics created or received by the laboratory in connection with conducting business such as procedural evidence, observations and notations.

Records are collected, maintained, stored and archived in a logical retrievable manner. Records, excluding electronic records (described later in this section) and quality records are maintained in a manner whereby access is limited to laboratory personnel. This system includes (but is dependent upon the type of record) type, date, job number or other unique identifying manner. For example, individual sets of analyses are identified and stored by analysis date and/or analytical method identification. Service request files (client job files) are filed by service request number (job number) and additional/supporting records are all retained in (or referenced) the associated client job file. Reference to additional information is also included such as the date and the instrument on which the samples were analyzed, the standard(s) identifications, etc and from this information supporting records may be obtained for review.

Quality records include reports from all audits, management reviews, records of corrective actions, complaints, preventive actions and other records collected and/or maintained by the Quality Assurance Program Manager including those associated with the laboratory quality system and other documents required under laboratory accreditation programs. These documents and records are maintained on file in the Quality Assurance Department, where access is controlled by the Quality Assurance Program Manager. Training records are stored by person, type of training and date; whereas audits consist of type of audit (internal or external), auditing body (where applicable), year and unique audit identification (date). Both complaints and

nonconformities are maintained and archived separately and by a unique identification number, which includes the date of occurrence and a sequential number for that date.

All records, both hardcopy and electronic, are held by the laboratory for a minimum of five years or as specified by the client after the date of analysis. However, the laboratory shall retain records of analyses for ten years if the client specifically identifies the job as being performed because of epidemiological or public health concerns. Jobs/projects requiring an archival of greater than five years (per the client's written request) are pulled and properly stored and identified for the appropriate duration. All records that have met the minimum retention duration are destroyed or erased, whichever is applicable. This is executed in such a manner as to conserve all applicable requirements of confidentiality.

Any revisions or changes to original data as well as the original data must be retained in the same file and appropriately marked with the reason and where appropriate initials and date of the person responsible. Records are kept in a secure location where they can be retrieved when necessary. Access to all hardcopy files is documented with an access card that includes the initials of the person retrieving the file, date out and date in as well as the initials upon return of the file.

For archival purposes, job files, along with other records such as obsolete SOPs, training records, method detection limit studies, and logbooks are placed in uniquely identified file boxes. For example, job file boxes are identified by the year in which the job was completed as well as a sequential number for each box (for that year).

A master logbook is maintained which identifies the box number and the contents of each box. A notation is made in the log once a box is moved to the remote sample preparation laboratory for continuing storage and when the files in the file box are destroyed (by shredding). Prior to destroying any year of job files, client/project archival requests are reviewed and those client jobs in which the required archival duration exceeds five years are filed, appropriately labeled and stored. Additionally, other related boxes, such as those specific to quality assurance are destroyed upon approval by the Quality Assurance Program Manager (at no less than five years). When retrieval of any physical record is needed, a storage and retrieval (access) log is completed and kept in each drawer or file box.

8.4 Tape Backup, Archival and Restoration

The plan for backup, archival and restoration of electronic data is written in the *Standard Operating Procedure for Electronic Data Tape Backup, Archiving & Restoration.* This document covers the steps necessary to perform the tape backup of local area networks and the archiving of these backup tapes, to solve common problems, and to ensure a minimal loss of data in case of a disaster, as well as the procedure necessary for restoration of such data.

Persons requesting access to electronic data is detailed with the use of a logbook and is maintained by the person responsible for Information Technology. Electronic data files which have been revised are given a unique file number or directory and both files are retained as detailed in this section. All electronic records are saved using a tape backup system administered by the local information technology supervisor, with adequate redundancy to allow for possible media failure. The laboratory maintains computer systems that allow archived records and the access to such records to be controlled for the duration of the retention period. Refer to the *Standard Operating Procedure for Electronic Data Tape Backup, Archiving & Restoration* for additional information.

8.5 Maintenance of Client Confidentiality and Proprietary Rights

It is the responsibility of all CAS/SIMI employees to safeguard sensitive company and client information (including national security). The nature of our business, the economic well-being of our company and of our clients is dependent upon protecting and maintaining proprietary company/client information. All information, data, and reports (except that in the public domain) collected or assembled on behalf of a client is treated as confidential. No information may be given to third parties without the written consent of the client. As a condition of employment, all employees are required to sign and adhere to *Confidentiality and Conflicts of Interest Employee Agreement* set forth in the Corporate "Employee Agreement" at date of hire.

8.6 Transmission of Test Results and Reports

Transmission of test results by telephone, facsimile, telex, or other electronic or electromagnetic means must follow the procedures detailed in this document to ensure that the client's confidentiality is preserved as best as possible. Refer to the *SOP for Data Integrity* for additional information on the transmission of results.

Telephone – The laboratory may not give results or discuss any results to any persons other than the client. However, the client may request, in writing to have results released to another individual or company. This request must be specific with regards to information, to whom the information is to be released and must be on the Client's letterhead or email.

Facsimile – Results may be faxed (as confidential) to the number supplied to the laboratory by the client. If the results are to be released to another individual or company the same procedure as specified above must be followed. Results may only be faxed following review by the laboratory and Data Validation.

Electronic – Results may be sent electronically (as confidential) to the address supplied by the client. However, results requested by other parties may not be sent without prior written consent of the client. Results may only be transmitted following review by the laboratory and Data Validation.

A copy of the report may not be released or the results discussed with another party without the prior written consent of the client, no verbal requests will be accepted. Another party may not request the release of report/results. The laboratory must convey the fact that all reports generated are confidential and results may only be released at the request of the client and they must be in writing on the Client's letterhead to be considered acceptable and in compliance with laboratory policy. A client may request to have results released on an on-going basis by the submittal of a single consent letter stating the details of the release.

8.7 Transfer of Ownership

In the event that the laboratory transfers ownership or goes out of business, laboratory records shall be maintained for a minimum of five years or for the contracted period (if exceeds five years) or transferred according to the clients' instructions. In addition, in cases of bankruptcy, appropriate regulatory and state legal requirements concerning laboratory records shall be followed.

9.0 SAMPLE HANDLING PROCEDURES

Standard operating procedures have been established for all aspects of sample management within the laboratory including sample receiving, acceptance, log-in, storage, shipping, and disposal. These procedures ensure that samples are handled properly and that all associated documentation is complete and consistent. The sample handling factors that must be taken into account to ensure accurate, defensible analytical results include but are not limited to:

- Amount of sample taken (sampling)
- Type of container used
- Existence and type of sample preservation
- Holding time
- Proper custodial documentation
- Sample storage, tracking and/or transfer
- Disposal

A record of all procedures to which a sample is subjected while in the possession of the laboratory including acceptance, rejection, login, identification, preservation checks, storage, tracking, and disposal are documented and maintained. In addition, all indirect procedures which supports each record of a sample and protects the integrity of a sample is documented and maintained (i.e., refrigerator and freezer temperature checks, thermometer calibrations, etc.).

9.1 Sampling

The quality of analytical results is highly dependent upon the quality of the procedures used to collect, preserve and store samples. CAS/SIMI provides localized and limited sampling services. The laboratory only provides sampling for aqueous samples; therefore, CAS/SIMI recommends that clients follow sampling guidelines described in the specific reference methods including 40 CFR 136 and/or USEPA SW-846, NIOSH, OSHA, ASTM, CARB and SCAQMD as appropriate for other matrices.

Samplers follow the procedures, preservation, transport and sampling and custody documentation requirements stated in the most recent version of the laboratory *SOP for Sampling*. This SOP along with client provided sampling plans and the EPA Handbook for Sampling and Sample Preservation of Water and Wastewater provide the procedures necessary to perform the sampling activities currently being provided. In addition, all sampling activities are clearly detailed in the final report and the applicable chain of custody and sampling documents included.

Since a number of tests performed are for compliance to federally promulgated rules and regulations, it is important to consult and obtain approval and requirements for sampling and analytical guidelines from the client, appropriate state or local regulatory agency prior to

sampling. When transporting samples to the laboratory, the most expedient but lawful route of transport should be utilized. Also, the hazardous potential of the samples needs to be considered when shipping samples via air freight or passenger airlines.

9.2 Preservation

CAS/SIMI uses sample preservation, container, and holding time recommendations published in a number of referenced documents including, but not limited to USEPA SW-846, USEPA 600/4-79-020, USEPA-600/R-94-111 (metals), USEPA 600/r-93-100 (inorganic substances), 600/4-91-010, and EPA/625/R-96/010b (air samples) and the US EPA Methods Update Rule effective 4/11/07. The complete citation for each of these and other references can be found in Section 18.0 of this document. The appropriate container, preservation and holding time information are summarized in Tables 9-1 and 9-2. However, additional information on this matter is addressed in each corresponding method SOP and the specific references are included in Section 18.0.

9.3 Shipping of Container and Samples

CAS/SIMI routinely provides sample containers to clients via media requests for all matrices (soil, water, air) with the appropriate preservatives (where necessary). These containers include 40mL vials, Summa canisters, silica-gel tubes, etc (Refer to Tables 9-1 and 9-2). CAS/SIMI keeps client-specific shipping requirements on file and utilizes all major transportation carriers to guarantee that sample shipping requirements (same-day, overnight, etc.) are met. CAS/SIMI also provides its own courier service that makes scheduled courier runs in the greater Los Angeles metropolitan area. The procedures for all requirements directed toward media requests follow the requirements detailed in the *Standard Operating Procedure for Media Request Fulfillment*.

9.3.1 Soil and Water Samples The containers are purchased as "precleaned", and conform to the requirements for analytical samples as established by the USEPA. Certificates of analysis for the sampling containers are available to clients upon request, where available. The soil and/or water sample kits typically consist of foam-lined, precleaned shipping coolers, (decontaminated inside and out with appropriate cleaner, rinsed thoroughly and air-dried), specially prepared and labeled sample containers individually wrapped in bubble wrap, (VOC vials are placed in a specially made, foam rubber holder), chain-of-custody (COC) forms, and custody seals (when required).

Figure 9-1 is a copy of the chain-of-custody form (soil and water) used at CAS/SIMI. For extremely large sample container shipments, the containers may be shipped in their original boxes. Such shipments will consist of several boxes of labeled sample containers and sufficient materials (bubble wrap, COC forms, custody seals, shipping coolers, etc.) to allow the sampling personnel to process the sample containers and return them to CAS/SIMI. The proper preservative will always be added to the sample containers prior to shipment, unless otherwise instructed by the client. If any returning shipping cooler

exhibits an odor or other abnormality after receipt and subsequent decontamination by laboratory personnel, a second, more vigorous decontamination process is employed. Containers exhibiting an odor or abnormality after the second decontamination process are promptly and properly discarded.

9.3.2 Air Samples Figure 9-2 is a copy of the chain-of-custody form for air samples used at CAS/SIMI. Certificates of Analysis are retained (where available) for purchased media. Each canister is permanently labeled with a unique identifier, which is used to tract canister shipments to and from the field.

9.4 Sample Receiving and Acceptance

It is the policy of CAS/SIMI to check and record the condition of each sample (i.e. temperature, preservation, etc.) delivered to the Sample Management Office (SMO) and received by the Sample Management Custodian or alternates against certain acceptance criteria as documented in the *Standard Operating Procedure for Sample Receiving, Acceptance and Log-In*. This policy is available to all sample management personnel for reference. Any samples, which deviate from these outlined areas, will be clearly flagged with the nature and substance of the deviation. The following are the assessments and conditions checks utilized by CAS/SIMI for the acceptance or rejection of samples. This verification of sample integrity is conducted by the Sample Custodian and may be dependent on the matrix (i.e., temperature, preservation, and headspace) being submitted and includes the following activities; Tables 9-1 and 9-2 or if applicable, the specific Quality Assurance Project Plan (QAPP) is available for a complete and accurate assessment:

- Assessment of custody seal presence/absence, location and signature
- Adherence to specified holding times
- Appropriate containers (size, type) are received for the requested analyses
- Proper temperature of sample, if applicable
- VOA vials (liquids) are inspected for the presence/absence of headspace (bubbles).
- Adequate sample volume
- Assessment of proper sample preservation, where applicable. SMO personnel perform no assessment of proper preservation in order to preserve the integrity of the sample prior to analysis.
- Sample containers checked for integrity (broken, leaking, Tedlar® bags are received flat, under inflated or with the valve open, Summa canisters are received under substantial vacuum or with the valve open, etc.)
- Sample submission documents are properly used, fully completed (in indelible ink) and shall include the client, sample identification, project name or location, date and time of collection, collector's name, sample type, preservation type (if applicable), required

analyses, relinquishing signature and data, was well as any special remarks concerning the sample.

- Samples are clearly marked with unique client sample identification (ID), durable labels (labels that are not easily removed) and the use of indelible ink, and preservation notation (where applicable).
- Sample container labels and/or tags agree with the sample documentation entries (i.e., canister & client IDs; preservation; required analyses, etc.).

Any abnormalities or discrepancies observed during the initial assessment including signs of damage are documented and are addressed by informing the appropriate Project Manager (PM). The Project Manager is to notify the client regarding specific integrity issues documented during sample receipt. The PM must document any decision made by the client with regards to proceeding with the requested analyses, where possible or cancellation. However, there may be a need to inform the client that a sample(s) is rejected and cannot be accepted for analysis into the laboratory. This situation includes, but is not limited to loss of sample or insufficient volume. The procedures for sample documentation, handling acceptance requirements and deviations from the sample acceptance policy are discussed in detail in the *Standard Operating Procedure for Sample Receiving, Acceptance and Log-in.* This procedure is also in place to ensure samples are received and properly logged into the laboratory, and that all associated sample documentation, including COCs (if utilized), is complete and consistent with the samples received. All associated documentation, including chain of custody forms, memos, transmittal forms, and phone logs, are kept with each project file.

9.5 Sample Log-in

Since the laboratory is in the process of implementing a Laboratory Information Management System (LIMS), each sample will temporarily be logged into the laboratory utilizing duel systems. The sample login is conducted on both systems in such a way as to ensure traceability and cross-reference with regards to the unique laboratory job number, sample identifications and client sample identifications. Additional information is provided in the *Standard Operating Procedure for Sample Receiving, Acceptance and Log-in.*

9.5.1 Service Request (SR) Status Each sample is given a computer generated unique laboratory code when sample log-in is completed. This code is given based upon the order of sample log-in. The service request contains the laboratory code, client information, client sample descriptions/identification, sample matrix information, requested analyses, sample collection dates, and analysis due dates as well as other useful information.

A laboratory code label is generated and affixed to the sample, where possible. Certain sample containers, such as solid adsorbent cartridges, are placed in a sealed bag identified with the service request number and all laboratory codes (samples) associated with that

particular service request number. If replicate samples are submitted, the following procedure is used to differentiate between the separate containers of the submitted field sample:

e.g. Original Sample ..... Laboratory Code P2701952-001
Replicate One..... Laboratory Code P2701952-001B
Replicate Two ..... Laboratory Code P2701952-001C

P CAS/SIMI Laboratory Network Identifier
27 Year 2007
01952 Job Number (1952nd job logged in Year 2007)
01 1st sample logged in for specified job

Note: LIMS allows for samples to be logged in the same manner except the year code is 07 instead of 27 and replicate samples are designated with ".01", ".02" ".03", etc.

Each group of received samples is sequentially assigned a Service Request (SR) number and using this service request number, a laboratory sample ID code is generated uniquely for each sample and its containers. Once the login procedure has been completed a SR summary is generated for each project. The appropriate Project Manager reviews this login information for accuracy, completeness, and consistency with the requests for the client's project. Once the login has been approved, the sample analyses information is distributed to the appropriate laboratory personnel.

9.5.2 LIMS Information pertaining to the samples is entered into the Laboratory Information Management System (LIMS) and a unique laboratory code is for the job is generated. Each sample is assigned a unique laboratory code and a Chain-of-Custody Summary and a Service Request Summary are generated for each project folder. These summaries contain client information, sample descriptions, sample matrix information, required analyses, sample collection dates, analysis due dates and other pertinent information. The appropriate Project Manager reviews the login information for accuracy, completeness, and consistency with the requests for the client's project. Once the login has been approved, the sample analyses information will appear in the analysts' responsibility List. The analysts use the information from this list to schedule their work.

9.6 Custody of Samples

9.6.1 External Chain-of-Custody (COC)

CAS/SIMI uses two Chain-of-Custody forms, one for air matrices and the other for soil and water matrices (Figures 9-1 or 9-2) (or clients may submit samples using a similar form) to document the handling of the samples by all individuals from sample collection to sample receipt by the laboratory. When packages are sent by outside couriers, receipts are retained as part of the permanent chain-of-custody documentation. The original Chain of Custody (COC) forms are retained and kept with the job file. In some cases, the client requests that the original custody form be submitted with the final report.

Chain-of-Custody records are used to establish the legal custody of samples, showing the continuous possession of samples from sample collection and transportation to final destination at the laboratory. Custody of each sample is maintained from receipt through disposal. When environmental samples are shipped by CAS/SIMI to other laboratories for analysis, the sample management office (SMO) follows formalized procedures for maintaining the chain of custody, which is written in *Standard Operating Procedure for Chain of Custody for Sample Transfer between Laboratories.*

9.6.2 Legal Chain-of-Custody

Legal (internal) Chain of Custody protocols are followed at the request of clients. For the purposes of litigation, it is necessary to have an accurate written record to trace the possession and handling of samples from collection through reporting. The procedures defined here represent a means to satisfy this requirement.

A sample is in someone's "custody" if:

1. It is in one's actual physical possession;
2. It is in one's view, after being in one's physical possession;
3. It is one's physical possession and then locked up so that no one can tamper with it;
4. It is kept in a secured are, restricted to authorized personnel only.

The laboratory is considered a secured area, restricted to authorized personnel only (CAS/Simi Valley employees).

Sample control procedures are necessary in the laboratory from the time of sample receipt to the time the sample is discarded. The following procedures are followed in this laboratory.

1. The samples are received by the sample custodian or alternate (designated to act as custodian in the custodian's absence). The custodian indicates receipt of samples by signing the accompanying custody/control forms and the signed forms are retained as permanent records.
2. The custodian must maintain a record for each sample of the person delivering the sample, the person receiving the sample, date and time received, source of sample, date the sample was taken, sample identification number, how transmitted to the laboratory, and condition received (sealed, unsealed, broken container , or other pertinent remarks). This is accomplished during the sample log-in procedure, which is performed in accordance with the *SOP for Sample Receiving, Acceptance and Log-In* (by the generation of the Service Request form and Sample Acceptance Check form, refer to Sections 9.0 through 9.5 for additional information). Also, an internal chain of custody form (as included in the *SOP for Sample Receiving, Acceptance and Log-In*) is generated at the time of sample login to show the movement of each sample within the laboratory. This internal chain of custody is utilized to document

all sample custody transfers through the secure laboratory (initial receipt through final disposal).

3. The custodian ensures that all heat-sensitive samples, light-sensitive samples, or other sample materials having unusual physical characteristics, or requiring special handling, are properly stored and maintained prior to analysis.
4. Laboratory personnel are responsible for the care and custody of the sample once it is received by them and must be prepared to testify that the sample was in their possession and view or secured in the laboratory at all times from the moment it was received from the custodian or other laboratory personnel relinquishing custody until the time that the applicable procedure(s) are completed; i.e., canister pressurization and/or analyses.
5. Once the sample analyses are completed the unused portion of the sample, together with all identifying labels, must be returned to the custodian (for soil and water samples) or sample disposal personnel (for canister samples). The returned tagged sample must be stored in the secured laboratory in the proper storage area until permission to destroy the sample is received. All labels are kept intact until which time the sample is properly disposed.
6. Samples will be destroyed only upon the order of the responsible laboratory official (Data Validation Coordinator for air samples and Project Manager for soil and water samples), when it is certain that the information is no longer required, as specified by the client or the when the samples have deteriorated. Sample tags for canisters are retained in the job file and maintained for a period of no less than five years.

When samples are removed from the fixed lab and transported to the off-site extraction facility for sample preparation, internal chain of custody procedures still apply. Relinquishing and receiving signatures, date and time of transfer and reason for the transfer (i.e., sample extraction) are required from the custodian and extraction technician to document transfer of the samples. When sample preparation is completed, sample extracts are returned to the laboratory and the extraction technician and the analyst will sign and date the internal chain of custody and give reason for the transfer to document and complete the custody transfer of the extract(s).

9.7 Sample Storage, Analysis and Tracking

The procedures and requirements for documenting the storage, analysis and tracking as well as maintaining integrity of samples are detailed in the *SOP for Laboratory Storage, Analysis and Tracking.*

9.7.1 Sample Storage Documented procedures are in place, which detail the laboratory facilities and methods used to avoid deterioration, contamination, or damage to the sample during storage, handling, preparation, and testing. Samples shall be stored away from all standards, reagents, food and other potentially contaminating sources. Also, samples are stored in such a manner as to prevent cross contamination.

To prevent a preservation error the refrigerators and freezers are labeled and segregated according to matrix type and in some cases method of analysis. CAS/SIMI has one walk-in refrigerator, which houses the majority of soil and water samples received at the laboratory. Any specialized storage requirements including those for encore and sediment samples are maintained. The temperature of each thermal storage unit used at CAS/SIMI is monitored daily (business days), using a NIST traceable calibrated thermometer, and the data is recorded in a bound logbook. However, a number of laboratory thermometers include a temperature range and for certain projects, the temperature compliance must be monitored every day of the week, which may be done so by recording the range following weekends and holidays.

9.7.2 Sample Analysis and Tracking A unique laboratory sample ID code is assigned to each sample upon sample login. Each sample is referred to by this unique laboratory sample ID code on all laboratory documents (e.g., run log, analysis benchsheets, and report). When a sample has more than one container, each container is further identified by a numerical suffix at the end of the laboratory sample ID code and the same documentation requirements apply. All extracts and digestates are traceable to the parent sample(s) by identifying them with the same unique identifier.

All pertinent information generated during sample analysis is maintained for each instrument (where applicable) and test method. Hard copies of data are initialed and dated by the analyst performing the test. The sequence log shows each analytical sequence in chronological order. For each sequence, the standards, field samples, and quality control samples are noted in the order analyzed. Results of manual analytical measurements are also recorded. All notebooks, instrument printouts, and benchsheets showing sample identification are also made part of the laboratory records.

9.8 Sample Retention and Waste Disposal

Upon completion of all analyses, the laboratory samples are retained in accordance with the requirements specified in the method SOPs and the *Standard Operating Procedures for Waste Disposal* and *Foreign Soils Handling and Treatment*. The samples are either returned to the client or disposed of according to approved disposal practices. All samples are characterized according to hazardous/non-hazardous waste criteria and are segregated accordingly. This evaluation is generally based on results from analyses performed on the sample by CAS/SIMI or a subcontracted laboratory. It should be noted that all wastes produced at the laboratory, including the laboratory's own various hazardous waste streams, are treated in accordance with all applicable local, State and Federal laws. Complete documentation is maintained for samples from initial receipt through final disposal. This ensures an accurate record of the samples from "cradle to grave."

9.9 Transfer of Samples

When environmental samples (usually soil and water only) are shipped by CAS/SIMI to other laboratories for analyses (e.g., for dioxin or radiological analysis, etc.), they are properly packed for shipment and preserved in accordance with Table 9-1 and 9-2 and the *Standard Operating Procedure for Solid Sample Preparation.* Unless otherwise specified by the client or receiving laboratory, each sample bottle is wrapped in bubble wrap and placed in a plastic bag, preferably Ziploc® to avoid any possible cross-contamination of samples during the transportation process. Blue or wet ice is used for temperature preservative, where necessary. The sample management office (SMO) follows formalized procedures for maintaining the chain of custody of the sample(s) (*Standard Operating Procedure for Chain of Custody for Sample Transfer between Laboratories).*

9.10 Subcontracting

Analytical services are subcontracted when CAS/SIMI needs to balance workload and/or CAS/SIMI does not perform the requested analyses. Subcontracting is done only with the approval and full knowledge of the client and review and approval by the Quality Assurance Program Manager. Subcontracting to another CAS laboratory is preferred over other laboratories. Where possible, work is placed with a laboratory accredited under NELAP for the tests to be performed or with a laboratory that meets applicable statutory and regulatory requirements for performing the tests and submitting the results of the tests performed. In addition, the subcontract laboratory must be capable of meeting the Data Quality Objectives (DQOs) of the project. Prior to shipment, a chain of custody is completed which includes all pertinent information such as laboratory sample identification, required method(s)/analytes of analysis, preservation, comments, etc.

When data are returned from the subcontract laboratory, the Project Manager reviews the data to ensure quality control requirements are met and the report is included with the in-house report. All subcontract work is clearly identified in the final report generated by CAS/SIMI. The laboratory maintains a register of all approved subcontractors and their corresponding methods/analytes for analysis. Established procedures are followed to qualify external subcontract laboratories and are found in *SOP for Qualification of Subcontract Laboratories Outside of CAS Network.*

Table 9-1
Soil and Water Sample Preservation and Holding Times[a]

Determination	Method	Matrix[b]	Container[c]	Preservation	Holding Time
Bromide	300.0	W	P,FP,G	None required	28 days
	9056			Cool, 4°C	ASAP
	9056	S	G	Cool, 4°C	ASAP
Chloride	300.0	W	P,FP,G	None required	28 days
	9056	W/S			ASAP
Color	110.2	W	P,FP,G	Cool, ≤6°C	48 hours
Color	SM 2120B	W	P,FP,G	Cool, ≤6°C	48 hours
Specific Conductance	120.1	W	P,FP,G	Cool, ≤6°C	If not completed w/in 24hours filter thru 0.45 micron
Specific Conductance	SM 2510B	W	P,FP,G	Cool, ≤6°C	28 days
Specific Conductance	9050A	W	P,FP,G	Cool, ≤6°C	28 days
Fluoride	300.0	W	P	None required	28 days
	9056	W/S		Cool, 4°C	ASAP
Hydrogen Ion (pH)	SM4500-H+ B	W	P,FP,G	None required	Analyze within 15 mins.
	150.1				In field or ASAP
	9040B/ 9040C				ASAP
	9045C/9045D	S			ASAP
Nitrate	300.0	W	P,FP,G	Cool, ≤6°C	48 hours
	9056	W/S		Cool, 4°C	ASAP
Nitrite	300.0/SM 4500-NO2-B/354.1	W	P,FP,G	Cool, ≤6°C	48 hours
	9056	W/S		Cool, 4°C	ASAP
Orthophosphate	300.0	W	P,G	Cool, ≤6°C	48 hours
	9056	S		Cool, 4°C	ASAP
Residue, Total	160.3	W	P,FP,G	Cool, 4°C	7 days
Residue, Total	SM 2540B	W/S	P,FP,G	Cool, ≤6°C	7 days
Residue, Total	SM 2540G	S	G	Cool, ≤6°C	7 days
Residue, Nonfilterable (TSS)	160.2	W	P,FP,G	Cool, 4°C	7 days
Residue, Nonfilterable (TSS)	SM 2540 D	W	P,FP,G	Cool, ≤6°C	7 days
Residue, Settleable	160.5	W	P,FP,G	Cool, 4°C	48 hours
Residue, Settleable	SM 2540 F	W	P,FP,G	Cool, ≤6°C	48 hours
Sulfate	300.0	W	P,FP,G	Cool, ≤6°C	28 days
Temperature	170.1	W	P,FP,G	None Required	Field
Temperature	SM 2550 B	W	P,FP,G	None Required	Field
Turbidity	180.1	W	P,FP,G	Cool, ≤6°C	48 hours
Turbidity	SM 2130B	W	P,FP,G	Cool, ≤6°C	48 hours

Table 9-1
Soil and Water Sample Preservation and Holding Times[a]

Determination	Method	Matrix[b]	Container[c]	Preservation	Holding Time
Chromium VI	218.6/SM 3500-Cr D	W	P,FP,G	Cool, ≤6°C or Cool, ≤6°C, Ammonium Sulfate Buffer to pH = 9.3-9.7	24 hours 28 days
	7196A/7199			Cool, 4°C	24 hours
	3060A/7196A/ 3060A/7199	S	P,G	Cool, 4 ± 2°C	30 days to digest; 7 days after digestion
Petroleum Hydrocarbons, Volatile (Gasoline-Range Organics)	5030B/8015B	W	G, Teflon-Lined Septum Cap	Cool, 4°C, No Headspace Cool, 4°C, HCl to pH<2; No Headspace	7 days 14 days
	5035/8015B	S	Encore Unit or Pre-weighed VOAs	Cool, 4°C Freeze MeOH or NaHSO4	NP – 48 hours 7 days 14 days
Petroleum Hydrocarbons, Volatile (Gasoline-Range Organics) – AZ samples	5030C/8015D	W	G, Teflon-Lined Septum Cap	Cool, 4°C, No Headspace Cool, 4°C, HCl to pH<2; No Headspace	7 days 14 days
	5035A/8015D	S	Encore Unit or Pre-weighed VOAs	Cool, 4°C Freeze MeOH or NaHSO4	NP – 48 hours 14 days 14 days
Volatile Organics / Purgeable - Halocarbons & Aromatic Hydrocarbons	5030B/8260B & 624	W	G, Teflon-Lined Septum Cap	Cool, 4°C, No Headspace No Residual Chlorine Present: HCl to pH<2, Cool, 4°C, No Headspace Residual Chlorine Present[g]: 10% Na2S2O3, HCl to pH<2, Cool, 4°C, No Headspace	7 days 14 days 14 days
	5035/8260B	S	Encore Unit or Pre-weighed VOAs	Cool, 4°C,	NP – 48 hours; Freeze – 7 days; MeOH or NaHSO4 – 14 days

Table 9-1
Soil and Water Sample Preservation and Holding Times[a]

Determination	Method	Matrix[b]	Container[c]	Preservation	Holding Time
Volatile Organics / Purgeable - Halocarbons & Aromatic Hydrocarbons (AZ Samples)	5030C/8260B & 624	W	G, Teflon-Lined Septum Cap	Cool, 4°C, No Headspace No Residual Chlorine Present: HCl to pH<2, Cool, 4°C, No Headspace Residual Chlorine Present[g]: 10% Na2S2O3, HCl to pH<2, Cool, 4°C, No Headspace	7 days 14 days 14 days
	5035A/8260B	S	Encore Unit or Pre-weighed VOAs	Cool, 4°C,	NP – 48 hours; Freeze – 14 days; MeOH or NaHSO4 – 14 days

Sub-Contracted Methods*

Determination	Method	Matrix[b]	Container[c]	Preservation	Holding Time
Alcohols and Glycols	8015B	W,S	G, Teflon-Lined Cap	Cool, 4°C[g]	14 days until extraction and analysis;
Coliform, Fecal and Total	SM 9221 B, C, E	W	PA,G	Cool, <10°C, 0.0008% $Na_2S_2O_3$[d]	6-24 hours[e]
Fecal Streptococci	SM 9230B	W	PA,G	Cool, <10°C, 0.0008% $Na_2S_2O_3$[d]	6-24 hours[e]
Acidity, as $CaCO_3$	SM 2310 B	W	P,FP,G	Cool, ≤6°C	14 days
Alkalinity, as $CaCO_3$ (Automatic titration)	310.2	W	P,FP,G	Cool, ≤6°C	14 days
Alkalinity, as $CaCO_3$ (Manual titration)	SM 2320 B	W	P,FP,G	Cool, ≤6°C	14 days
Ammonia (Automated Phenate)	350.1/SM 4500-NH3 G	W	P,FP,G	Cool, ≤6°C, H_2SO_4 to pH<2	28 days
Ammonia (Electrode)	SM 4500-NH3 D or E	W	P,FP,G	Cool, ≤6°C, H_2SO_4 to pH<2	28 days
Biochemical Oxygen Demand (BOD)	405.1/ SM 5210 B	W	P,FP,G	Cool, ≤6°C	48 hours
Cyanide, Total (manual distillation followed by) Titrimetric Spectrophotometric (Semi-Automated) Spectrophotometric (Manual) Ion Selective Electrode	SM-4500 CN D 335.4 SM-4500 CN E SM-4500 CN F	W	P,FP,G	[h]Cool, <6°C, NaOH to pH>12, plus 0.6 g Ascorbic Acid	14 days

Table 9-1
Soil and Water Sample Preservation and Holding Times[a]

Sub-Contracted Methods*					
Determination	**Method**	**Matrix[b]**	**Container[c]**	**Preservation**	**Holding Time**
Chemical Oxygen Demand (COD)	410.4/SM 5520 D	W	P,FP,G	Cool, ≤6°C, H_2SO_4 to pH<2	28 days
Chlorine, Total Residual	SM-4500 Cl G	W	P,G	None required	Analyze within 15 minutes
Cyanide, Total & Amenable to Chlorination	9010B followed by 9012 or 9014	W S	P,FP,G G	[h]Cool, ≤6°C, NaOH to pH>12, plus 0.6 g Ascorbic Acid Cool, 4°C	14 days
Cyanide Amenable to Chlorination	SM-4500 CN G	W	P,FP,G	[h]Cool, ≤6°C, NaOH to pH>12, plus 0.6 g Ascorbic Acid	14 days
Cyanide, Weak Acid Dissociable	SM 4500-CN I	W	P,G	[h]Cool, 4°C, NaOH to pH >12	14 days
Ferrous Iron	SM 3500-Fe D	W	P,G	No headspace, cool, 4°C	24 hours
Hardness by Calculation Titration	 SM 2340 B SM 2340 C	W	P,FP,G	HNO_3 or H_2SO_4 to pH<2	6 months
Kjeldahl and Organic Nitrogen – Digestion & Distillation followed by: Titrimetric Ion Selective Electrode Automated Phenate Semi-automated block digestor colorimetric	SM-4500 NH_3 B SM-4500 NH_3 C SM-4500 NH_3 D or E 351.1 351.2	W	P,FP,G	Cool, ≤6°C, H2SO4 to pH<2	28 days
Nitrate-Nitrite	353.2	W	P,FP,G	Cool, <6°C H2SO4 to pH<2	28 days
Odor	140.1	W	G	No headspace, cool, 4°C	24 hours
Oxygen, Dissolved (Probe)	SM 4500-O G	W	G, Bottle & top	None required	Analyze within 15 minutes
Oxygen, Dissolved (Winkler)	SM 4500-O C	W	G, Bottle & top	Fix on site and store in dark.	8 hours

Table 9-1
Soil and Water Sample Preservation and Holding Times[a]

Sub-Contracted Methods*					
Determination	**Method**	**Matrix[b]**	**Container[c]**	**Preservation**	**Holding Time**
Phenolics, Total	420.1	W	G	Cool, 4°C, CuSO4, H_2SO_4 to pH<2 If chlorinated, $Fe(NH4)_2(SO4)_2$	28 days
Phenolics, Total	9065/9066	S	G	Cool, 4°C	28 days
Phosphorus, Total	365.1/365.3/365.4	W	P,FP,G	Cool, <6°C, H_2SO_4 to pH<2	28 days
Residue, Filterable (TDS)	160.1	W	P,FP,G	Cool, 4°C	7 days
Residue, Filterable (TDS)	SM 2540 C	W	P,FP,G	Cool, <6°C	7 days
Sulfide, Dissolved	SM 4500-S^{2-}D	W	P,FP,G	Cool, <6°C, Sodium Hydroxide, pH>9	7 days after Aluminum Hydroxide Floc, decant or filter steps and addition of Zinc Acetate
Silica (as SIO2)	200.7	W	P Only	Cool, 4°C	28 days
Sulfide, Total	SM 4500-S^{2-}D	W	P,FP,G	Cool, <6°C, Add Zinc Acetate plus Sodium Hydroxide to pH>9	7 days
Sulfide, Total	9030 followed by 9034	S	P,FP,G	Cool, 4°C	14 days
Surfactants (MBAS)	SM 5540 C	W	P,FP,G	Cool, <6°C	48 hours
Tannin and Lignin	SM 5550B	W	P,G	Cool, 4°C	28 days
Mercury	7470A/245.1	W	P,FP,G	HNO_3 to pH<2	28 days
	7471A	S	G, Teflon-Lined Cap	Cool, 4°C	28 days
Organic Carbon, Total (TOC)	SM 5310 B, C or D 9060	W	Amber G, Teflon-Lined Cap	Cool, 4°C, H_2SO_4 to pH<2 Cool, 4°C	28 days
Metals, except Chromium VI and Mercury	6010B/200.7/6020/ 200.8/7060/206.2/ 7421/239.2/7740/2 70.2/7841/279.1	W	P,FP,G	HNO_3 to pH<2	6 months
	6010B/6020/7060/ 7421/7740/7841	S	G, Teflon-Lined Cap	Cool, 4°C	

Table 9-1
Soil and Water Sample Preservation and Holding Times[a]

Sub-Contracted Methods*					
Determination	**Method**	**Matrix[b]**	**Container[c]**	**Preservation**	**Holding Time**
Organic Halogens, Total (TOX)	9020B	W	G, Teflon-Lined Cap	Cool, 4°C, H_2SO_4 to pH<2	28 days
Organic Halogens, Adsorbable (AOX)	1650	W	G, Teflon-Lined Cap	Cool, 4°C, HNO_3 to pH<2[g]	28 days
Petroleum Hydrocarbons, Extractable (Diesel-Range Organics)	8015B	W, S	G, Teflon-Lined Cap	Cool, 4°C; Adjust to pH <2 w/H2SO4 or HCl (water)	14 days until extraction; 40 days after extraction
EDB and DBCP	504	W	G, Teflon-Lined Cap	Cool, 4°C, No Headspace	14 days
Semivolatile Organics	8270C/625	W	G, Teflon-Lined Cap	Cool, 4°C, Store in Dark[g]	7 days - extraction[f]; 40 days - analysis
		S			14 days – extraction[f]; 40 days – analysis
Polynuclear Aromatic Hydrocarbons (PAH)	8270-SIM/8310	W	G, Teflon-Lined Cap	Cool, 4°C, Store in Dark[g]	7 days - extraction[f]; 40 days - analysis
		S			14 days – extraction[f]; 40 days – analysis
Organochlorine Pesticides and PCBs	8081/8082/608	W	G, Teflon-Lined Cap	Cool, 4°C	7 days - extraction[f] 40 days – analysis
	8081/8082	S	G, Teflon-Lined Cap	Cool, 4°C	14 days – extraction[f]; 40 days – analysis
Organophosphorus Pesticides	8141A	W	G, Teflon-Lined Cap	Cool, 4°C[g]	7 days - extraction[f] 40 days – analysis
	8141A	S	G, Teflon-Lined Cap	Cool, 4°C	14 days – extraction[f]; 40 days – analysis
Chlorinated Herbicides	8151A	W	G, Teflon-Lined Cap	Cool, 4°C[g]	7 days - extraction[f] 40 days – analysis
	8151A	S	G, Teflon-Lined Cap	Cool, 4°C	14 days – extraction[f]; 40 days – analysis

a See Section 18.0 for sources of information.
b W = Water; S = Soil or Sediment; HW = Hazardous Waste
c P = Polyethylene; G = Glass; FP = fluoropolymer (PTFE; Teflon) ir other fluoropolymer; PA =
d For chlorinated water samples
e The recommended maximum holding time is variable, and is dependent upon the geographical proximity of sample source to the laboratory.
f Fourteen days until extraction for soil, sediment, and sludge samples.
g If the water sample contains residual chlorine, 10% sodium thiosulfate is used to dechlorinate.
h per requirements of Table II in the 40 CFR 136
* Refer to Section 9.10 for information on the approval process for subcontract laboratories. .

TABLE 9-2
Sample Preservation and Holding Times[a]

Determination/Method	Matrix	Container	Preservation	Holding Time	Sample Vol.[d]
Amines	Air	Treated Alumina Tubes	Laboratory Storage, 4°C±2°C	30 days	100L
BTEX / Modified CARB 410	Air	Tedlar Bag, Mylar Bag, Summa Canister	No Direct Sunlight	Bag – 72 hours; Canister[b] – N/A	Bags - 500mL; Canisters – 6.0L
BTU / ASTM D 3588 (SULFUR, ASTM D 5504; C1-C6+, TO-3M; FIXED GASES, 3C)	Gaseous Fuels	Tedlar Bag, Mylar Bag, Summa Canister	N/A	Sulfur (Bag – 24 hours; Canister[c] – 7 days)	Bags - 500mL; Canisters – 6.0L
				C1-C6+ (Bag – 72 hours; Canister[b] – N/A)	
				3C (Bag – 72 hours; Canister[b] – N/A)	
C_1-C_6+ / Modified TO-3	Air	Tedlar Bag, Mylar Bag, Summa Canister	N/A	Bag – 72 hours; Canister[b] – N/A	Bags – 500mL; Canisters – 6.0L
Carbonyl Compounds/ TO-11A	Air	DNPH-Coated Silica Gel Cartridge w/ Polypropylene Cap; SKC UME[x] and Bacharach GMD 570 Passive Monitors (formaldehyde only)	Sample Receipt, 4°C±2°C; Laboratory Preservation, 4°C±2°C	14 days until extraction; 30 days for analysis	100 – 150L
Carboxylic Acids	Air	Treated Silica Gel Tubes	Laboratory Storage, 4°C±2°C	30 days	100L
EPA 25C/Total Gaseous Non-methane Organics (TGNMO)	Air	Tedlar Bag, Mylar Bag, Summa Canister	N/A	Bag – 72 hours; Canister[b] – N/A	Bags - 500mL; Canisters – 6.0L
Fixed Gases / EPA 3C & ASTM D 1946	Air	Tedlar Bag, Mylar Bag, Summa Canister	N/A	Bag – 72 hours; Canister[b] – N/A	Bags – 500mL; Canisters – 6.0L

TABLE 9-2 (Continued)
Sample Preservation and Holding Times[a]

Determination/Method	Matrix	Container	Preservation	Holding Time	Sample Vol.[d]
Helium & Hydrogen	Air	Tedlar Bag, Mylar Bag, Summa Canister	N/A	Bag – 72 hours; Canister[b] – N/A	Bags – 500mL; Canisters – 6.0L
Massachusetts Air-Phase Petroleum Hydrocarbons, Public Comment Draft 1.0	Air	Summa Canister	N/A	28 days	6.0L
Modified EPA Method 8315A (Procedure 1)	Aqueous, Soil	Glass w/Teflon- Lined Lid	All samples @ 4°C±2°C	Aqueous – prep. - 72 hours, analysis - 72 hours; Soil – prep. minimum, analysis - 72 hours	(2) 40mL Vials
NCASI – DI/MeOH 94.03/Methanol	Aqueous – Effluent	Glass w/Teflon- Lined Lid	No Headspace; 4°C±2°C; HCl to pH 2-3 (Effluent only)	30 days	(1) 40mL Vial
NCASI-DI/HAPS-99.01	Aqueous – Effluent	Glass w/Teflon- Lined Lid	No Headspace; 4°C±2°C	14 days	(1) 40mL Vial
NCASI-IM/CAN/WP-99.02	Air	Summa Canister	N/A	3 Weeks	3.0L
Organic Vapors / NAPHTHAS (Diesel; etc.) NIOSH 1550 / OSHA 7	Air	Charcoal Tube; 3M 3500 or 3520 Badge; Silica Gel Tube w/ plastic caps	N/A	14 days	Various
RSK 175/Methane, Ethane, Ethene, Propane, Propene,	Aqueous	Glass w/Teflon- Lined Lid	No Headspace; HCl to pH<2; 4°C±2°C	14 days	(3) 40mL Vials
RSK 175/Carbon Dioxide	Aqueous	Glass w/Teflon Lined Lid	No Headspace; neutral pH (5-8); 4°C±2°C	14 days[c]	(3) 40mL Vials
Sulfur / In-House Method	Aqueous	Glass w/Teflon- Lined Lid	No Headspace; pH>4; 4°C±2°C	Following pH adjustment – 24 hours	(2) 40mL Vials
Sulfur Gases / Modified SCAQMD 307 & ASTM D 5504	Air	Tedlar Bag, Fused Silica Lined SS Canister	No direct sunlight	Bag – 24 hours; Canister[c] - 7 days	Bags – 500mL; Canisters – 6.0L

TABLE 9-2 (Continued)
Sample Preservation and Holding Times[a]

Determination/Method	Matrix	Container	Preservation	Holding Time	Sample Vol.[d]
TO-13A/Polycyclic Aromatic Hydrocarbons (PAHs)	Air	Polyurethane Foam (PUF) plugs, XAD Tube, PUF / XAD-2	Sample Receipt, <4°C; Laboratory Preservation, 4°C±2°C	7 days until extraction; 40 days after	130 – 400 m^3
TO-14A & TO-15/VOC	Air	Tedlar Bag, Mylar Bag, Summa Canister	N/A	Bag – 72 hours; Canister - 30days	Bags - 500mL; Canisters – 6.0L
TO-17/VOC	Air	Sorbent Tubes w/Swagelock Caps & PTFE Ferrules	<4°C; organic solvent free environment; Laboratory Storage, 4°C±2°C	30 days	1-4L
TO-2 (as Modified TO-15)/VOC	Air	Sorbent Tubes w/Swagelock Caps & PTFE Ferrules	<4°C; organic solvent free environment; Laboratory Storage, 4°C±2°C	Desorb into Tedlar Bag- 7 days; Analyze – 72 hours	10L
TO-3 Modified/Methanol, Ethanol, Isopropyl alcohol, Freon, and Methylene chloride	Air	Tedlar Bag, Mylar Bag, Summa Canister	N/A	Bag – 72 hours; Canister[b] – N/A	Bags – 500mL; Canisters – 6.0L
TO-3 Modified/Total Petroleum Hydrocarbons (TPHG)	Air	Tedlar Bag, Mylar Bag, Summa Canister	N/A	Bag – 72 hours; Canister[b] – N/A	Bags – 500mL; Canisters – 6.0L
TO-4A & TO-10A/Pesticides and Polychlorinated Biphenyls (PCBs)	Air	Glass PUF and PUF/XAD-2 Cartridge; TO-4A (High Volume); TO-10A (Low Volume)	Sample Receipt, 4°C±2°C; Store sample and extract @ 4°C±2°C	7 days until extraction; extract – 40 days	2 m^3

a Refer to Section 18.0 for reference information
b Some methods do not specify the utilization of canisters; therefore, there is no required hold time and this will be noted in the case narrative.
c Laboratory recommended hold time; therefore, samples analyzed outside this hold time will be noted in the case narrative accordingly.
d Sample volumes are the minimum, which should be received by the laboratory; however, canister volumes should match the canister size utilized.

Figure 9-1
Water & Soil - Chain of Custody Record & Analytical Service Request

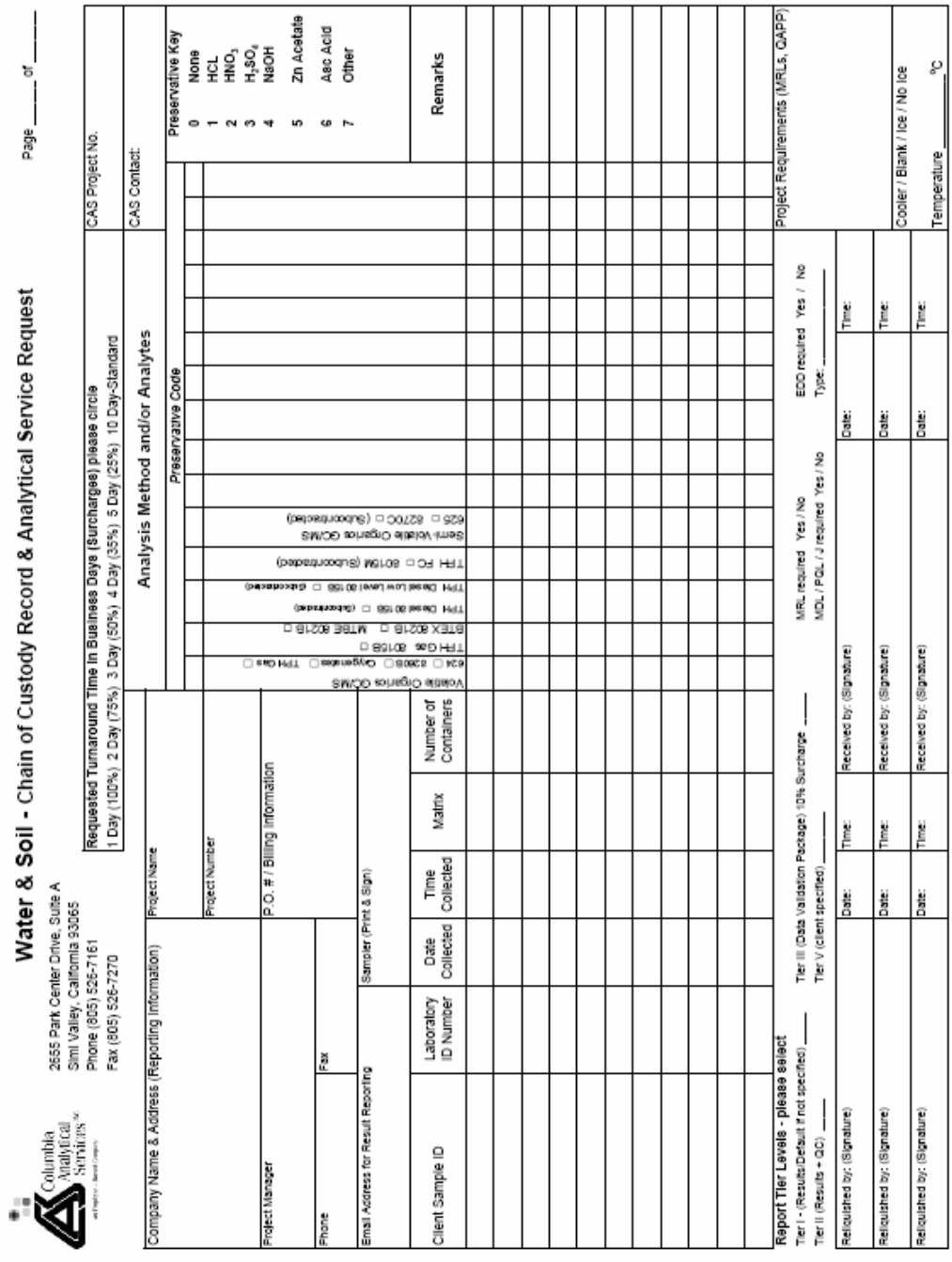


Figure 9-2
Air - Chain of Custody Record & Analytical Service Request

Columbia Analytical Services

Air - Chain of Custody Record & Analytical Service Request

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2655 Park Center Drive, Suite A
Simi Valley, California 93065
Phone (805) 526-7161
Fax (805) 526-7270

Requested Turnaround Time in Business Days (Surcharges) please circle 1 Day (100%) 2 Day (75%) 3 Day (50%) 4 Day (35%) 5 Day (25%) 10 Day-Standard	CAS Project No.

Company Name & Address (Reporting Information)	Project Name
	Project Number
Project Manager	P.O. # / Billing Information
Phone / Fax	
Email Address for Result Reporting	Sampler (Print & Sign)

CAS Contact:

Client Sample ID	Laboratory ID Number	Date Collected	Time Collected	Sample Type (Air/Tube/ Solid)	Canister ID (Bar code # - AC, SC, etc.)	Flow Controller (Bar code - FC #)	Sample Volume	Analysis Method and/or Analytes				Comments e.g. Actual Preservative or specific instructions

Report Tier Levels - please select
Tier I - (Results/Default if not specified) ____ Tier III (Data Validation Package) 10% Surcharge ____
Tier II (Results + QC) ____ Tier V (client specified) ______

EDD required Yes / No
Type: ____________ EDD Units: __________

Project Requirements (MRLs, QAPP)

Relinquished by: (Signature)	Date:	Time:	Received by: (Signature)	Date:	Time:
Relinquished by: (Signature)	Date:	Time:	Received by: (Signature)	Date:	Time:
Relinquished by: (Signature)	Date:	Time:	Received by: (Signature)	Date:	Time:

Cooler / Blank Temperature ________°C

10.0 QUALITY CONTROL CAPABILITIES AND OBJECTIVES

A primary focus of the CAS/SIMI Quality Assurance (QA) Program is to ensure the accuracy, precision, reliability, legality, and comparability of all analytical results. CAS/SIMI has established Quality Control (QC) objectives that are used to determine the acceptability of the generated data. The actual types of QC samples required for each analysis is discussed in corresponding method standard operating procedures and are further discussed in Section 11.0 of this manual.

All quality control measures are assessed and evaluated on an on-going basis and quality control acceptance criteria are used for verification (to determine the usability of the data). Quality control data is analyzed (per method procedures) and, where they are found to be outside pre-defined criteria, planned action is taken to correct the problem (where possible) and to prevent incorrect results from being reported. The laboratory provides validity of environmental tests undertaken through a number of procedures including:

- Initial calibrations and continuing calibrations as specified in method SOP;
- These include regular use of certified reference materials and secondary reference materials;
- Participation in proficiency testing programs (where applicable);
- Replicate tests using the same or different methods as specified in method SOP;
- Retesting of retained samples;
- Correlation of results for different characteristics of a samples (where applicable);
- Analysis of client supplied double blind samples (where available).

10.1 Demonstration of Capability

Prior to the utilization of any analytical method, specified method performance as defined in the analytical method must be demonstrated by a qualified analyst, whose training has been documented in accordance with *SOP for Documentation of Training.* Additional information concerning analyst training and qualification is detailed in Section 17.0.

As required by mandatory test method, regulation, or accreditation protocols, a demonstration of capability (DOC) is performed. This demonstration is made following regulatory, accreditation, or method specified procedures. In general, this demonstration does not test the performance of the method in real world samples, but in the applicable clean matrix, free of target analytes and interferences.

The following steps are performed annually to document the demonstration of capability.

1. A quality control sample will be prepared independently from those used in instrument calibration.
2. The analyte(s) is (are) diluted in a volume of clean matrix (for analytes which do not lend themselves to spiking, e.g. air samples, the demonstration of capability may be performed using quality control samples) sufficient to prepare four aliquots at the concentration

specified. If not specified, use a concentration approximately 1-4 times the method stated or laboratory calculated method reporting limit.

3. Four aliquots are prepared and analyzed according to the test procedure either concurrently or over a period of days.
4. The mean recovery and standard deviations (population sample, n-1) are calculated for each parameter of interest.
5. Compare the information from #4 to the corresponding acceptance criteria for precision and accuracy in the test method (if applicable) or in laboratory-specified acceptance criteria (if no established mandatory criterion exists). All parameters must be met in order for the demonstration to be considered successful. If any one of the parameters do not meet the acceptance criteria, the performance is unacceptable for that parameter. The DOC must be repeated for all parameters that fail to meet criteria. A repeated failure confirms a general problem with the measurement system. The problem must then be located and corrected at the source and the DOC repeated. A demonstration of capability must be completed and approved each time there is a change in instrument type, personnel, or method, where possible and/or applicable. A demonstration of capability certification statement is completed indicating acceptability and including information such as date of demonstration, analyst, method, parameters, and matrix. The DOC is reviewed and approved by the Quality Assurance Program Manager and retained on file, along with the raw data for the capability.

In addition, acceptable PT results may also be used to demonstrate capability as long as all of the measured analytes are present and found to be acceptable. In accordance with AIHA requirements, acceptable performance must be demonstrated every six months.

10.2 Accuracy

Accuracy is a measure of the closeness of an individual measurement (or an average of multiple measurements) to the true or expected value. Certain method portions are monitored to assure accuracy. These include the analysis of initial calibrations, continuing calibrations, laboratory-fortified blanks (blank spikes or laboratory control samples), and proficiency test samples (Section 14.1.3), and use of certified reference materials. In addition, laboratory-fortified (i.e. matrix-spiked) samples may also measured; depending on the method/matrix, and indicates the accuracy or bias in the actual sample matrix. Refer to Section 11.4 and each method SOP for additional information regarding these measures.

Accuracy is expressed as percent recovery (% REC) of the measured value, relative to the true or expected value. If a measurement process produces results whose mean is not the true or expected value, the process is biased. Bias is the systematic error either inherent in a method of analysis (e.g., extraction or desorption efficiencies) or caused by an artifact of the measurement system (e.g., contamination). CAS/SIMI utilizes several quality control measures to eliminate analytical bias, including systematic analysis of method blanks, laboratory control samples and initial calibration verification standards. Because bias can be positive or negative, and because

several types of bias can occur simultaneously, only the net, or total, bias can be evaluated in a measurement.

The percent recovery (%R) is calculated as:

$$\%R = \frac{Amount\ Recovered}{True\ Value} x\ 100$$

The average percent recovery *(Ave.%R)* is calculated as:

$$\%R = \frac{\Sigma\ Ri}{N}$$

where: R_i = The individual recovery values
N = Number of determinations

10.3 Precision

Precision is the ability of an analytical method, instrument, and analyst to reproduce a measurement of the same parameters under prescribed similar conditions. It is a measure of the variability, or random error, in sampling, sample handling and laboratory analysis.

The American Society of Testing and Materials (ASTM) recognizes two levels of precision: repeatability - the random error associated with measurements made by a single test operator on identical aliquots of test material in a given laboratory, with the same apparatus, under constant operating conditions, and reproducibility - the random error associated with measurements made by different test operators, in different laboratories, using the same method but different equipment to analyze identical samples of test material.

At CAS/SIMI, our "within-batch" precision is measured through the analysis of either duplicate quality control (QC) sample analyses (LCS/LCSD) or injections of field samples aliquots (LD) as detailed in each method SOP and is expressed as the relative percent difference (RPD) between the measurements.

$$RPD = \frac{|D_1 - D_2|}{\overline{D}} x100$$

where: D_1 = Original Result
D_2 = Duplicate Result
$\overline{D}$ = Average

In addition, the precision of an analytical method is calculated as the standard deviation of the percent recoveries calculated as described above in determining the accuracy of the method, and then expressed as percent relative standard deviation (RSD) of the recoveries.

The standard deviation(s) is calculated as:

$$SD = \sqrt{\sum_{i=1}^{N} \frac{(X_i - X)^2}{N-1}}$$

where:
X_i = The individual recovery values
X = Arithmetic average of the recovery values
N = Number of determinations

Percent relative standard deviation (%RSD) is then calculated as:

$$\%RSD = (S / X) \times 100$$

where S and X are as defined above.

10.4 Acceptance Limits and Control Charts

The acceptance limits for each method are available based on statistical evaluation of the data generated by the analysis of quality control check samples, unless specific acceptance limits are established by the method or there are not enough points available (non-routine analyses and/or analytes). Control charts are used to record quality control data and compare them with acceptance limits. For new methods, where internal control limits have not been established and method required/recommended control limits are not available, fixed limits (based on method, QC type, analyte, instrumentation and detector type, and linearity) will be utilized until such time that enough points are available. The QC limits are either specified in the methodology, or are statistically derived based on the laboratory's actual historical data obtained from control-charting the various QC measurements for each analytical method.

The Quality Assurance Program Manager updates control charts on an annual basis and semi-annually for selected methods, where applicable and as specified in the appropriate method standard operating procedure. In addition, method conformity is assessed using the calculated values. If trends in the data are perceived, various means of corrective action may then be employed in order to prevent future problems with the analytical system(s). The procedure for generating control charts and implementing limits is detailed in the *Standard Operating Procedure for Control Limits.*

Note: There is no widely accepted procedure for spiking Summa canister and Tedlar bag samples with analytical surrogates, which is not specifically addressed in referenced air methods. Therefore, for the analyses of air samples utilizing surrogates, which are added to the sample

stream during pre-concentration, these are not considered true surrogates and therefore, are assessed utilizing fixed limits.

10.5 Method Detection Limits / Method Reporting Limits

The Method Detection Limits (MDL) is the minimum concentration of a substance that can be measured and reported with a 99% confidence that the analyte concentration is greater than zero and is determined from the analysis of a sample in a given matrix containing the analyte. Method detection limit studies are determined annually or semi-annually (as dictated by the method) for all the target compounds in a quality system matrix in which there are neither target analytes nor interferences at a concentration that would impact the results. MDL studies are determined in accordance with the *Standard Operating Procedure for the Determination of Method Detection Limits and Limits of Detection* which is based on the procedure outlined in 40 CFR 136, Appendix B. Note: For multi-component analyses, the appropriate spiking compounds and concentrations varies among analytes and are specified in method procedures, where applicable.

MDL studies are performed on each instrument (with identical configurations) for which the method is performed. Where multiple instruments are used, the MDL used for reporting purposes represents the least sensitive instrument. However, if a lower detection limit is reported, then the samples must have been run on that specific instrument on which the lower MDL was generated. If more than seven replicates are analyzed, all results must be used to calculate the MDLs, unless exclusion of a result is technically justified and documented. MDLs are established for each matrix, method and extraction/cleanup method combination employed for samples. No results are reported below the determined MDL and results reported outside the quantitation range of the initial calibration are reported as estimated.

The Method Reporting Limit (MRL) or Practical Quantitation Limit (PQL) is generally the lowest quantitation level of a given analyte that can be reliably achieved within the specified limits of precision and accuracy of a given method during routine operating conditions. The MRLs used at CAS/SIMI are the reported lower limits of quantitation (at or above the low point in current initial calibration and above the method detection limit or as designated below), which take into account day-to-day fluctuations in instrument sensitivity as well as other factors. These MRLs are the levels to which CAS/SIMI reports results in order to minimize false positive or false negative results. The MRL is generally two to ten times the method detection limit (MDL), but differs between methods. However, in some cases the MRL is less than two times, but always higher than the calculated MDL. Measures are taken to ensure that the data reported to the client at low levels is both accurate and real including the requirement that the low concentration level of the initial calibration be at or below the MRL. A successful initial calibration also confirms the validity of MRL values. However, the MRL for each analysis may be influenced by the regulatory limits set by local, state, or federal agencies, and specific projects. *For example*, for Navy (Department of Defense Manual) samples the method reporting limit must be at least 3 times (AFCEE, 2 times) the current verified method detection limit.

10.6 Method Detection Limit Verification

Upon completion of the method detection limit study, the method detection limit (also referred to as limit of detection, LOD) for each target analyte of concern in the quality system matrices is verified, where applicable. MDL verifications shall be performed on all instruments (performing a given method) immediately following the MDL study. The analyte concentrations are verified at approximately 1-4 times the detection limit for multiple analyte tests and 2-3 times for single analyte tests (or approximately 2 times the MDL for Navy and AFCEE samples) and taken through all preparatory and analytical steps. Every effort must be made to verify the MDL by spiking at an appropriate concentration. If the MDL is not verified, per the stated spike requirements, spikes at successively higher concentrations are performed until the verification criteria are met. However, due to variances in the determined MDLs (by analyte per study) and the target analyte list, this may not be feasible. Therefore, in cases where the spike concentration from the method detection limit study would comply with the above stated requirement(s), the last replicate may be used for the verification. Regardless, if the MDL verification is not analyzed, with a spike meeting the above stated criterion, the reported MDL must be raised according to the actual spike performed and any necessary adjustments also made to the MRL (to meet the Navy 3 times the MDL requirement).

If the method has no confirmation criteria, the MDL verification is acceptable if the analyte can reliably be detected and identified by the method-specific criteria (i.e, ion confirmation) and produce a signal that is at least 3 times the instrument's noise level (3:1 signal to noise ratio) or acceptable percent recovery (as in the case of specific conductance where there is no ratio to measure). All verification documentation and acceptability information is retained on file with the method detection limit study.

MDL verification is not required for any component for which spiking solutions or quality control samples are not available such as temperature, or, when test results are not to be reported to the detection limit.

10.7 Desorption Efficiency and Method Reporting Limits (Industrial Hygiene)

The desorption efficiency (DE) is the ability of the analytical method to recover the analyte from the collection media. Desorption efficiencies are determined initially and for each analyte to be reported. In addition, a DE study is performed each time there is a change in the test method, or with each new lot of media. Desorption efficiency shall be determined using sorbent media from the same lot number used for the field samples, if possible, and of the identical size and type. The DE values are used to correct the sample results (for all samples except passive samplers) before reporting.

Minimum-reporting limits for each reportable analyte are determined initially by the analysis of spiked media, prepared at the desired reporting limit and carried through the entire analytical process. The reporting limit is verified or re-established annually (or if there is a change in

methodology or instrumentation) and instrument performance (at the reporting limit) is checked with each analytical batch through the analysis of an analytical standard prepared at the reporting limit.

10.8 Completeness

Completeness is a measure of the amount of valid data that is obtained, compared to the amount that is expected. For purposes of this plan, completeness is calculated by dividing the number of samples having valid data by the total number of samples in the project, expressed as a percentage. The CAS/SIMI objective for completeness is 100% for air samples, 95% for aqueous, and 90% for soil samples, although other less stringent criteria may be utilized if specified in a project specific QA plan.

10.9 Representativeness

Representativeness is the degree to which a sample aliquot that is analyzed gives results identical to analysis of the whole. CAS/SIMI has sample preparation procedures (where necessary) to ensure that the sample that is to be analyzed is representative of the entire sample before the aliquot of sample is removed for analysis. Furthermore, analytical SOPs specify appropriate sample sizes to ensure the sample aliquot that is analyzed is representative of the whole. However, air samples received by the laboratory in canisters and bags are considered to be homogenous and therefore, no special sample preparation procedures are necessary.

10.10 Comparability

Comparability expresses the confidence with which one data set can be compared to another. To ensure comparability, procedures are in place for the preservation, handling, and analysis of all samples. Data is reported in units specified by the client.

10.11 Initial Test Method Evaluation

As part of method development, and to ensure continuous quality of data, the laboratory proposes standard QC requirements consistent with similar methods or technology. At a minimum these QC requirements deal with (where applicable): Calibration, Contamination, Precision and Bias, Interference and Analyte Identification (including retention times). Upon initial method setup, the laboratory performs an initial calibration with verification, method detection limit study and verification (or desorption efficiency study, where appropriate), and a precision and bias study.

The laboratory addresses precision and bias utilizing replicate QC samples. Examples of a systematic approach to evaluate precision and bias is by analyzing QC samples in triplicate containing all of the analytes in question (at three levels of interest over three days). The acceptability is contingent on percent recovery, mean recovery and relative standard deviation, and standard deviation.

11.0 QUALITY CONTROL PROCEDURES

The specific types, frequencies, processes, procedures, acceptance, corrective actions, and results qualifications for quality control sample analyses are described in detail in method-specific standard operating procedures or client project plans, where applicable. These sample types and frequencies have been adopted for each method and a definition of each type of QC sample is provided below. In addition, a number of other quality control processes which may impact analytical results are also described below.

11.1 Procurement and Approved Vendors

Purchasing of critical items and services is performed in such a way as to ensure that the items and/or services purchased/performed are of the necessary quality to uphold the standard by which the laboratory operates and/or by which analytical methods require. The laboratory evaluates all vendors of critical consumables, supplies and services that may affect the quality of testing. Records of these evaluations and the list of approved suppliers are available to the appropriate personnel. The following are the minimum requirements for approval.

- Consumables and Laboratory Supplies – All reference materials received at CAS/SIMI are traceable to the vendors that have fulfilled the requirements for ISO9001 certification and/or are accredited by A_2LA, and the standard also came with certificates of analysis to verify standard purity and concentration. However, there may be instances, particularly with obscure standards or reagents that finding a certified vendor is not possible. In these cases, the vendor shall be approved if a history is available indicating the minimum quality or through independent testing that shows that the quality conforms to the minimum requirements of the method (the use of applicable QC data is sufficient). Primarily, vendors are ISO certified to an appropriate standard. In addition, items may be purchased from distributors (that are not ISO certified), but that supply materials from ISO certified companies that have previously been approved. However, in some instances, those vendors for which CAS/SIMI has a history and found those vendors to supply materials with the necessary quality are considered acceptable without such an evaluation. Materials are handled in accordance with the *Standard Operating Procedure for Handling Consumable Materials*. They are inspected for container integrity upon receipt and any material with suspected integrity problems is returned to the vendor. The SRMs are stored under conditions that provide maximum protection against deterioration and contamination.
- Services – Critical services within the laboratory are the calibration of equipment such as weights and balances, pressure/vacuum gauges, thermometers, and flowmeters. The procedure for evaluating such suppliers of critical services is performed using a checklist, and whenever possible, obtaining certifications of NIST traceability for specific calibrations/certificates supplied to CAS/SIMI by said vendor. In addition, if ISO certification is available, this certificate is also obtained. The requirement for approval for such metrology laboratories is that they must conform to the following requirements:

- All calibrations must be NIST traceable.
  - Perform calibrations in accordance with the appropriate standards (to be determined during evaluation).
  - Whenever possible, be ISO certified or conform to the requirements of appropriate ISO standards.

All evaluations and approvals are on file and shall be retained for a period of five years or longer if they are still being used by the laboratory for the services for which they were originally approved. All current approved vendors are made available to all the appropriate personnel who order from or use the services of suppliers of critical consumables, supplies or services.

11.2 Standard Reference Materials (SRM)

All certificates are retained on file for a minimum period of five years. In addition, refer to Section 11.1 for information regarding selection criteria, approval and maintenance of lists of approved service suppliers and vendors for Standard Reference Materials (SRMs).

11.2.1 Metrology All analytical measurements are performed using materials and/or processes that are traceable to a Standard Reference Material (SRM). Metrology equipment (analytical balances, weights, pressure/vacuum gauges, thermometers, etc.) is calibrated against primary laboratory SRMs traceable to the National Institute of Standards and Technology (NIST) or are sent to an approved service supplier as specified in Section 11.1 of this document. These primary SRMs are themselves recertified, by an approved service supplier, on an annual basis. Each piece of equipment is labeled with the associated calibration status and certificates are retained on file for a period of at least five years. The frequencies and procedures for calibration are specified in the *SOP for Calibration and Use of Laboratory Support Equipment*. Refer to Section 12.1 for additional information.

11.2.2 Consumable Standard Reference Materials Consumable primary stock standards are obtained from certified commercial sources. All standard reference materials (SRMs) that are received at CAS/SIMI are recorded by the technical staff in the appropriate notebook(s) according to the *Standard Operating Procedure for Making Entries into Logbooks and onto Benchsheets* and *Standard Operating Procedure for Handling Consumable Materials.* In addition, information required in this SOP is recorded on certificates and labels.

SRMs are stored under conditions that provide maximum protection against deterioration and contamination. Stock solutions and/or calibration standard solutions are prepared fresh as often as necessary according to their stability and are specifically stated in method SOPs. After preparation, all standard solutions are properly labeled as to analyte concentration, date, analyst, and expiration date. Generally, expiration dates are assigned per the guidance information provided in the *Standard Operating Procedure for Handling Consumable Materials.*

Prior to introduction into the analytical system/process, all reference materials are verified with a second, independent source of the material. Once the reference material has been verified to be accurate, it may then be used for the deemed purpose. In addition, the independent source of reference material is also used to check the calibration standards for signs of deterioration.

11.3 Reagents

Upon receipt, all chemical containers are inspected for integrity and recorded in an inventory log. The "date received," "date opened," and "date expired" are noted on the container label. Placing the date on the container label facilitates use of chemicals on a first-in, first-out basis.

There is a control system for the receiving and the releasing of lots of reagents. For critical chemical reagents, such as organic solvents and acids used for sample preparation, each lot is tested for analytes of concern prior to use. Reagents from a certain lot cannot be used until the lot has been released. Refer to the SOPs for *Checking New Lots of Chemicals for Contamination* and *Handling Consumable Materials* for additional information on the necessary quality verification procedures. Once the solvent or acid is opened for use, the date opened is documented on the container label and in the inventory log.

All reagents used in the laboratory are of sufficient quality to support the intended use as specified in the referenced method and method SOP. Typically reagents are prepared from Analytical Reagent Grade (AR) chemicals or higher purity grades, unless such purity is not available. The preparation of all reagents is documented in bound, laboratory notebooks including source, mass, and dilutions. Each reagent is clearly labeled with the composition, concentration, date prepared, date opened, analyst initials, expiration date, and special storage requirements, if any. Solvents and reagent solutions are routinely checked for contamination by analyzing them as method and/or instrument blanks for each analysis in which they are used.

Reagents are stored in appropriate glass, plastic, or metal containers under conditions designed to promote safety and maintain integrity (refrigerated, dark, etc.). Shelf life is listed on the label. All reagents are properly disposed of after the expiration date. Dry reagents, such as sodium sulfate, silica gel, and glass wool are either heated to dryness at 400°C or extracted with the appropriate solvent prior to use for organic analyses.

11.4 Analytical Batch

The basic unit for analytical quality control is the analytical batch. There are two types of analytical batches defined by CAS/SIMI and (Field) samples are assigned to batches commencing at the time that sample processing begins. These definitions are described in the *Standard Operating Procedure for Sample Batches*. The overriding principle of describing an analytical batch is that all the samples in a batch, both field samples and quality control samples are to be handled and processed in exactly the same manner.

Specific program requirements or method requirements may be exceptions to particular requirements stated in the above mentioned SOP. These exceptions will be addressed in program-specific Quality Assurance Project Plans (QAPPs) or in method Standard Operating Procedures (SOPs).

The following shall apply to all analytical batches and sequences; however, exceptions and/or additions may be made and are dependent on the matrix, method and method standard operating procedure.

- Initial calibration or calibration verification standard (if ICAL not performed in batch). Refer to Section 12.2 for additional information on initial calibrations.
- A method blank (however named) shall be analyzed to assess contamination.
- A duplicate sample (laboratory duplicate, laboratory control sample duplicate, matrix spike duplicate) shall be analyzed to assess batch precision. A sample identified as a field blank, an equipment blank, or a trip blank is not to be duplicated.
- Laboratory control sample shall be analyzed, as best defined by the corresponding method SOP to assess method performance.
- Matrix spiked (field) sample shall be analyzed to assess method performance with regards to matrix, including interferences. A sample identified as a field blank, an equipment blank, or a trip blank is not to be spiked. Due to limitations, certain analytical batches for air matrices cannot include a matrix spike.

In all instances the following requirements shall be observed:

- The number of (field) samples in a batch is not to exceed 20 including duplicates and matrix spikes.
- All (field) samples in a batch shall be of the same matrix
- A single lot of reagents, whenever possible, are used to process the batch of samples
- Field samples are to be prepared and analyzed along with the corresponding QC samples as described in the method specific SOP
- Where possible, all samples in a batch (field and QC) are analyzed on the same instrument or otherwise specified in the final report. All samples are to be handled and processed in exactly the same way, and all of the data from each analysis is to be manipulated in exactly the same manner.

11.5 Collection Efficiency

In the case of sampling trains (consisting of one or more multi-section sorbent tubes), which are received intact by the laboratory, the “front” and “back” sections shall be separated if required by the client. Each section shall be processed and analyzed separately and the analytical results reported accordingly.

11.6 Method Blanks

A method blank (MB) is an analyte-free matrix and is included with the analysis of every analytical batch of 20 or fewer samples, or as stated in the method, whichever is more frequent. The method blank is analyzed to evaluate the process for contamination. The analyte concentration in the sample is not to be corrected for the method blank concentration, except as specified in the SOP for the analysis.

When a method blank fails the method standard operating procedure stated criteria (see note below), the cause of contamination must be investigated and measures taken to minimize or eliminate the problem. Ideally, in such cases the associated method blank and samples should be re-prepared and/or reanalyzed; however, constraints such as holding time or sample quantity may preclude reanalysis. If a sample is past the recommended holding time, the Project Manager must be consulted prior to determining if reanalysis is necessary. When reanalysis is not practical or possible, the method blank result(s) will be reported as described below:

- The MRL for an analyte is not to be increased when the analyte is found in the method blank above the MRL.
- Samples associated with the same batch are evaluated as to the best corrective action (e.g., re-analyze sample or qualify data). The procedure for the qualification of data is considered to be the inclusion of a flag to the affected analyte in the MB, MB and sample(s), and/or a notation in the case narrative. The selection is generally dependent on the concentration of the analyte in the MB and affected sample(s).

Note: For Navy projects only, the threshold for qualification is <1/2 the MRL.

11.6.1 Air Matrices The method blank is an analyte-free matrix, usually ultra high purity nitrogen, helium, humidified zero air, or an unused solid sorbent cartridge, impinger solution, or extracts solvent, and subjected to the entire analytical process. In the case of industrial hygiene samples, blank sampling media are analyzed, when applicable, by the same procedure as that used for field samples.

A method blank may be otherwise named as in the case of RSK analysis, where water naturally contains both oxygen and carbon dioxide. In this case, the method blank is referred to as a method control sample (MCS). In addition, a TO-15 QC canister may serve as a method blank as long as the requirements of the method SOP are fulfilled.

11.6.2 Soil and Water Matrices A method blank is an analyte-free matrix, usually ASTM Type II water or analyte-free soil (Ottawa sand or Sodium Sulfate, depending on methods), to which all reagents are added in the same volumes or proportions as used in the entire analytical process. The method blank is analyzed to demonstrate that the analytical system is not contaminated with the analyte(s) being measured.

11.7 Calibration Blanks

Calibration blanks are prepared with analyte free water or solvent, used to provide the zero point of the calibration in many of the inorganic analyses. The frequency, processes, procedures, acceptance, corrective actions, and results qualifications are described in detail in method-specific standard operating procedures or client project plans, where applicable.

11.8 Initial and Continuing Calibration Blanks

Initial Calibration Blanks (ICB) and continuing calibration blanks (CCBs) are solutions of either analyte-free water or solvent that is analyzed in order to verify the zero point of the analytical system. These calibration blanks are usually associated with inorganic method analyses, but the frequency, processes, procedures, acceptance, corrective actions, and results qualifications are described in detail in method-specific standard operating procedures or client project plans, where applicable. In the case of air samples where there may or may not be a sample preparation step required, the CCB and method or reagent blanks may be the same sample and referred to as any one of these.

11.9 Calibration Standards

Calibration standards are vapors, liquids or solutions of known concentration obtained from vendor-purchased sources or prepared from in-house stock standard materials. Calibration standards are used to calibrate the instrument response with respect to analyte concentration. Standards are purchased, prepared and analyzed in accordance with the requirements stated in the corresponding method standard operating procedure being used.

11.10 Initial (or Independent) Calibration Verification Standards

Initial (or independent) calibration verification standards (ICVs) are standards that are analyzed *after* calibration but *prior to* sample analysis, in order to verify the calibration of the analytical system. This standard must be prepared from materials obtained from a source (manufacturer or lot) other than that used for preparing the calibration standards. The ICV is used to verify the standard calibration curve prior to sample analysis. The frequency, processes, procedures, acceptance, corrective actions, and results qualifications are described in detail in method-specific standard operating procedures or client project plans, where applicable.

11.11 Continuing Calibration Verification Standards

When an initial calibration is not performed on the day of analysis, the validity of the initial calibration shall be verified prior to sample analysis by a continuing calibration verification (CCV) standard. The percent recoveries of the CCVs, or the percent difference calculated between the true and the expected value must meet the acceptance criteria specified in the method SOP. The frequency of CCV analysis is either once every ten samples, every 12-hour period, or as indicated in the method SOP. The frequency, processes, procedures, acceptance,

corrective actions, and results qualifications are described in detail in method-specific standard operating procedures or client project plans, where applicable. Unless otherwise specified in the applicable method and method SOP, the quantitation of all results must be performed utilizing the initial calibration and are determined using the CCV.

11.12 Internal Standards (IS)

Internal standards consist of known amounts of specific compounds that are added to each sample, standard and QC sample following sample preparation or extraction. Internal standards are generally used for GC/MS procedures to correct sample results that have been affected by changes in instrument conditions or changes caused by certain matrix effects.

11.13 Surrogates

Surrogate standards are chosen to have properties similar in chemical composition and chromatographic behavior to the analytes of interest, but which are not normally found in environmental samples. Depending on the analytical method, one or more of these compounds is added to method blanks, calibration and check standards, and samples (including batch QC samples) prior to sample preparation; e.g., extraction or purging. The surrogate results are compared with the true values spiked into the sample matrix prior to sample preparation and analysis (percent recovery) and are used to monitor the method performance on each sample.

The following are specific requirements for surrogates depending on the sample matrix of interest.

- Air Samples – Surrogates shall be used as specified in each method SOP.
- Aqueous, Soil, etc. Samples – Surrogate compounds must be added to all samples, standards, blanks, and QC samples prior to extraction and analysis, for all organic chromatography methods except when the method or matrix precludes its use or when a surrogate is not available.

Note: There is no widely accepted procedure for spiking Summa canister and Tedlar bag samples with surrogates, which is not specifically addressed in referenced air methods (specifically TO-15) for these sampling containers. Therefore, surrogates, which are added to the sample stream during pre-concentration, are not considered true surrogates.

11.14 Matrix Spikes (Laboratory Fortified Sample Matrix)

Matrix spiked (MS) samples are aliquots of samples to which a known amount of the target analyte (or analytes) has been added. The samples are prepared and analyzed in the same analytical batch and in exactly the same manner, as are routine samples. The stock solutions used for spiking the sample(s) are prepared independently of calibration standards. The spike recovery measures the effects of interferences caused by the sample matrix and reflects the accuracy of the method for the particular matrix in question. Spike recoveries are calculated as follows:

Recovery (%) = (S - A) x 100 ÷ T

Where: S= The observed concentration of analyte in the spiked sample,
A= The analyte concentration in the original sample, and
T= The theoretical concentration of analyte added to the spiked sample.

Generally, the matrix spiked samples are prepared and analyzed at a minimum frequency of one per batch or one spiked sample (and one duplicate spiked sample, if appropriate) per twenty samples or fewer samples, whichever is more frequent.

The following are specific requirements for the analysis of the matrix spikes depending on the matrix of interest.

- Air Samples – Matrix spiked samples are often not feasible for air matrices. Therefore, the MS shall be used as required by the test method and as specified by the corresponding SOP.
- Aqueous, Soil, etc. Samples – If the mandated or requested test method does not specify the spiking components, the laboratory shall spike all reportable components. However, a representative number (at a minimum 10%) of the listed components may be used to control the test method if the components interfere with an accurate assessment (such as simultaneously spiking chlordane, toxaphene and PCBs), the test method has an extremely long list of components, the components coelute or the components are incompatible. The selected components of each spiking mix shall represent all chemistries, elution patterns and masses permit specified analytes and other client requested components. However, the laboratory shall ensure that all reported components are used in the spike mixture within a two-year time period, unless the spiking list is specified by the referenced method.
- For industrial hygiene samples, a laboratory control sample (LCS) and laboratory control sample duplicate (LCSD) are typically analyzed in lieu of MS/MSD, due to the lack of replicate samples submitted. This is the case in a number of other methods and is discussed in each method standard operating procedure.

11.15 Duplicates

The laboratory duplicate (LD) is defined as an aliquot of a sample taken from the same container under identical laboratory conditions and processed and analyzed independently. The analysis of laboratory duplicates give a measure of the precision associated with laboratory procedures, but not with sample collection procedures.

Depending on the matrix and/or method of analysis, either a laboratory duplicate, duplicate matrix spiked sample (DMS), or duplicate laboratory control sample (DLCS) are analyzed at a frequency of 1 per batch of 20 or fewer samples. The relative percent difference between duplicate analyses is a measure of the precision for a given method and analytical batch. The relative percent difference (RPD) for these analyses is calculated as follows:

Relative Percent Difference (RPD) = (S1 - S2) x 100 ÷ S_{ave}

Where:

S1 and S2 = The observed concentrations of analyte in the sample and its duplicate, or in the matrix spike and its duplicate matrix spike, and

S_{ave} = The average of observed analyte concentrations in the sample and its duplicate, or in the matrix spike and its duplicate matrix spike.

Generally, if a client requests a MS/MSD to be processed with their samples and provides adequate sample volume to do so, that MS/MSD will be used for the analytical batch. Whenever possible, the laboratory will randomly select samples for processing the MS/MSD. When insufficient sample is received from the client(s) to perform the necessary duplicate sample analyses or MS/MSD on any sample in the analytical batch as prescribed in the method, a duplicate LCS will be extracted and analyzed to assess the precision of the method.

Note: Submitted field duplicates are treated as separate samples and reported accordingly.

11.16 Laboratory Control Samples (Laboratory Fortified Blanks)

A laboratory control sample (LCS) is 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 used to assess the performance of all or a portion of the measurement system (NELAC). The percent recovery (%R) of the target analytes in the LCS assists in determining whether the methodology is in control and whether the laboratory is capable of making accurate measurements at the required reporting limit. The following are general requirements, which apply to the preparation and analysis of laboratory control samples; however, SOPs will preclude those listed below.

- Spiking standards are purchased or prepared independently of calibration standards.
- A commercially purchased standard reference material (SRM) of known matrix type, containing certified amounts of target analytes, may also be used as an LCS.
- An LCS is prepared and analyzed at a minimum frequency of one LCS per 20 or fewer samples, or as stated in the method, whichever is more frequent.
- The LCS sample is prepared and analyzed in the same analytical batch, and in exactly the same manner, as field samples.

The following are requirements for the analysis of the LCS depending on the matrix of interest.

- Air Samples – The laboratory control sample is usually an aliquot of ultra high purity nitrogen, helium or humidified zero air, unused extract solvent, blank sorbent cartridge, etc. to which known amounts of the method analyte(s) is(are) added. If a spiking solution is not available, a

calibration solution whose concentration approximates that of the samples shall be included in each batch and with each lot of media.

- Aqueous, Soil, etc. Samples – The laboratory control sample (LCS) is an aliquot of analyte-free water (ASTM Type II) or analyte-free soil (or anhydrous sodium sulfate or equivalent) to which known amounts of the method analyte(s) is (are) added.

- Industrial Hygiene Samples - Desorption efficiency studies are performed for each batch of samples received for a given analytical method. Spiking standards are prepared at known concentrations, and blank sorbent media (same lot as the sampling media if possible) are spiked at a minimum of two concentration levels.

Laboratory control samples with large number of analytes are statistically likely to include a few analytes that will be outside control limits. This may not indicate that the system is out of control; therefore, corrective action may not be necessary. For this reason, upper and lower marginal exceedance (ME) limits may be established and used to determine when corrective action is necessary. A ME is defined as being between 3 and 4 standard deviation around the mean. The number of analytes allowable to fall within this marginal exceedance is based on the number of analytes in the LCS. If more analytes exceed the LCS control limits than is allowed, or if any one analyte exceeds the ME limits, the LCS fails, and proper corrective action is necessary. This marginal exceedance approach is relevant for methods with long lists of analytes. It will not apply to target analyte lists with fewer than 11 analytes.

The number of allowable marginal exceedances is as follow:

>90 analytes in LCS, 5 analytes allowed in ME of the LCS control limit;
71-90 analytes in LCS, 4 analytes allowed in ME of the LCS control limit;
51-70 analytes in LCS, 3 analytes allowed in ME of the LCS control limit;
31-50 analytes in LCS, 2 analytes allowed in ME of the LCS control limit;
11-30 analytes in LCS, 1 analytes allowed in ME of the LCS control limit;
<11 analytes in LCS, no analytes allowed in ME of the LCS control limit;

Marginal exceedances must be random. If the same analyte exceeds the LCS control limit repeatedly, it is an indication of a systemic problem. The source of the error must be located and corrective action taken. Affected samples and laboratory control samples will be re-extracted and/or reanalyzed if necessary. Due to certain restrictions detailed in client specific project plans, State, Federal or other Agency requirements, the use of marginal exceedances may not be allowed and are only utilized for those methods where it is deemed appropriate.

11.17 Field and Trip Blanks

Field and trip blanks are analyzed when they are submitted to the laboratory for analysis. The actual field samples are flagged (when analytes are found in the blank) if and only if the

laboratory is able to analyze the samples in the same analytical sequence as the corresponding field or trip blank. If this is not possible due to client submission restrictions then the results for the samples and blanks shall be reported independently with no flag. However, an explanation of this is included in the final report. This laboratory does not feel that Summa canisters are suitable for use as field blanks. It is for this reason that the results for these types of containers are reported as separate samples and flagging is not considered appropriate, except for project specific requirements.

11.18 Glassware Washing

The use of glassware at this facility is at a minimum; however, all glassware that is to be used undergoes a rigorous cleansing procedure following every usage. Glassware cleaning at the main laboratory and remote sample preparation laboratory are performed in accordance with the *Standard Operating Procedure for Cleaning Glassware.* In addition, other equipment that is routinely used at the laboratory is also cleaned following instructions in the determinative method SOP.

12.0 CALIBRATION PROCEDURES AND FREQUENCY

For the purposes of this laboratory, equipment calibration requirements are applicable to both support equipment and instrumentation. The requirements for instrument calibration include initial and continuing calibration verification. Prior to being placed into service and on a consistent basis, CAS/SIMI ensures that all equipment and applicable software is capable of achieving the required accuracy relevant to the environmental test(s) of concern.

All equipment used at CAS/SIMI are operated, maintained, calibrated, and/or recertified according to the manufacturer's guidelines and recommendations, as well as to criteria set forth in the applicable methodology. Depending on equipment and instrument type, calibration techniques are either performed by CAS personnel who have been properly trained in accordance with the standard operating procedures or performed by an approved service supplier (on or off site). Documentation of calibration information is maintained in the appropriate reference files.

Any instrument or piece of equipment that has been subjected to overloading, mishandling, or has been shown by verification or otherwise to be defective; is taken out of service until it has been repaired (see Section 15.0). The equipment is placed back in service only after verifying by calibration that the equipment performs satisfactorily and is labeled or marked to indicate calibration status. Brief descriptions of the calibration procedures for the major laboratory equipment and instruments are described below. Refer to Section 11.1 for information on the approval process for service suppliers.

12.1 Support Equipment

Certain support equipment is vital to laboratory operations and quantitative results are dependent on their accuracy. The equipment list includes, but is not limited to: balances, ovens, refrigerators, freezers, and flow meters, temperature measuring devices, pressure/vacuum gauges, volumetric dispensing devices, and a water purification system. If the use of any support equipment is deemed to be non-vital with regards to the need for accuracy, it is labeled accordingly. All necessary instructions and/or manuals for the use and operation of the equipment are maintained on file and are readily available to personnel. All support equipment shall be maintained in proper working order and records of all repair, maintenance, calibration, and recertification are maintained on file for review. The acceptability for use or continued use is in accordance to the requirements of the analysis or application for which the equipment is intended. For additional information on the calibration and calibration verification of laboratory support equipment, refer to the *Standard Operating Procedure for Calibration and Use of Laboratory Support Equipment*.

12.1.1 Temperature Control & Measuring Devices Temperatures are monitored and recorded for all critical measurement temperature-regulating devices including freezers, refrigerators and ovens. Each piece of equipment is labeled with a unique identifier, the required temperature or range of use according to the needs of the analysis or application. Bound record books are kept which contain equipment identifier, daily-recorded temperatures (if in use, business days), acceptance criteria and the initials of the

laboratory staff member who performed the checks for all temperature-regulating devices in daily use. A number of thermometers include a temperature range and per certain project requirements (complies with Department of Defense Quality Systems Manual for Environmental Laboratories), this range is recorded to document consistent compliance with required temperatures for refrigerators and freezers.

All thermometers are identified by a unique identifying number (i.e., serial number), and the calibration of these thermometers is checked annually against a National Institute of Standards and Technology (NIST) certified thermometer. All corresponding correction factors are noted on the device as well as in the thermometer calibration logbook. The NIST thermometer is recertified by an approved professional metrology organization on an annual basis and the certificate is retained on file for review. All temperature monitoring is conducted in accordance with the *Standard Operating Procedure for Sample Receipt, Acceptance and Log-in* and thermometer calibration requirements are performed in accordance with the *Standard Operating Procedure for Calibration and Use of the Laboratory Support Equipment.*.

12.1.2 Volumetric Dispensing Devices The accuracy of pipettes used to make critical-volume measurements is verified on a quarterly basis. Typically, the indicated volume or range (where applicable) of the pipette is checked and both the accuracy and precision verification are performed using the above-mentioned procedure. The calibrations are evaluated against the intended use (volume or range) of the pipette and if the calibration is not approved for the specified volume(s) it is tagged accordingly (i.e. "Do Not Use Below 5uL"). The results for all calibration verifications are recorded and maintained.

Note: Glass microliter syringes including gas-tight syringes are considered in the same manner as Class A glassware and are not held to the calibration/verification requirements as are other volumetric dispensing devices.

12.1.3 Analytical Balances and Weights Analytical balances and weights are calibrated / recertified and certificates issued annually by an approved professional metrology organization. The calibration of each balance is checked once each day of use in the expected range, utilizing the calibrated weights. Bound record books are kept which contain the identification of balance (serial number), recorded measurements and the initials of the analyst who performed the check. All certificates for the balances and weights are available for review.

12.1.4 Pressure/Vacuum Gauges CAS/SIMI digital pressure/vacuum gauges are used in a number of critical measurements within the laboratory. The following is a list of the uses for this gauge type.

- Canister cleaning and conditioning
- Measure the vacuum on canisters before they are sent to the client for sampling.
- Measure the initial/final vacuum/pressure of canisters prior to analysis.

- Measure pressure during the preparation of selected standards.

Digital pressure/vacuum gauges are calibrated and certificates issued once per year by an approved metrology organization. All calibrations are performed against standards traceable to the National Institute of Standard and Technology (NIST) or other recognized national metrology institutes. In addition, CAS/SIMI performs a calibration check for each gauge six months following the calibration date. The laboratory retains all corresponding calibration and verification documentation for review.

12.1.5 Water Purification System Purified water is utilized for a number of functions including instrument and method blanks, trip blanks, sample dilutions, and washes for the General chemistry department. The water purification system utilizes a mixed-ion bed exchange mechanism supplied by three mixed resin bed, constant water recirculation, four filters, and resistively lights. It is designed to produce deionized water of ASTM Type II quality, with 16-18 megohm-cm resistance @25°C and is checked and recorded daily (prior to and if in use). Maintenance and repair on the system is conducted by an approved service supplier and all records including purification checks/verifications are maintained on file for review. For procedures on additional purification (i.e., boiling and/or purging) and purification checks/verifications, refer to the applicable method standard operating procedures.

12.2 Instrumentation Calibration

The laboratory specifies the procedures and documentation for initial instrument calibration and continuing calibration verification in the applicable method standard operating procedures to ensure that data is of known quality and is appropriate for a specific regulation and/or client requirement. The procedural steps for calibration including, frequency, number of points, integration, calculations, acceptance criteria (appropriate to the calibration technique employed), corrective action, associated statistics, and data qualifications are included in applicable methods, method standard operating procedures and/or client project plans. The essential elements that define the procedures and required documentation for initial instrument calibrations are specified below.

- Sufficient raw data records are retained to permit reconstruction of all calibrations.
- If a reference or mandated method does not specify the number of calibration standards, the initial calibration range shall consist of a minimum of 5 contiguous calibration points for organics and a minimum of 3 contiguous calibration points for inorganics. The actual numbers of points utilized is specified in the corresponding method SOP.
- The concentrations should bracket the expected concentration range of samples.
- Initial instrument calibration procedures referenced in test methods (either directly or indirectly) are retailed by the laboratory and are readily available to the analysts.
- All samples results are quantitated from the initial instrument calibration and are not

quantitated from any continuing instrument calibration verification unless otherwise specified by regulation, method or program.

- The initial instrument calibration is verified with a standard obtained from a second manufacturer or lot and traceability to a national standard is maintained, where available.
- The acceptance criteria utilized is appropriate for the calibration technique employed.
- The lowest calibration standard in the initial calibration is at or below the lowest concentration for which quantitative data are to be reported and is referred to at this laboratory the method reporting limit (MRL). Some programs and/or agencies refer to this limit as the practical quantitation limit (PQL) (or level).
- Any data reported below the MRL or above the highest calibration standard is considered to have an increased quantitative uncertainty and is appropriately qualified in the report.
- The lowest calibration standard is above the limit of detection or method detection limit (MDL).

12.2.1 Internal and External Calibrations

Internal standard calibration involves the comparison of instrument responses from the target compounds in the sample to the responses of specific standards added to the sample or sample extract prior to injection. The ratio of the peak area of the target compound in the sample or sample extract to the peak are of the internal standard in the sample or sample extract is compared to a similar ratio derived for each calibration standard. The ratio is termed the response factor (RF) or relative response factor (RRF) in some methods.

External standard calibration involves comparison of instrument responses from the sample to the responses from the target compounds in the calibration standards. Sample peak areas are compared to peak areas of the standards. The ratio of the detector responses to the amount (mass) of analyte in the calibration standard is defined as the calibration factor or in some cases it may be referred to as response factor.

12.2.2 Continuing Calibration Verification

The essential elements that define the procedures and required documentation for continuing instrument calibration verification are specified below.

- When an initial calibration is not performed on the day of analysis, continuing instrument calibration verification is analyzed with each batch.
- Calibration is verified for each reported compound, element or parameter; however, for multi-component analytes such as aroclors or total petroleum hydrocarbons a representative chemical related substance or mixture may be used. The allowance for this exception is dependent on applicable regulatory, method, or client project plans.
- Generally, the instrument calibration verification is performed at the beginning, end and every ten samples of each analytical batch (except, if an internal standard is used, only one verification needs to be performed at the beginning of the analytical batch);

whenever it is or expected that the analytical system may be out of calibration; if the time period for calibration or most previous calibration verification has expired; or for analytical systems that contain a specific calibration verification requirement. Specific requirements for the frequency of continuing calibration verification, for a particular method, is specified in the corresponding method standard operating procedure.

13.0 DATA RECORDING, REDUCTION, VALIDATION, AND REPORTING

The success of a result is dependent on the credibility of the data collected and the controlled processes used to establish data quality. If controlled processes are not in place, the assurance of the data may be questioned. The data users need to be assured of the integrity of the processes performed during data recording, reduction, validation and reporting of the final results. For detailed information on these processes refer to the *Standard Operating Procedures for Software and Data Quality Assurance; Data Review and Reporting; Ensuring Data Integrity*.

CAS/SIMI reports the analytical data produced in its laboratory to the client via the certified analytical report. This report generally includes a transmittal letter, case narrative, client project information, specific test results, quality control data, chain of custody information (where available), and any other support and project-specific support documentation including sample receiving information. The actual documentation (report) provided differs depending on the needs of the client; therefore, refer to Section 13.5.1 for reporting requirements and format and Table 13-1 specified data deliverables. The following sections describe an overview of the procedures required for data recording, reduction, validation and reporting.

13.1 Data Acquisition and Recording

Data are acquired and recorded (either electronically or hardcopy by laboratory personnel) in such a way that allows historical reconstruction of all laboratory activities which produce or supports the production of analytical results. All computers, software and automated equipment utilized by the laboratory for data acquisition and recording are of sufficient quality to protect the integrity and confidentiality of data entry or collection. Such computers or equipment are maintained to ensure proper function necessary to uphold the integrity of environmental test data.

To identify the personnel involved in each step of the process, initials and dates are documented (either electronically or handwritten) for the activities performed. A list of employee signatures and initials used to identify personnel are compiled and retained on file by the QA Program Manager. To ensure that all information is legible, any manual entries or correction on logbooks and data records follow procedures written in the *Standard Operating Procedure for Making Entries into Logbooks and Onto Benchsheets*. In addition, the information required for a specific record is detailed in the corresponding standard operating procedure.

13.2 Data Reduction

Data reduction is the process of transforming raw data by arithmetic or statistical calculations into a more useable and complete form. The data reduction, calculations and statistical interpretations specified by each method and/or method standard operating procedure are followed. All data are initially processed by analysts using appropriate methods (e.g. chromatographic software, instrument printouts, hand calculation, etc.). Software developed by CAS for the purpose of data reduction/calculation is subject to validation as written in the *Standard Operating Procedure for Ensuring Data Integrity* and *Standard Operating Procedure for Software*

and Data Quality Assurance. Some of the information and procedures necessary for the reduction of data include retention time windows, analyte confirmation, data qualifiers, and calculations and are generally described in this section.

13.2.1 Qualitative Identification Qualitative identification of an analyte is specified in each method (e.g., Section 7.7 of EPA Method 8082 and Section 7.6 of EPA Method 8260) and method standard operating procedure. The criteria used for GC or GC/MS methods in qualitative identification are summarized below:

- GC Methods – Retention time windows are calculated, where appropriate, in accordance with method standard operating procedures and are used in the qualification of target analytes. In most cases the windows are generated from either the initial calibration or a standard analyzed over a 72-hour period.
- GC/MS Methods - The qualitative identification of each compound is determined by:
    1. The retention time of target analytes as compared with that of the standard.
    2. The mass spectrum of the analyte in the sample must, in the opinion of a qualified analyst or the department manager, correspond to the characteristic ions in the spectrum of the standard or the current GC/MS reference library.

13.2.2 Analyte Confirmation Confirmation is performed as specified in method and/or corresponding SOPs, as well as the *Standard Operating Procedure for Confirmation of Organic Analyte Identification and Quantitation.* However, identification criteria for GC/MS methods as well as multi-component analytes are summarized below:

- GC/MS Methods – Confirmation is not necessary for MS analyses. However, mass spectral confirmation must meet the criteria stated in the applicable method and the analyte in the sample must, in the opinion of a qualified analyst, correspond to the spectrum of the analyte in the standard or the current GC/MS reference library.
- Multi-Component Analytes – Confirmation is not necessary for analytes such as gasoline, diesel, and other "pattern" generating analytes (except when required by the method).
- Gas Chromatograph and Liquid Chromatographic Analyses - For gas chromatographic (GC) and liquid chromatographic (LC) analyses, all positive results are generally confirmed by a second column, a second detector, or by GC/MS analysis, unless exempted by one of the following situations:

    - The sample is analyzed for benzene, toluene, ethylbenzene and xylenes (BTEX), and the sample is found, by a separate analysis, to contain gasoline. In a sample containing no gasoline, the presence of BTEX compounds will be confirmed.
    - The sample meets all of the following requirements:
        1. All samples (liquid or solid) come from the same source (e.g., groundwater samples from the same well) for continuous monitoring.

samples of the same matrix from the same site, but from different sources (e.g., different sampling locations) are not exempt.

2. All analytes have been previously analyzed, identified and confirmed by a second column or by GC/MS. The documents indicating previous confirmation must be available for review.
3. The resulting chromatogram is relatively simple and does not contain complex or overlapping peaks.
4. The chromatogram is largely unchanged from the one for which confirmation was carried out.

13.2.3 Calculations The calculations utilized to obtain a final reportable result must contain all dilutions, volumes analyzed, pressure dilution factors, etc., where applicable. The calculations are specified in the corresponding method standard operating procedures.

All manual calculations including manual integrations are documented to ensure both traceability and integrity of the result. The documentation for manual integrations follows the requirements specified in the *Standard Operating Procedure for Manual Integration of Chromatographic Peaks*.

13.3 Data Validation

All analytical records (e.g., strip charts, printouts, computer data files, notebooks, and logbooks) include information that allows the events of the analyses to be reconstructed and validated. The analytical records include information such as sample ID, date of analysis, instrument ID, sample type, sample preparation and analysis method, and any observations and calculations preformed on the sample, analyst initials, dates, and standard ID, etc. as specified in the applicable standard operating procedures.

The integrity of the data generated in the laboratory begins with the initial laboratory validation of test methods as specified in Section 10.11 of this manual. Additionally, the assessment is achieved through the use of a variety of measures that may include reagent blanks, laboratory control samples, duplicates, matrix spikes and other QC samples. The numerical criteria for evaluation of these QC samples are listed within each method-specific Standard Operating Procedure and include method and statistically derived limits (refer to Section 10.4 for additional information).

Other validation measures of the data include a check of the linearity of the calibration curve, an accuracy check of the QC standards and a system sensitivity check. Data transcriptions and calculations are also reviewed. Additional information and procedures used to validate and verify the quality of reported data are described below.

13.3.1 Data Qualifiers Whenever necessary, data qualifiers are included on the final report as a means to describe out of control situations, estimated concentrations,

interferences, and other pertinent information. The table included in Appendix D of this document is a list of qualifier flags available for use at CAS/SIMI. Modifications and/or additions to the list, and designations and/or wording may be made as long as both the flag and corresponding definition is included in the report. If there is not a specific flag included, the final report shall contain a sufficient explanation of the data provided to the client.

To the extent possible, samples shall be reported only if all quality control measures are acceptable. If a quality control measure is found to be out of control, and the data is to be reported, all samples associated with the failed quality control measure shall be reported with the appropriate data qualifier(s) and/or case narrative explanations.

13.3.2 Computers and Electronic Data Related Requirements The plan for assuring the quality of computer software and integrity is written in *the SOP for Software and Data Quality Assurance Plan.* It covers the policies for procurement, configuration, development, validation/verification, security, maintenance, and use of computer software.

13.3.3 Estimation of Uncertainty of Measurement Uncertainty is associated with most of the results obtained in laboratory testing. The laboratory ensures that a reasonable estimation (based on laboratory records) is attempted and that the form of reporting does not give a wrong impression of the uncertainty of a result. An estimation of the uncertainty of the measurements is available upon request using the procedures written in the *Standard Operating Procedure for Estimation of Uncertainty*.

13.4 Data Review

The data review procedure is conducted in such a manner as to ensure that all reportable and supporting data:

- are correct and complete;
- have met the data quality objectives of the method, corresponding standard operating procedure (against data review checklist) and/or client;
- anomalies have been clearly qualified in an acceptable fashion
- does not misrepresent the quality of the results

The data review procedure is conducted in accordance with the requirements detailed in the *Standard Operating Procedure for Data Review and Reporting*; however, an overview is described below.

Depending on the processing software utilized for a particular method (i.e., Enviroquant, STEALTH, etc.), the resulting raw data are manually or otherwise entered into an electronic report, spreadsheet or processed by a program that electronically reviews the data against the appropriate

set of acceptance criteria and transfers the data into a reportable format. Once the data have been entered into the appropriate form (final report form, results spreadsheet, or other), it is then printed and the analyst reviews all raw data, quality control results, field sample(s) results, and forms for both accuracy and acceptability. The analyst also makes notations of any analysis anomalies and data qualifiers (refer to above section).

After the primary review, a second level (peer or secondary) of review is conducted by an analyst, supervisor, or the department manager. The secondary review consists of checking for errors (against the same criteria as the initial review) and properly approving any manual integrations (refer to Section 13.2.3) for acceptability. The reviewer initials and dates the checklist when the review is complete and found to be acceptable.

Following the secondary or peer review, the data including hardcopy report forms goes through another review by a qualified person (either a Data Validation Coordinator or Project Manager). If one of the automatic reporting systems including STEALTH or Blackbird is not utilized, then the data report is reviewed by a Data Validation Coordinator (DVC); otherwise the Project Manager is responsible for the review. If a DVC is performing the review, a check of all GC/MS calculations, a verification of GC data against the analysis spreadsheet, check for data entry errors, and a review of quality control results associated with the sample are included, where applicable. Any analytical or typographical errors associated with the report will be flagged and the report with the associated data will be returned to the person who generated the report forms (Systems Analyst or analyst) for review and correction. The Project Manager must review the entire body of data for completeness and to ensure that any and all client-specified objectives were successfully achieved and any anomalies and qualifiers are properly included.

When the entire data set (report) has been found to be acceptable, the report is submitted for final approval and signatures of the persons authorizing the test report. A copy of the report is made and retained at the laboratory for a period of five years (unless otherwise specified by the client) while the original is forwarded to the client (refer to Section 8.6).

13.5 Data Reporting

The quality objective, with regards to data reporting, is that the laboratory shall report results accurately, clearly, unambiguously and objectively, and in accordance with any specific instruction in the referenced method(s). The report shall include all of the information requested by the client (Refer to Table 13-1 for available report tiers) and necessary for the interpretation of the results as well any additional information required by the method. All data are calculated and reported in units consistent with project specifications, to enable easy comparison of data from report to report.

The client is contacted in writing (email is sufficient) regarding any event that casts doubt on the validity or completeness of results. All information of this type is included in the final report and

the following describes each section of the CAS/SIMI final report and the information that should be consistently provided to the client for proper interpretation of the results. If the results have already been reported, refer to Sections 13.5.2 for information on report revision and 13.5.3 for amendments.

13.5.1 Laboratory Report Format and Contents The information included in the report issued by CAS/SIMI is listed below, which complies with the NELAC requirement. CAS/SIMI certifies that the test results meet all requirements of NELAC or will provide reasons and/or justification if they do not.

- A title, (i.e., Analytical Report);
- Name and address of laboratory, and location where the test was carried out if different from the address of the laboratory and phone number with name of contact person for questions;
- Unique identification of the report (such as serial number), and on each page an identification in order to ensure that the page is recognized as part of the test report and a clear identification of the end of the report;

  This requirement may be presented in several ways:

  - The total number of pages may be listed on the first page of the report as long as the subsequent pages are identified by the unique report identification and consecutive numbers, or
  - Each page is identified with the unique report identification, the pages are identified as a number of the total report pages (example: 3 of 10, or 1 of 20).
  - Other methods of identifying the pages in the report may be acceptable as long as it is clear to the reader that discrete pages are associated with a specific report, and that the report contains a specified number of pages.

- Name and address of client and project name if applicable;
- Description and unambiguous identification of the tested sample including the client identification code;
- Identification of test results derived from any sample that did not meet NELAC sample acceptance requirements such as improper container, holding time, or temperature;
- Date of receipt of sample, date and time of sample collection, date(s) of performance test, and time of sample preparation and/or analysis if the required holding time for either activity is less than or equal to 48 hours;

  The following are the laboratory criteria for evaluating compliance with required hold times.

1. If no sampling time is provided, hold times are considered valid until the end of the day. However, for projects that require compliance with theDepartment of Defense Quality Systems Manual for Environmental Laboratories, the most conservative time (earliest) will be utilized.
2. Time zones are not taken into consideration unless requested by the client.
3. Dates and times of collection must be taken into account when provided. If not provided, a notation will be made in the case narrative.
4. The start of sample preparation (e.g., addition of solvent), where applicable, is considered the end of the hold time.

- Identification of the test method used, or unambiguous description of any nonstandard method used;
- If the laboratory collected the sample, reference to sampling procedure;
- Any deviations from (such as failed quality control), additions to or exclusions from the test method (such as environmental conditions), and any non-standard conditions that may have affected the quality of results, and including the use and definitions of data qualifiers;
- Measurements, examinations and derived results, and any failures identified; identify whether data are calculated on a dry weight or wet weight basis; identify the reporting units;
- When required, a statement of the estimated uncertainty of the test result;
- A signature and title, or an equivalent electronic identification of the person(s) accepting responsibility for the content of the certificate or report (however produced), and date of issue;
- Statements to the effect that the results relate only to the items tested or to the sample as received by the laboratory and the report shall not be reproduced except in full, without the written approval of the laboratory;

    - The results included in this report relate only to the sample(s) submitted and identified herein, and in the documented condition received by the laboratory.
    - All results are intended to be considered in their entirety, and CAS is not responsible for utilization of less than the complete report.

- Clear identification of all test data provided by outside sources, such as subcontracted laboratories, clients, etc.; and,
- Clear identification of numerical results with values outside of quantitation levels.

13.5.2 Report Revision After issuance of a hard copy formal report (submitted to the client), the original laboratory report shall remain unchanged. However, a revised report or revised pages may be issued and regardless of the circumstances of the revision, the procedures described below shall be consistently followed. The issuance of either a revised report or revised pages is at the discretion of the laboratory.

1. The revised report shall be identified with an "R" following the original CAS/SIMI Project Number on every generated page. Previously revised reports shall be identified with an "R2".
2. The cover page of the report also includes a reference to the original report number.
3. The date of revision shall be included.
4. A revision letter (approved and signed by the Quality Assurance Program Manager) shall accompany the revised report and shall include:

    - CAS/SIMI report file number being revised
    - Identification of revision including all affected samples
    - Statement detailing that the enclosed is a revised report as indicated by the "R" identifier.
    - Statement that the revision letter should be kept on file
    - Statement that the original report is no longer valid and it must be destroyed or returned to the laboratory.
    - CAS/SIMI contact and phone number

Revised Page(s)

1. The revised page(s) shall be identified with and "R" following the original CAS/SIMI page number. Previously revised pages shall be identified with an "R2". Pages added will be denoted with "a", "b", etc.
2. A revision letter (approved and signed by the Quality Assurance Program Manager) shall accompany the revised pages and shall include:

    - Date of revision
    - CAS/SIMI report file number being revised
    - Page numbers that were revised
    - Identification of revisions
    - Statement detailing that the enclosed are revised pages as indicated by the "R" identifier.
    - Statement to the effect that the revised pages must be inserted into the original report.
    - Statement that the original report page(s) is no longer valid and it must be destroyed or returned to the laboratory.
    - Statement that the revision letter should be kept on file
    - CAS/SIMI contact and phone number

13.5.3 Report Addendum An addendum may be issued if there is an omission of data information from the original report such as quality control data or analytical results. The original report once issued shall remain unchanged. Therefore, the addendum shall be identified as a separate document and must reference the original report (an "A"

following the corresponding CAS/SIMI project number). This identification must be present on every generated page. Additionally, addendum pages may be added. The addendum pages shall be identified with an "A", "B" and "C", and so on following the original page number after which the page(s) is/are to be inserted.

An addendum letter (approved and signed by the Quality Assurance Program Manager) shall accompany the addendum report or pages and include:

- CAS/SIMI report file number
- Identification of addendum including all affected samples
- Statement detailing that the enclosed is an addendum report or pages and how they are identified.
- Statement that the letter should be kept on file
- CAS/SIMI contact and phone number

13.6 Documentation

CAS/SIMI maintains a records system which ensures that all laboratory records of analysis are retained and available. A service request number (project number) is electronically assigned to each project for reporting and filing purposes. Analysis data shall be maintained for a period of five years (from date of report issuance) unless the client has made other arrangements.

13.6.1 Documentation of Analysis Data

The analysis documentation system includes, but is not limited to, the following items (where appropriate) for each set of analyses performed:

- Instrument parameters; and
- Sample analysis sequence; and
- Analysis benchsheets, instrument printouts, results spreadsheets; and
- Chromatograms and peak integration reports for all samples, standards, blanks, duplicates and reruns; and
- Initial calibration and data review checklist(s); and
- Copies of report sheets submitted to the work request file; and
- Applicable standard identification numbers; and
- Chain of custody, service request and sample acceptance check forms; and
- Nonconformity and Corrective Action Report (NCAR) form.

13.6.2 Reporting Deliverables

In order to meet individual project needs, CAS/SIMI provides several levels of analytical reports. Basic specifications for each level of deliverable are described in Table 13-1. Variations may be provided based on client or project specifications.

13.6.3 Electronic Data Deliverables

When requested, CAS/SIMI provides Electronic Data Deliverables (EDDs) (as confidential) in the format specified by the CAS, client, project or specific EDD specifications, where appropriate. The EDD is prepared by either the Systems Analyst or Data Processor using the electronic version of the laboratory report to minimize transcription errors. In addition, any data not previously reviewed is reviewed and compared to the hardcopy report for accuracy.

Table 13-1
Descriptions of CAS Default Data Deliverables[1]

Deliverable	Tier I	Tier II	Tier III	Tier V[3]
Transmittal/Cover Letter[2]	■	■	■	■
Case Narrative[2]	■	■	■	■
Chain of Custody (COC) Document(s)	■	■	■	■
Cooler Receipt/Sample Acceptance Check Form	■	■	■	■
Sample Handling Records (Storage Records; Internal COC, etc.)			O	O
Sample Analysis Results with Preparation and Analysis Dates	■	■	■	■
Method Blank Results	■	■	■	O
Surrogate Recovery Report		■	■	O
LCS/DLCS Analyses with Recovery Report and RPD Results		4	4	O
Laboratory Duplicate Analysis with RPD Results		4	4	O
MS/DMS Analyses with RPD Results		4		O
MS/DMS Analyses with Recovery and RPD Results			■	O
Confirmation Summary Report			■	O
Tune Summary Report (for GC/MS Analyses)			■	O
Internal Standard Summary Report			■	O
Initial Calibration (ICAL) Summary Report			■	O
Initial Calibration Verification (ICV) Summary Report			■	O
Continual Calibration Verification (CCV) Summary Report			■	O
Continuing Calibration Blank (CCB) Summary Report			■	O
Standards Preparation Log			O	O
Instrument Run/Injection Log			■	O
Sample Preparation Benchsheet(s)			■	O
Raw Data including Analysis Benchsheet(s), Quantitation Reports, Chromatograms, Spectra, and Other Instrument Printouts			■	O

[1]Only those deliverables which are applicable to a particular matrix, method, standard operating procedure, analytical batch, and/or client-specific QAPP will be included.

[2]Inclusion is at the discretion of the laboratory (one or both will be included).

[3]The specific contents of a certified analytical report may be customized to satisfy client-specific requirements (Tier V).

[4]Precision data is to be reported from either sample duplicates, DLCS or DMS data and is dependent upon analytical batch, matrix, method, standard operating procedure, and/or client-specified requirements.

O – Optional, at the request of the Client

14.0 LABORATORY AUDITS, REVIEWS AND ACCREDITATIONS

Audits are an essential part of the QA program and two types of audits are used at this facility (system audits and performance audits). System Audits are conducted to qualitatively evaluate the operational details of the QA program. The Performance Audit is conducted to evaluate the analytical activities of an analyst, as well as the data produced by that analyst. Management reviews are conducted by individuals with executive responsibility to review the laboratory's quality system in order to ensure continuing suitability and effectiveness, and to introduce any necessary changes or improvements. These changes may include the addition and/or deletion of offered test methods and analytes. In addition, results from such laboratory audits (whether conducted internally or by an external entity) and managerial reviews, regardless of the severity, are shared with the appropriate laboratory personnel.

All audits are conducted to verify compliance with laboratory standard operating procedures and policies, AIHA policies, ISO/IEC 17025, and NELAC standards, Arizona Department of Health, and DOD Quality Systems Manual, where appropriate. In addition, it may be necessary to audit methods or systems in accordance with client specified requirements. If any findings from an audit or review cast doubt on the correctness or validity of the laboratory's calibrations or test results, the laboratory will take immediate corrective action and shall notify, in writing (within five business days), any client whose work was involved. Whenever testing discrepancies are detected, or departures from documented policies and procedures occur (as detected by client feedback, nonconformity reports or audits), the Quality Assurance Program Manager reviews all pertinent information/documentation to determine and/or implement the proper corrective action (i.e., training, procedural changes, etc.).

14.1 Audits

14.1.1 System Audit

The system audit examines the presence and appropriateness of laboratory systems. External system audits of CAS/SIMI are conducted regularly by various regulatory agencies and clients. Table 14-1 summarizes some of the major programs in which CAS/SIMI participates. The Quality Assurance Program Manager (QAPM) acts as a point of contact and coordination between the auditing group and the laboratory, and is responsible for working with the appropriate laboratory personnel to resolve any deficiencies and to prepare an audit response report. The final audit response report is then reviewed and signed by the Quality Assurance Program Manager and Laboratory Manager.

The internal system audits are scheduled and performed by the Quality Assurance Program Manager. These audits are conducted a minimum of four times per year with an additional comprehensive lab-wide system audit. Each audit examines one (or many) of the different quality assurance systems used at CAS, and the results of each audit and corrective actions are documented and retained by the QAPM. Any deficiencies noted by the auditor are

summarized in the audit report and corrective action is mandated within a specified length of time to provide closure for each audit.

The Laboratory Manager and other personnel are informed for review and comment of all audit findings, suggestions, and corresponding corrective actions, where appropriate. Should problems impacting data quality be found during an internal audit, any client whose data is adversely impacted will be given written notification (an email may be sufficient) if not already provided. Additional details of the internal audit program can be found in the *Standard Operating Procedure for Conducting Internal Laboratory Audits.*

14.1.2 Performance Audit

There are a number of separate reviews that can be considered part of the overall performance audit including a review of the analytical reports and generated data (hardcopy and electronic), logbook reviews and on-site analyst work reviews as well as electronic data audits (Refer to Section 14.1.4 for additional information).

14.1.3 Performance Evaluation Program

CAS/SIMI participates in a proficiency testing (PT) (minimum of twice per year per matrix per analyte) program from a NELAC approved provider. CAS/SIMI participates in PE studies that are required by programs listed in Table 14-1. The programs are water pollution (WP) for wastewater, underground storage tank (UST) for petroleum hydrocarbons, and hazardous waste (HW) for soil/hazardous waste. Results of the PT samples are sent directly to the appropriate state agencies by the PT vendor.

Successful quarterly participation in the American Industrial Hygiene Association (AIHA) PT program is a prerequisite to obtaining and maintaining accreditation for the analysis of industrial hygiene samples.

CAS/SIMI uses the results of PT samples to evaluate the accuracy of the analyses performed as well as analyst proficiency. Trends of acceptable and unacceptable results provide an assessment of the analytical performance of the laboratory. The PT reports are reviewed by the Laboratory Manager, QAPM, and the appropriate laboratory staff. Any "not acceptable' results in the PT final report is subject to corrective investigation. Corrective actions are documented and submitted to management for review. A response letter is sent to the appropriate agencies after the corrective investigation, explaining what action has been taken to correct the deficiency.

PE samples are processed in the same manner as field samples. At a minimum, the Laboratory Manager and QA Program Manager each review the results. The QA Program Manager reports the results to the appropriate agency or study coordinator. For

any results outside acceptance criteria, the analysis data is reviewed to identify a possible cause for the deficiency, and corrective action is taken and documented. The analysis of performance evaluation samples is performed according to the requirements specified in the *Standard Operating Procedure for Proficiency Testing Sample Analysis*.

Additionally, as a way to further monitor the quality of the laboratory's analytical activities, the laboratory may perform replicate analysis using the same method or where possible retest any retained samples.

14.1.4 Electronic Data Audit

Electronic data audits are conducted on a quarterly basis. A minimum of three electronic audits (initial calibration, analytical sequence and/or service request) should be performed per quarter. These audits include random selections of initial calibration, analytical sequence and/or service request for a method(s) and analyst. They are selected in such as way so that the same analyst or analysis is not audited in sequential quarters. However, this may be necessary if requested by the Laboratory Manager or other personnel, in relation to a complaint, or in conjunction (or as a result of) with an internal or external audit. These audits are conducted in accordance with the *Standard Operating Procedure for Electronic-Data Auditing.*

14.2 Quality Assurance Reports to Management

Quality assurance requires an active, ongoing commitment by CAS/SIMI personnel at all levels of the organization. Information flow and feedback mechanisms are designed so that analysts, supervisors and managers are aware of quality assurance issues in the laboratory.

The Quality Assurance Program Manager prepares a quarterly report to management detailing all QA activities from the past three months. The purpose of this report is to keep the Laboratory Manager and corporate QA Department apprised of these activities and to document the actions taken to correct problems that have impacted laboratory operations. This report includes discussion of the following issues related to laboratory QA/QC:

- Training
- QA Manual and SOP Reviews
- Audits (Internal and External)
- Corrective Actions (including patterns or persistent NCARs)
- Certifications, Accreditations, and Approvals
- Method Detection Limit (MDL) Studies Status
- Proficiency Documentation
- Statistical Control Limits Status
- Performance Evaluation Studies
- Current QA Issues, Priorities, and Accomplishments

Any problems noted by the Laboratory Manager are then discussed either during the regularly scheduled staff status meetings or at a specially scheduled management meeting. The Laboratory Manager performs an annual documented review of the quality system to identify any necessary changes or improvements to the quality system

14.3 Managerial Review

In accordance with a predetermined schedule and procedure, the laboratory's top management periodically (minimum – annually) conducts a review of the management system (quality system) including policies, procedures and testing activities to ensure their continuing suitability and effectiveness, and to recommend and introduce necessary changes and/or improvements. Management, through the use of this review, provides evidence of its commitment to the development and implementation of the management system and to continually improving its effectiveness.

This review takes into account, at a minimum, the suitability of policies and procedures, reports from managerial and supervisory personnel, internal audit reports, and assessments by external bodies, corrective and preventive actions, results of interlaboratory comparisons and proficiency tests, changes in the volume and type of work undertaken, feedback from clients, complaints, and recommendations for improvement, as well as other relevant factors (including quality control activities, resources and staff training). This review is conducted in accordance with the requirements stated in this document and in the *Standard Operating Procedure for Managerial Review.* Results of this review are incorporated into the laboratory's planning system and include goals, objectives and action plans for the coming year. Findings from this review are recorded and any actions are carried out within an appropriate and agreed upon timescale. Management shall ensure that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system.

Table 14-1

ACCREDITATIONS AND REGISTRATIONS

- American Industrial Hygiene Association (AIHA)
  Industrial Hygiene Laboratory Accreditation Program Laboratory
  Laboratory # 101661
- State of California, Department of Health Services, National Environmental Laboratory Accreditation Program (NELAP)
  Certification No. 02115CA
- State of New York, Department of Health
  Environmental Analyses/Air and Emissions (NELAP)
  Laboratory ID No. 11221
- State of Arizona, Department of Health Services
  License No. AZ0694
- State of New Jersey, Department of Environmental Protection (NELAP)
  Laboratory ID: CA009
- State of Oregon, Environmental Laboratory Accreditation Program (NELAP)
  Laboratory ID: CA200007
- State of Florida, Department of Health (NELAP)
  Laboratory ID No.: E871020
- Department of the Navy, Naval Facilities Engineering Service Center, Navy Environmental Restoration (ER) Quality Assurance (QA) Program
- Commonwealth of Pennsylvania, Department of Environmental Protection Bureau of Laboratories
  Registration Number: 68 3307

Note 1: Refer to Attachment E for the corresponding Certificates and Scope of Accreditations/Parameters.
Note 2: This Quality Assurance Manual is revised annually and the Certificates, Scope of Accreditations/Parameters are revised annually (where necessary). During this interim period Certificates may expire and the Scope of Accreditations/Parameters may change; therefore, these may not be updated until the annual revision. However, current Certificates and Scope of Accreditations/Parameters are on file and are on display in the front lobby. Updated accreditation documentation is also available upon request.

15.0 INSTRUMENTATION AND INSTRUMENT MAINTENANCE

All equipment is properly maintained, inspected and cleaned and all maintenance activities documented and retained on file. The laboratory furnishes all items of equipment required for the correct performance of tests. No instruments, outside the permanent control of CAS/SIMI, are used for sample analyses. Each item of equipment and its software that is significant to the results are uniquely identified and records maintained. All instructions and manuals regarding the use and operation of all relevant equipment are maintained and are readily available to personnel.

15.1 Instrument Maintenance / Preventive Maintenance

Preventive maintenance is a crucial element of the Quality Assurance program. Instruments at CAS/SIMI (e.g., GC/MS systems, gas and liquid chromatographs, etc.) are maintained by qualified, in-house personnel or outside service supplier, where necessary. All instruments are operated and maintained according to laboratory procedures and instrument operating manuals.

The preventive maintenance schedules are based primarily on manufacturer guidance, literature recommendations, and the experience of our analysts and supervisors. Some maintenance is performed as an integral part of each procedure (e.g., changing the injection port septum in GCs). Other preventive activities and maintenance schedules are followed as closely as possible, balancing between the workload and the urgency of the need for preventive maintenance (e.g., changing oxygen traps on GC's). Common sense and familiarity with the performance of each instrument will dictate whether the schedule needs to be advanced or delayed for that instrument. Trends within and excursions from control limits for QC sample results are monitored to determine if there is an instrument malfunction, and in such cases preventive maintenance is provided on an as-needed basis.

The Laboratory Manager has the responsibility for ensuring that all maintenance is performed. In the case of non-routine repair of capital equipment, the Laboratory Manager is responsible for providing repair, either by assigning the repair to a qualified analyst or by acquiring on-site manufacturer repair. Preventive maintenance procedures, frequencies, etc. are available for each instrument used at CAS/SIMI and are listed in Table 15-1, method SOPs or in the operating or maintenance manuals provided with the equipment at the time of purchase.

15.2 Documentation

All routine and special maintenance activities pertaining to the instruments are recorded in instrument maintenance logbooks. The maintenance logbooks used at CAS/SIMI contain extensive information about the instruments used at the laboratory.

Instrument downtime is minimized by keeping adequate supplies of all expendable maintenance items, where "expendable" means an expected lifetime of less than 1 year. A list of these items

includes gas tanks, gas line filters, syringes, septa, GC columns and packing, ferrules, printer paper and ribbons, pump oil, jet separators, and MS filaments. When performing maintenance on an instrument (whether preventative or otherwise), information about the problem, attempted repairs, etc. is also recorded in the notebook. Typical logbook entries include the following information:

- Details and symptoms of the problem
- Repairs and/or maintenance performed
- Description and/or part number of replaced parts
- Source(s) of the replaced parts
- Analyst's signature and date
- Demonstration of return to analytical control

Each instrument must be recalibrated following any instrument maintenance which may change or effect the sensitivity or linearity of the instrument or if the continuing calibration verification acceptance criteria have not been met as specified in the standard operating procedure. However, if an instrument is modified or repaired, a demonstration of return to analytical control is required before subsequent sample analyses can continue. Any instrument that cannot be repaired by maintenance procedures and has been shown to be defective is taken out of service.

15.3 New Instrumentation

An initial demonstration of analytical control is required on every instrument used at CAS/SIMI before sample analyses may begin and generally includes at a minimum an initial calibration and method detection limit or desorption efficiency study. When an instrument is acquired by the laboratory, the following information is noted in a bound maintenance notebook specifically associated with the new equipment:

- CAS/SIMI Instrument Identification No.
- Manufacturer’s name, model identification, and serial number or other unique
- Date the equipment was received.
- Major components associated with the instrument; e.g., autosampler or purge and trap units.
- Date the equipment was placed into service.
- Condition of equipment when received (new, used, reconditioned, etc.)
- Prior history of damage, malfunction, modification or repair (if known).

15.4 Out of Service Instruments

Samples are not analyzed on any instrument that is in need of repair. Any instrument that has been shown by verification or otherwise to be defective is taken out of service, clearly identified and wherever possible stored at a specified place until it has been repaired. All maintenance must be complete and the instrument either successfully calibrated or the calibration verified prior to the analysis of samples.

15.5 Contingency Plan for Analytical Emergencies

For most major analytical instruments in the organic department, the laboratory has at least one backup piece of identical instrumentation. This enables the laboratory to continue analytical work in that specific area while repairs are performed. In addition to the redundancy in instruments, the laboratory has the ability to off-load samples to other CAS laboratories if necessary.

TABLE 15-1

PREVENTIVE MAINTENANCE PROCEDURES		
Instrument	**Activity**	**Frequency**
Gas Chromatographs	Replace septum	As required
	Check system for gas leaks	With cylinder change/Open system
	Check for loose/fray wires and insulation	As required
	Replace injection port liner	As required
	Replace trap(VOA)	As required
	Polish PID lamp	As required
	Change PID O-rings	As required
	Clean PID lamp window	As required
	ECD wipe test	Every 3 years
	Replace ECD source	As required
	Clean FID	As required
	Hall detector electrolyte charge	As required
	Clean Hall detector cell	As required
	Replace Hall detector reactor tube/Teflon connecting tube	As required
	Change TCD assembly	As required
	SCD – Change reaction tube	As required
	FPD – Replace O-ring seal	As required
	PDD – Check for leaks	Annually
	Catalyst check	
GC/MS	Change Semi-VOA capillary column	Every 2 months or as required
	Change Semi-VOA injection port septum	As required
	Change Semi-VOA injection port liner	As required
	Replace trap (VOA)	As required
	Clean ionizer source	As required
	Change filament	As required
	Clean quadrupole rods	As required
	Adjust quadrupole rods	As required
	Change electron multiplier	As required
	Vacuum System: • Mechanical pumps: change oil, change trap pellets (HP only) • Diffusion pump: check oil • Turbo pump: change oil, check cooling fan	 Check every 6 months, check level monthly, change if necessary Annually, change as required As required
	Air Preconcentrators/Autosampler: • Change traps	 As required
	Computer System: • Clean cooling fans • All PCBAs: reseat boards, cables	 Quarterly As required

TABLE 15-1 (Continued)

PREVENTIVE MAINTENANCE PROCEDURES		
Instrument	**Activity**	**Frequency**
Purge and Trap Concentrators	Change trap Change transfer lines Clean purge vessel	As needed As needed As needed
HPLC	Replace/clean check valve filter Replace lamp UV/vis detector Replace flow cell Check flow	As required As required As required Quarterly
Analytical Balances	Clean pan and compartment Check with Class "S" traceable weights Field service	Prior to and after use Prior to use Annually
Refrigerators and Freezers	Monitor Temperature Adjust Temperature Clean	Daily As required As required
Ovens	Clean	As needed or if temperature is outside limit
pH probes	Condition probe	When fluctuations occur
Fluoride SIE	Store in storage solution	Between uses
Ammonia SIE	Store in storage solution	Between usees
UV-visible Spectrophotometer	Wavelength check	Annually
Ion Chromatographs	Change column bed supports Clean column Change column Change valve port face & hex nut Clean valve slider Change tubing Eluent pump	Monthly or as needed Monthly or as needed Every six months or as needed Every six months or as needed Every six months or as needed Annually or as needed Annually
Restek Thermal Gas Purifier	Check getter tube	Monthly, change as required

16.0 CORRECTIVE ACTION

Applicable problems, as well as the corresponding corrective actions taken, are documented on Nonconformity and Corrective Action Reports (NCAR) as a means to investigate and prevent recurrence (See Figure 16-1, form may be revised assuming all current topics are included) following the requirements in the *Standard Operating Procedure for Nonconformity and Corrective Action Documentation.* This SOP describes a systematic procedure for the identification of nonconformities, investigation into the causes, the necessary actions to take, as well as the procedures for notifying affected parties. The laboratory has implemented general procedures to be followed to determine when departures from documented policies, procedures and quality control have occurred. These procedures include specifying responsibility for adhering to and implementing standard operating procedures, defining how an analyst shall treat unacceptable QC measurements and procedures for the documentation and review of subsequent corrective actions.

An evaluation of nonconforming work including its significance and acceptability is performed and if it is determined that it could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, appropriate and immediate corrective action procedures are followed starting with the determination of the root cause. The corrective actions taken are to a degree appropriate to the magnitude and the risk of the problem and are based on the nonconformity assessment. If is determined that the nonconformity has put data into question, the Laboratory Manager along with the Quality Assurance Program Manager has the responsibility and authority to ensure the client is notified (in writing) within five business days and that any affected data is recalled, test reports are withheld, and/or the corresponding work is halted. It is also the responsibility of the Laboratory Manager and the Quality Assurance Program Manager to authorize any resumption of work once the appropriate corrective action has been taken and it has been determined that data is no longer affected.

Every laboratory employee has the responsibility to initiate the process to restore normal function to the system. Therefore, anyone who identifies a nonconformity or problem may initiate a corrective action. The Quality Assurance Program Manager reviews all corrective actions, ensuring that the appropriate personnel have taken effective corrective action. If a potential problem develops that cannot be solved directly by the responsible analyst, the supervisor, Project Manager, Laboratory Management and/or the Quality Assurance Program Manager may examine and pursue alternative solutions.

In general, corrective action may take several forms and may involve a review of the calculations, a check of the instrument maintenance and operation, a review of analytical technique and methodology, and reanalysis of quality control and field samples. The NCAR form is electronically completed and approved and is utilized for all corrective action documentation including errors, deficiencies, deviations, laboratory events, or data that falls outside of established acceptance limits and their resolutions. The original form is printed and added to the raw data file of each affected job, if applicable and a copy is filed with the QAPM and other job files, where necessary. The QAPM periodically reviews all NCARs looking for chronic, systematic problems that require a more in-depth investigation and alternative correction action

consideration. The Quality Assurance Program Manager is also responsible for initiating corrective actions due to a performance audit, check sample problem or internal or external audit finding (Refer to the *Standard Operating Procedure for Conducting Internal Laboratory Audits* for the corrective action report form).

Each method standard operating procedure provides acceptance criteria and specific protocols for corrective actions for the method in question. In addition, the laboratory has implemented general procedures to be followed to determine when departures from documented policies, procedures and quality control have occurred. These procedures include but are not limited to the following:

1. Each QC data type is assessed by the performing analyst and the associated secondary reviewer;
2. The analyst, secondary reviewer and Team Leader are responsible for initiating and/or recommending corrective actions. The Quality Assurance Program Manager may recommend specific corrective actions;
3. Each standard operating procedure defines how the analyst must treat a data set if the associated quality control measurements are unacceptable;
4. The documentation of out-of-control situations and subsequent corrective actions are specified in this section (16.0), the *Standard Operating Procedure for Nonconformity and Corrective Action Documentation*, and each method SOP;
5. The supervisor (Team Leader), of the employee initiating the report, and QAPM reviews all nonconformity and corrective action reports for correctness, completeness including the extent and significance of the nonconformity, root cause analysis and the corrective action for acceptability measures.

To the extent possible, samples shall be reported only if all quality control measures are acceptable. If a quality control measure is found to be out of control, and the data is to be reported, all samples associated with the failed quality control measure shall be reported with the appropriate data qualifier(s) and/or case narrative explanations.

16.1 Root Cause Analysis

Each investigation (root cause analysis) is different and is due to the type and source of the nonconformance, complexity of the problem and the range of impact. No data shall be reported until the root cause or causes have been determined and corrected or it has been demonstrated that the issue was random and that data is no longer affected. The procedure for determining root cause is dependent upon five basic areas and these areas are the primary cause for nonconformities and include personnel, samples, methods, controls and data. Depending upon the source of the nonconformance each one of these areas may need to be addressed and determined if any or all, had a contributing affect on the nonconformance. This is done on the NCAR, whenever possible. There are some cases where the nonconformance was beyond the control of the laboratory and this case is noted on the form. The chart presented below and the accompanying points are not intended to be all inclusive but to give guidance to the

investigator(s). The nature of the matter requiring corrective action will dictate the starting point in the investigation.

Work Flow

A - Personnel	B - Sample	C - Method	D - Controls	E - Data
Policies	Log-in	Validation	Preparation	Sample Trail
Procedures	Routing	Reagents	Handling/Storage	Logbook entries
Training	Storage	Instrumentation	Control Charts	Calculations
				Software
				Final Report

A. Personnel

- Interviews: Interviewing all employees involved in the work associated with the affected sample(s) is a key element of the investigation.
- Training: What was the level of expertise of the staff members involved in the matter under investigation? Could any training or skill deficiencies be a causal factor?

B. Sample

- Were all minimum sample receipt criteria met? Was anything unusual about the sample(s) noted upon receipt?
- Log-in: Check for discrepancies in the log-in records. Can the paperwork received with the sample(s) be reconciled with the log-in?
- Routing: Was the sample split or simply transferred from one employee to another? If split, was there a written procedure (record?)? If transferred, is the chain of custody intact? Were analyses performed by two or more units within the laboratory?
- Storage: Were the sample(s) stored properly upon receipt and up to the time of analysis?

C. Method

- Was the technical procedure followed? Are there deficiencies in the procedure as written?
- Validation: Review records compiled during the validation of the method? Have any of the established method parameters changed over time?
- Reagents: Check the preparation of standards, QC check of reagents and any test supplies having a critical impact on the test results.
- Instrumentation: Were the calibration procedure requirements carried out? If the event under investigation is occurring over a given time period, it is important to look back into the calibration history of the instrument. Review the instrument logbook records.

D. Controls

- Critically review all aspects of the QC data itself.
- Preparation: Review all preparation steps for the controls, e.g. if a spike was used, was the spiking procedure followed?

- Handling/Storage: Were control material(s) properly stored prior to use. Are there storage issues regarding the control samples during the analysis time frame? Had any control materials expired?
- Control Charts: Review the raw data and its transfer to the control charts carefully. Check the formulae embedded within the spreadsheet for automatic calculations.

E. Data

- Review the raw data carefully. Transcription or transposition errors can be culprits.
- Sample Trail: Check for gaps from sample receipt until the final report was issued.
- Logbook entries: Can the history of the sample be reconstructed from the logbook(s) used?
- Calculations: Recheck the calculations.
- Software: Insure the integrity of the formulas used for computer calculation steps.
- Final Report: Is all the information provided on the final report accurate? Are there any inconsistencies between the final report and the analytical history traced via the investigation?

16.2 Preventive Action

The identification of needed improvements, continual improvements and potential sources of nonconformance, either technical or concerning the quality system, are identified through a number of avenues including but not limited to managerial reviews, audits (both internal and external), client feedback and input from laboratory personnel. Additionally, this procedure involves the evaluation of analytical data, control charts (including any trends), proficiency test results, complaints and results from blind samples. If it is deemed necessary based on information provided, the laboratory shall develop an action plan, which will be implemented and monitored to reduce the likelihood of the occurrence. The procedure for preventive action includes a manner with which to determine the effectiveness of preventive action by monitoring the area in which the action occurred such as analytical data, control charts, proficiency test results and/or performing an internal audit (by the Quality Assurance Program Manager). Documentation may include the use of a Nonconformity and Corrective Action form or some other form or report as long as all documentation and outcomes are noted and approved.

Figure 16-1
Nonconformity and Corrective Action Report (CAS/SIMI)

CLIENT AFFECTED / JOB(S) / SAMPLES / SYSTEMS **NCAR No.:**_____

NONCONFORMITY

Procedure (SOP Affected): _____ Instrument/System: _____ Event Date: _____

EVENT: □ Missed Hold Time □ QC Failure □ Leaking Canister □ Pressurization Error □ Other

Detailed Description:

Originator: _____ Date: _____

CORRECTIVE ACTION AND IMMEDIATE ACTION TAKEN

Re-establishment of conformity must be demonstrated and documented. Describe the steps that were taken, or are planned to be taken to correct the particular Nonconformity and prevent its reoccurrence.

Immediate Action:
□ Flag Affected Data □ Revise Report □ Note in Case Narrative □ Other: _____

ROOT CAUSE ANALYSIS

□ Calculations □ Human Error □ Instrumentation □ Lab Control Charts □ Policies and/or Procedures □ Training
□ Sample Documentation □ Sample Log-in □ Sample Preparation □ Sample Storage □Software/Templates □ Other

Detailed Description:

NONCONFORMITY NOTIFICATION AND APPROVAL/ACCEPTANCE OF CORRECTIVE ACTION

Supervisor Notification & Approval of Corrective Action _____ Date_____

PM Notified? □ NO □ YES Customer Notified by □ Telephone □ Email □ Fax □ Narrative □ Not notified

Project Manager: _____ Date: _____ Comments:_____

_____

QUALITY ASSURANCE PROGRAM MANAGER - ASSESSMENT AND APPROVAL:

Error: □ Random □ Systematic Is Data Affected? □ Yes □ No Is Data Acceptable? □ Yes □ No
Is Corrective Action required, implemented and determined to be effective? □Yes □No □ NA

QAPM Verification and Approval of Corrective Action _____ Date: _____

Comments: _____

_____

17.0 PERSONNEL TRAINING

All laboratory employees, including part-time, full-time and contracted support personnel, whether employment is technical or key support, the laboratory ensures that such personnel are supervised and competent and that they work in accordance with the laboratory's quality system. When any staff member is undergoing training, appropriate supervision is provided. The training program is set up in such as way as to be relevant to both present and anticipated tasks of the laboratory. Evaluations of the effectiveness of training actions include but are not limited to the acceptance of quality control samples, initial and continuing proficiencies and PT samples.

17.1 Qualification

Technical position descriptions are available for all employees, regardless of position or level of seniority. These documents are maintained by the Human Resources personnel and are available for review. In order to assess the technical capabilities and qualifications of a potential employee, all candidates for employment at CAS/SIMI are evaluated, in part, against the appropriate technical job description. Any previously acquired skills or abilities of a new employee are entered into the database at the beginning of their tenure with CAS/SIMI. The Human Resources personnel also record the various technical abilities of all employees via a centralized database, and all skills acquired by an employee while in the employment of CAS/SIMI are added to the employee's permanent file. Information in the database includes the employee's name, a description of the skill including, where appropriate, the method reference, and the date the training was completed.

17.2 Employee Orientation

There is an employee orientation program given to every new employee. The program consists of the review of the Employee Handbook on the first day of employment which includes business ethics, confidentiality, conflict of interest and the laboratory's open door policy. Every employee is required to sign the Handbook Acknowledgment Form after reading the Employee Handbook. In addition, new employees are required to review and sign both the CAS Holdings Inc. Confidentiality and Conflicts of Interest Employee and Commitment to Excellence in Data Quality Agreements at the beginning of employment and every year there after. The Quality Assurance Program Manager provides a thorough quality assurance program orientation to each new employee, regardless of position, which includes overviews of the quality assurance program, policies and procedures, documentation practices and an understanding and compliance of the quality assurance manual, which they are required to read.

17.3 Initial and Continuing Proficiency

Training begins the first day of employment at CAS/SIMI when the company policies are presented and discussed. In addition, the new employee must become familiar with all

applicable administrative procedures, ethical behavior (refer to Section 6.0 for additional information) and the contents of this document. Training in analytical procedures typically begins with the reading of the standard operating procedure for the method they are expected to carry out. Hands-on training begins with the observation of an experienced analyst performing the method, followed by the trainee performing the method under close supervision, and culminating with independent performance of the method on quality control samples. A periodic demonstration of proficiency is required to demonstrate and maintain qualification, as described in the *Standard Operating Procedure for Documentation of Training.* However, documented demonstrations of proficiency are required every six months for those analysts which perform analyses associated with the laboratory's American Industrial Hygiene Association (AIHA) accreditation. Once training is complete the Quality Assurance Program Manager and/or the Laboratory Manager will document the authorization of certain personnel to perform specific analyses and operate any associated equipment as well as those personnel performing other critical job functions.

CAS/SIMI encourages its personnel to continue to learn and develop new skills that will enhance their performance and value to the Company. Ongoing training occurs for all employees through a variety of mechanisms. The "CAS University" education system, external and internal technical seminars and training courses, laboratory-specific training exercises and performance of external (independent) performance testing (PT) sample analyses are all used to provide employees with professional growth opportunities. Training records are kept in a file created for each employee. This file is kept and maintained in accordance with the guidelines contained in the *Standard Operating Procedure for Documentation of Training.* The department supervisor and other personnel, where appropriate, are responsible for the training and documentation of training activities. Also, the QAPM is responsible for maintaining employee training record files including those for both method and administrative procedures.

17.4 Environmental Health and Safety

Safety and QA/QC requirements are integral parts of all technical SOPs and, consequently, are integral parts of all training processes at CAS/SIMI. Safety training begins with the reading of the *Environmental, Health and Safety Manual*. All employees must receive a safety orientation, which includes a safety tour of the laboratory. In addition, technical employees are required to attend quarterly safety training sessions during which the various aspects of laboratory safety are discussed.

17.5 Training Needs

The policy for CAS/SIMI is to identify the ongoing training needs of all laboratory personnel and to provide relevant training with respect to continuing requirements of the laboratory. The identification of these needs is determined based on findings from proficiency testing, internal audits, external audits and managerial reviews (refer to Section 14.3), evaluations of industry including the volume and type of work undertaken, corrective actions, and personnel changes.

18.0 REFERENCES

The analytical methods used at CAS/SIMI generally depend upon the end-use of the data. Since some work involves the analysis of vapor phase samples for regulatory purposes, specified federal and/or state testing methodologies are used and followed closely. Several factors are involved with the selection of analytical methods to be used in the laboratory. These include the method detection limit, the concentration of the analyte being measured, method selectivity, accuracy and precision of the method, the type of sample being analyzed, and the regulatory compliance objectives. Typical methods used at CAS/SIMI are taken from the following references. In addition, applicable policies, quality standards and other reference documents have been included which are utilized as references for method performance and the continued maintenance of the laboratory's quality system.

- 3M Organic Vapor Monitor Sampling and Analysis Guide, *Organic Vapor Monitors 3500/3510 and Organic Vapor Monitors 3520/3530*, September, 1996.
- 40 CFR Part 60, Test Methods for Standards of Performance for New Stationary Sources, Appendix A.
- 40 CFR Part 63, Methods for Organic Chemical Analysis of Municipal and Industrial Wastewater, Appendix A.
- 40 CFR Part 63, National Emission Standards for Hazardous Air Pollutants for Source Categories, Subchapter C.
- 40 CFR Part 136, Definition and Procedure for the Determination of the Method Detection Limit, Appendix B
- American Industrial Hygiene Association, *LQAP Policy Modules,* Effective Date: April 1, 2007.
- American Society for Testing and Materials (ASTM), *Gaseous Fuel, Coal and Cok*e, Volume 05.06, September 2006.
- American Society for Testing and Materials (ASTM). *Annual Book of ASTM Standards*. Part 31, "Water." Philadelphia, Pennsylvania. 1981.
- American Society for Testing and Materials (ASTM), Annual Book of ASTM Standards, Philadelphia, PA.
- Arizona Administrative Code*, Department of Health Services – Laboratories,* Title 9, Ch. 14, Article 6. *Licensing of Environmental Laboratories,* R9-14-601 through R9-14-621, December 31, 2006 (Supp. 06-4).
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