ANATEK LABS

Quality Assurance Plan

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Introduction

Anatek Labs is a private, full service, multi-state certified analytical laboratory. We are committed to providing the highest quality environmental, agricultural, residential, and industrial testing services in a timely and cost-effective manner. We have established quality systems to ensure the quality and integrity of our work, and we are committed to enacting these quality measures and ensuring compliance with applicable *National Environmental Laboratory Accreditation Program* (NELAP) / *The NELAC Institute* (TNI) standards.

Anatek Labs has integrated many *Quality Assurance* (QA) practices into its measurement activities. These QA practices are designed to generate high quality data in an efficient and cost effective manner. Anatek Labs employs a laboratory-wide Quality Assurance Program designed to assess and monitor the ongoing quality of the testing performed in its facilities. Its purpose is to identify and correct problems as they occur and, if possible, to determine in advance potential problem areas and institute measures for their resolution. The Quality Assurance Committee will oversee all QA activities to assure the accurate, reliable, and prompt reporting of testing results. This document describes Anatek Labs' Quality Assurance Plan as it relates to operations within the laboratory. While this document strives to be inclusive, much of the Anatek Labs quality plan is incorporated in the laboratory and method *Standard Operating Procedures* (SOPs) referenced in the Appendix.

This QA Plan addresses all the minimum required elements described in the Guidelines and Specifications for Preparing Quality Assurance Program Plans (QAMS-004 / 80), Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans (QAMS-005 / 80) and Guidance on Preparation of Laboratory Quality Assurance Plans (EPA 910 / 9-92-0332).

Quality Assurance Policy Statement

It is the policy of Anatek Labs that there shall be sufficient quality assurance activities conducted to ensure that all data generated, processed, and reported will be scientifically valid and of known and documented quality. In addition, the use of all aspects of this quality system will continually improve the effectiveness of the laboratory and the quality system. All data generated by Anatek Labs, unless acknowledged and authorized by the submitting party, will be of known precision and accuracy and legally defensible. Quality assurance activities are designed in the most cost-effective fashion possible without compromising data quality objectives. The laboratory staff adheres to the requirements and specifications stated in this Quality Assurance Plan. All data reported meets the applicable requirements for TNI, *Environmental Protection Agency* (EPA) and/or any State specific methods used. For specific method requirements refer to SOPs, current EPA methods, the most current edition of Standard Methods, and/or state specific methods.

All employees must read, understand, and follow the provisions of this Quality Assurance Plan.

Confidentiality Policy Statement

All client information at Anatek Labs is considered confidential. No information will be given out without the express verbal or written permission of the client. All reports generated will be held in the strictest of confidence and issued only to the client. The exceptions to this policy would be those mandated by law (e.g., positive *E. coli* in public water systems that are required to be reported to State Regulatory Agencies). All employees of Anatek Labs will at all times adhere to this policy.

Code of Ethics/Conduct

The Anatek Organization is a team and each team member is expected to maintain a high level of professionalism. Each employee is responsible for his or her work, and that work must be conducted ethically, legally, and in accordance with standard operating procedures and applicable methods and regulations. Employees are expected to perform their duties with excellence, and to contribute to an environment where their co-workers can efficiently perform their duties and maintain focus on the overall benefit of the Anatek team, our customers, public health, and the environment. The penalties for violating the Code of Ethics can range from verbal reprimands to loss of

position. No person at Anatek Labs will in any way be put under undue pressure, financial or other, to complete their assigned tasks in violation of this code.

Data Integrity, Fraud Prevention & Detection

Anatek Labs actively works to insure that the data produced is of the highest quality and legally defensible. The data integrity system includes data integrity training for all new employees and annual refresher training for all employees, signed data integrity documentation, in-depth monitoring and review of data, and proficiency testing samples. At a minimum, 10% of all data packets generated are reviewed by the QAU or laboratory supervisors. If discrepancies are found management is notified. Blind samples are prepared as needed to check for fraud. If an employee is found to have committed a fraudulent act they will be dismissed.

Investigations resulting from data integrity issues will be conducted in a confidential manner until they are completed.

Policy on Waste, Fraud and Abuse

Under no circumstances is the willful change or fraudulent manipulation of analytical data condoned. Such acts are to be reported immediately to management for appropriate corrective action. Reported acts will be assessed on an individual basis, and resulting actions will be consistent with Anatek policies and could result in dismissal.

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.

Customer Service

Anatek's reputation has been built upon service to the customer. The laboratory is always willing to communicate and cooperate with customers to ensure their requirements are met, provided confidentiality to other customers can be ensured. Feedback from customers, including complaints, is used to improve laboratory operations and services.

New Work Requests and Contracts

It is the policy of Anatek Labs to consider new projects and customer testing requests that fall within the scope of our services and expertise. The lab is constantly expanding its abilities by seeking new certifications, purchasing new equipment, and hiring quality personnel. New work requests are reviewed to ensure that the lab has the appropriate facilities, resources, and expertise to perform the analyses required.

Most of the work contracted to Anatek Labs is for regulated projects analyzed by accredited methods. Specialty projects are reviewed and established by the Lab Director, Lab Manager, and/or Technical Directors, and the technical, legal, and financial considerations are established via correspondence and contracts, and reviewed as necessary. Project–related documentation (e-mail, contracts, quotes, etc.) is maintained (and reviewed as necessary) by the Lab Manager and/or Lab Director.

If Anatek Labs is unable to perform a particular analysis we will find a certified lab to subcontract the work. The above policy is at the discretion of the Lab Director and is subject to change.

Quality Assurance Program Management and Implementation

Overall responsibility for quality assurance lies with the Laboratory Director. The primary QA management of the laboratory rests with the Laboratory Manager. To provide technical assistance to the Laboratory Manager, a QA Officer is appointed by the Laboratory Director. The QA Officer is granted sufficient resources to ensure the proper execution of the QA Plan and to recommend and implement specific QA policies and procedures. A Quality Assurance Committee exists to further facilitate adherence and development of QA policies and procedures.

QA Committee

The Quality Assurance Committee is comprised of the QA Officer, Laboratory Manager, Laboratory Director, and Laboratory Supervisors. The QA Committee is responsible for overseeing lab-wide QA Plan implementation and addressing QA complaints or concerns brought to its attention from internal or external sources. The QA Committee directs the efforts of the QA Officer and enforces any necessary corrective actions. The QA Committee shall convene if needed to assess and/or address laboratory QA concerns and any actions taken by the QA Officer. Any QA complaints or problems that are received from outside the laboratory will be referred to the committee in order to resolve such issues.

QA Officer

The QA Officer is appointed by the Laboratory Director to oversee specific QA policy and procedure development, implementation, and adherence at Anatek Labs. The QA Officer is responsible for auditing internal operations and ensuring compliance with QA criteria established by this QA Plan and other documented policies and procedures. The QA Officer assesses all QA systems on an annual basis. Results of all findings are documented and corrective action recommendations, if any, are submitted to the QA Committee, Laboratory Manager and affected staff members.

The QA Officer is responsible for documentation and evaluation of specific policies and procedures. Standard Operating Procedures are kept on file documenting specific procedures employed to ensure the validity and acceptability of data generated at Anatek Labs. Materials purchased for quality control purposes are received with a Certificate of Analysis from the manufacturer. Certificates are kept on file for review if necessary. The QA Officer is responsible for coordinating and reporting for all performance evaluation samples, maintaining and updating certifications and accreditations, and monitoring corrective actions.

Laboratory Organization, Position Responsibilities and Personnel Qualifications

All employees maintain a copy of all training certificates and diplomas on file with certificates of capability for each method they perform. Job descriptions are maintained in employee training files. Organizational charts for Anatek Labs are shown in the Appendices.

Laboratory Director

The Laboratory Director is responsible for overall technical direction and business leadership of Anatek Labs. The Laboratory Director oversees laboratory operations, and appoints a Laboratory Manager and Quality Assurance Manager to implement laboratory procedures, based on the current market, technological advances in equipment, and methods.

The Laboratory Director is responsible for assuring that the provisions of this QA Plan are met, and that adequate resources are available for technical operations and quality systems oversight.

The Laboratory Director is a direct liaison to the Corporation's Board of Directors (BOD) and must attend a BOD meeting at least once a year, or as necessary to discuss equipment purchases, managerial changes, contracts, and major SOP and QA changes.

All Laboratory Managers and QA Officers report directly to the Laboratory Director.

The Laboratory Director may serve as Laboratory Manager, Technical Director, Systems Manager, and/or Analyst if these positions are not filled for any reason.

The Laboratory Director must have a minimum BS in a science or engineering field and 5 years of managerial experience in an environmental laboratory or an equivalent combination of education and experience.

Laboratory Manager

The Laboratory Manager is responsible for overseeing the daily operations of Anatek Labs. The Laboratory Manager, in conjunction with the Technical Directors, is responsible for coordinating laboratory activities with the overall goal of efficiently producing high quality data in a reasonable time. The Laboratory Manager is responsible for monitoring the validity of the analyses performed and data generated and for monitoring standards of performance in quality control and quality assurance.

The Laboratory Manager reports directly to the Laboratory Director and may act as Interim Director during extended absence of the Laboratory Director.

Additionally, the Laboratory Manager will provide technical support to customers and coordinate projects to meet specific customer needs.

The Laboratory Manager is responsible for the maintenance of standards and materials in accordance with the QA Plan, to ensure uninterrupted operation of the laboratory.

All Section Managers and Analysts not reporting to the Technical Directors report directly to the Laboratory Manager.

In events where employee scheduling or current workload is such that new work cannot be incorporated without missing holding times or data quality objectives, the Laboratory Manager has authority to refuse samples, modify employee scheduling, or re-schedule projects.

The Laboratory Manager, in coordination with the area Supervisors, QA personnel, and Technical Directors, is responsible for determining in which QA proficiency testing programs the laboratory will participate, and which accreditations the laboratory will pursue. It is the responsibility of the Laboratory Manager to ensure that the laboratory sections perform the tasks necessary to complete the proficiency testing required to maintain certification and accreditation

The Laboratory Manager will attend managerial and/or staff meetings at which the topic of QA is discussed.

The Laboratory Manager can act as Analyst, Supervisor, or Technical Director if, for any reason, the positions are not filled.

The Laboratory Manager is responsible for all human resource decisions within the laboratory except for employees reporting directly to the Laboratory Director.

If the Laboratory Manager is to be absent for more than 15 days, a Technical Director (or other supervisor) will be named to serve as the temporary Laboratory Manager.

The Laboratory Manager must have a minimum BS in a science or engineering field and 5 years of managerial experience in an accredited environmental laboratory, or an equivalent combination of education and experience.

QA Officer

The QA Officer is designated by the Laboratory Director. The QA Officer serves as the focal point for QA/QC and is responsible for the oversight and/or review of quality control data. The QA Officer functions independently from laboratory operations (answering directly to the Lab Director), and is able to evaluate data objectively without managerial influence. The QA Officer is responsible for conducting internal audits, and for notifying management of any deficiencies in the quality system, and for monitoring corrective actions. The QA Officer is responsible for maintaining the currency of this QA Plan, and will help develop, implement, and maintain Standard Operating Procedures appropriate to the procedures employed within Anatek Labs. The QA Officer is responsible for ensuring all applicable regulatory agency requirements are met.

The QA Officer must have a minimum BS in a science or engineering field and two years experience in QA/QC or an equivalent combination of education and experience.

Inorganic Supervisor

The Inorganic Supervisor is responsible for training, overseeing and assisting inorganic technical staff and operations. The Inorganic Supervisor assures adherence to Standard Operating Procedures and Quality Assurance activities. The Inorganic Supervisor should be a Chemist II or III.

The Inorganic Supervisor must have a minimum BS in a science or engineering field and 2 years of laboratory experience, or an equivalent combination of education and experience.

Microbiology Supervisor

The Microbiology Supervisor is responsible for quality microbiological results by maintaining the laboratory microbiology program and services within the framework of the lab QA guidelines. He/She is responsible for department oversight and training/supervising the microbiology technicians.

Microbiology Supervisor must have at least two years experience performing microbiological analysis in an environmental laboratory.

Organic Supervisor

The Organic Supervisor is responsible for overseeing and assisting organic chemistry technical staff in their daily duties. The Organic Supervisor assures adherence to Standard Operating Procedures and Quality Assurance activities. The Organic Supervisor should be a Chemist III.

The Organic Supervisor must have a minimum BS in a science or engineering field and 2 years of laboratory experience, or an equivalent combination of education and experience.

Radiation Safety Officer

The *Radiation Safety Officer* (RSO) is responsible for overseeing and assisting radiochemistry technical staff in their daily duties, and for radiation safety training for employees. The Radiation Safety Officer assures adherence to NRC, EPA, and NELAC regulations relating to radionuclides, as well as to the Anatek Radiation Safety Plan and applicable SOPs.

The Radiation Safety Officer must have a minimum BS in a science or engineering field, 2 years of radionuclide experience, and/or an equivalent combination of education and experience. In addition, the RSO must have completed Radiation Safety Officer training.

Technical Staff (Chemists, Lab Technicians, etc.)

Technical Director

The company Technical Directors are responsible for providing scientific leadership and vision. One or more Technical Directors will manage and coordinate activities of laboratory departments as designated by the Laboratory Manager. The Technical Directors will work with the Laboratory Manager to ensure that all lab QA/QC practices are met, to produce data that meets or exceeds the quality objectives of the QA Plan, specific customers or projects, and regulatory requirements.

The Technical Directors will provide technical support to laboratory staff and investigate new areas of interest to the company by utilizing methods development and technical advancements. The Technical Directors will be available as needed to fill in for Chemist(s) in the event of an absence or job opening. Technical Directors may serve as area Supervisors, and vice versa.

The Technical Directors will be the primary contact for specified customers and provide project management and advice to those customers. Additionally, the Technical Directors will prepare final customer reports as needed.

The Technical Directors will be responsible for non-routine instrument maintenance and troubleshooting and, if needed, obtain outside technical assistance for equipment maintenance or repairs as necessary.

The Technical Directors must have at least 5 years of applicable laboratory experience and a minimum of a BS in a science or engineering field.

Chemist (I, II, III)

The Chemist is responsible for the analysis of samples and the generation of high quality data in accordance with the laboratory SOPs and QA/QC.

The Chemist is responsible for making sure all data generated by him/her is entered into the appropriate database in the correct manner and that raw data packets are signed and archived properly.

The Chemist reports daily to an area Supervisor.

Additional duties of the Chemist may include, but not be limited to, preparation of samples for analysis, maintenance of lab equipment, and providing technical assistance to lower-level laboratory staff. The Senior Chemist in the laboratory may be asked to perform supervisory duties as related to operational aspects of the laboratory. In the event that this is required for any reason, these supervisory duties will be assigned by the Lab Manager and/or Lab Director. The Chemist may perform all of the duties of Laboratory Technician.

The position of Chemist is a full time or part time hourly position and may be divided into three levels, Chemist I, II, and III. Chemist I must have the equivalent of a Bachelors degree in Chemistry or a closely related science. Additionally, Chemist II must have at least 2 years of environmental or closely related lab experience. Chemist III must have a Bachelors degree plus 5 years of environmental or closely related lab experience.

Laboratory Technician/Microbiology Technician

The Laboratory Technician (chemistry or microbiology) is responsible for providing support in the form of sample analyses, sample preparation, and general lab maintenance. This may include tasks such as filling out daily maintenance logs, chemical inventories, and laboratory cleaning (glassware, etc).

The Laboratory Technician reports to an area Supervisor or the Laboratory.

The Laboratory Technician may be divided into three levels, Technician I, II and III. Lab Technician I must have a high school diploma or GED. Lab Technician II must have at least 1 year of experience in an environmental lab or equivalent secondary education. Lab Technician III must have a bachelor's degree in chemistry or closely related science or equivalent work experience.

Staff

Systems Administrator

The Systems Administrator is responsible for overseeing all information systems infrastructure. Infrastructure is defined as all hardware including computer workstations, servers and IT support equipment plus all laboratory equipment that interfaces with the network or database as well as all software and applications resident on the system.

The Systems Administrator reports directly to the Laboratory Director. The Systems Administrator must have a minimum BS in a computer science or information technology field or an equivalent combination of education and experience.

Client Services/Project Manager

The Client Services/Project Manager is responsible for all phases of customer service including but not limited to project management, client interaction, reporting, invoicing, office management, sample distribution, and purchasing. The Client Service/Project Manager works with laboratory management and staff to address client needs and requests.

The Client Service/Project Manager must have a minimum AA in Business Administration, Accounting or other relevant field and 5 years experience in office administration/supervision or an equivalent amount of education and experience.

Bookkeeper

The Bookkeeper is responsible for: invoicing customers, processing payments, invoices and packing slips, paying A/P invoices, payroll, payroll taxes, federal and state taxes, issuance of purchase orders, and deposits.

The Bookkeeper is responsible for all Human Resource management including insurance and 401K.

The Bookkeeper must have a minimum AA in Business Administration, Accounting or other relevant field and 1 year experience in business accounting or an equivalent amount of education and experience.

Sample Custodian, Shipping/Receiving

The Sample Custodian is responsible for the log-in and tracking of all samples throughout the laboratory. The Sample Custodian is additionally responsible for tracking of all samples sent to subcontract labs. All shipping and receiving is performed and/or monitored by the sample custodian, including sampling kits, trip blanks and pre-preserved sample bottles. The Sample Custodian takes customer orders and insures that incoming samples are correct. If a discrepancy is noted the Sample Custodian will contact the customer to resolve any questions or problems. The Sample Custodian is an integral part of the customer service team.

The Sample Custodian must have a high school diploma or equivalent.

Sample Procedures
(Sample Collection, Storage, Handling and Acceptability)

All samples sent to Anatek Labs are received, logged in and distributed by the Sample Custodian or designees. Samples that are unsatisfactory will not be analyzed unless authorized by the customer. Any such sample will be noted on the Chain of Custody form and with a qualifying statement on the final report noting unsatisfactory sample submission. Corrective measures to ensure proper specimen collection and/or handling on future sample sets will be supplied to the customers.

Collection

Samples must adhere to requirements for container, preservation and holding times described on the Anatek Labs website (www.anateklabs.com). Consult the Standard Operating Procedure, EPA SW-846 Manual on Test Methods for Evaluating Solid Waste, the Federal Register on EPA Test Methods Determining Contaminants in municipal and industrial wastes, *Standard Methods for the Analysis of Water and Wastewater* (Standard Methods), or other appropriate documentation for specific instructions on sample collection.

Sample Containers

Most sampling containers are supplied to the customer by the laboratory. Containers are generally used only once and discarded. Some analytical methods utilize containers of a type that is conducive to recycling. In these cases, containers are cleaned according to Standard Operating Procedures to ensure cleanliness. Samples must not be exposed to interfering materials. Consult the laboratory for the proper container material and size for a specific analysis or project. If the samples are collected and stored for transport in inappropriate types of containers, the laboratory may not be able to accurately quantify the amount of the desired components. In this case resampling may be required.

Preservation Methods

All samples should be preserved according to the type of matrix, analysis required, and data objectives. If the samples are not properly preserved the analytical results may be inaccurate due to loss by volatilization and/or

degradation. Anatek Labs provides sample containers with appropriate preservatives already in the container, when possible. Table 2 in the Appendices contains information on appropriate preservation methods.

Transportation

Samples should be transported to the laboratory by the fastest means possible. In general, samples should be chilled from time of collection to delivery at the laboratory.

Hand Delivery

Personal delivery of samples is ideal, as it is the most secure method. A Chain-of-Custody record must accompany the transfer of the sample if results will potentially be used as evidentiary. The field sampler is responsible for the proper packaging and dispatch of their samples. This responsibility includes sample preservation and the completion of all necessary documents concerning custody.

Shipped Samples

A sealed container should be used to ship samples via a common carrier. Samples within these containers should also be properly sealed, identified and accompanied by appropriate paperwork such as a Chain-of-Custody record or a test request form. Particular care must be taken with shipped samples to ensure that temperature requirements are met. Best results occur when the samples are pre-chilled prior to packing, and are packed with wet ice or a mixture of wet and blue ice packs. Particularly in the summer, expedited shipping helps to prevent samples being received over temperature.

Sample Acceptability

Samples received after holding times have expired, in inappropriate containers, or lacking appropriate preservative measures are generally not accepted for testing. Occasionally, a customer will request that a sample be processed even if it is received in an unacceptable condition. In such a case, testing will only proceed after the customer has provided written or verbal acknowledgement of the unacceptable status of the sample and authorized continued testing. Further, a comment, narrative, or explanation of possible negative effects of unacceptable sample submission is placed on the report or attached as a more detailed description.

Sample Logging and Tracking

Standard Operating Procedures have been established for the receiving of samples into the laboratory (SOPs ALI-02 & ALI-18). These procedures ensure that samples are received and properly logged into the laboratory, and that all associated documentation, including chain of custody forms, is complete and consistent with the samples received. Documentation of all sample storage is maintained in order to preserve the integrity of the samples.

Samples delivered to the lab are received by a designated Sample Custodian(s). Verification of sample integrity by the Sample Custodian includes the following activities:

- Assessment of custody seal presence/absence, location and signature
- Temperature of sample containers upon receipt
- Chain-of-Custody documents properly completed (entries in ink, signature present, etc.)
- Sample containers checked for integrity (broken, leaking, etc.)
- Sample is clearly marked and dated (bottle labels complete with required information)
- Appropriate containers (size, type) are received for the requested analyses
- Sample container labels and/or tags agree with chain of custody entries (identification, required analyses, etc.)
- Assessment of proper sample preservation (if inadequate, corrective action is employed)
- *Volatile Organic Compounds* (VOC) containers are inspected for the presence/absence of headspace bubbles (No assessment of proper preservation is performed for VOC containers at time of receipt; preservation is checked after analysis to avoid loss of sample)

Any anomalies or discrepancies observed during the initial assessment are recorded on the chain of custody documents and/or in the *Laboratory Information Management System* (LIMS) sample tracking software. Potential problems with a sample shipment are addressed by contacting the client and discussing the pertinent issues. When a satisfactory resolution has been reached by coordination with the client, the log-in process may commence and analysis may begin. Any changes in documentation resulting from these discussions are documented and authorized directly by the customer. During the log-in process, each sample is given a unique laboratory code and a login report is generated. The login report contains client information, sample descriptions, sample matrix information, required analyses, sample collection dates and analysis due dates and other pertinent information.

Facility security and access is important in maintaining the integrity of samples received at Anatek Labs. Access to the laboratory is limited to authorized personnel except for the sample receipt areas, which are manned during business hours.

Samples are stored appropriate to the analysis requested until they undergo analysis. Anatek Labs stores samples in one of many refrigerators, freezers or other storage locations, depending on the type of analysis and the matrix of the sample. Anatek Labs has several refrigerators for storage of samples. These refrigerators are segregated by matrix type (soil or water) and method of analysis. Drinking water, wastewater and soil samples are segregated and placed in separate refrigerators. The samples are further separated into dedicated refrigerated storage of VOC samples. A walk-in refrigerator is used for sample archival. The temperature of each sample storage unit used at Anatek Labs is monitored daily during operations and the data recorded in a file for future reference.

Samples and sample extracts are retained for up to six weeks then disposed of unless other arrangements have been made in advance. All samples are either returned to the client or disposed of according to approved disposal practices.

Logging

Samples are assigned a unique laboratory identification number. All samples are assigned a number with the following format: MBAZZZZ-XX
Where:

M = Lab identification – M=Moscow, W=Spokane
B = year (B=2021, C=2022, etc.)
A = month (A=January, B=February, etc.)
ZZZZ = sample batch (for that month)
XX = sample number

For example, MBI0222-02 would be the second sample of MBI0222, the 222nd batch work order in Moscow in September 2021. WCA0007-01 would be the first sample WCA0007, the 7th work order received in Spokane in January 2022.

Tracking

Samples are tracked by their individual log-in numbers. As testing is completed the LIMS is updated and the data archived.

Sample Custody and Legal Defensibility

Anatek Labs routinely tests samples used as legal evidence. A primary consideration for the legal credibility of analytical data is the ability to demonstrate that samples were obtained, reached the laboratory and analyzed without improper alteration or contamination. In most instances, Chain-of-Custody forms function only as a sample receipt form and initiate normal, standard sample handling procedures. Samples whose testing results may become evidentiary utilize a formal Chain-of-Custody protocol where evidence of sample collection, shipment, laboratory receipt and laboratory custody until disposal are documented. Chain-of-Custody forms document how physical custody of a particular sample is maintained, how custody is transferred and the identity of individuals responsible for sample collection, shipping, receipt, analysis, storage and disposal. Formal (evidentiary) Chain-of-Custody protocol must be specifically requested by the sample submitter.

The Sample Custodian is responsible for receiving Chain-of-Custody linked samples. Upon receipt of these samples, the Sample Custodian immediately inspects the documentation and the samples to ensure the integrity of the sample shipping container, sample bottles, custody seals and sample temperature upon receipt. Samples received in broken or leaking containers are noted on the Chain-of-Custody form and specific instructions for the lab are then requested of the submitter. If discrepancies between accompanying documentation and information on labels or sample containers exist, clarification is requested from the submitting party and a notation is placed on the Chain-of-Custody form explaining the discrepancy.

After receipt in the laboratory, samples are logged into the internal tracking system. Samples are stored in appropriate refrigerators according to matrix until analyzed. After analysis samples are stored for up to six weeks in designated areas in the walk-in refrigerator.

Collection

All samples should be collected using standard field sampling techniques. The sample container should be labeled with the following information:

1. Date and time of collection
2. Source of sample
3. Preservative used (if any)
4. Name of person collecting sample
5. Sample ID and project name

When appropriate, the container should be sealed so that it cannot be opened without disrupting the seal. Gummed tape or another type of sealant is recommended. The person collecting the sample should date and initial the seal, particularly across the junction of the tape to ensure a tamper-proof seal.

Pertinent data concerning each sample should be entered into a field log book or on the chain of custody. This information may be used to refresh the memory in the event that the collector is summoned as a witness.

The sample should be kept in the custody of the collector or a designated custodian. A sample is in a person's custody if:

1. It is in one's physical possession, or
2. It is in one's view after being in one's physical possession, or
3. It has been placed into a locked area to which the custodian retains the key.

Analytical Procedures

Analytical Standard Operating Procedures are based upon methods appearing in a variety of publications. Most commonly, procedures are adopted from EPA publications, "Methods and Guidance for Analysis of Water," "Test Methods for Evaluating Solid Waste: SW-846," or "Standard Methods for the Examination of Water and Wastewater" online edition. Refer to the Appendices for a listing of the test procedures utilized at Anatek Labs

Data Generation – Data Reduction, Validation and Reporting

Data Reduction

Test results are calculated manually and electronically as specified in the method-specific SOP and SOP ALI-05. Formulae are contained in the manual testing procedures and algorithms are contained in software controlled procedures. All data and calculations are verified by the analyst and posted to the LIMS for review by Supervisors or the Laboratory Manager.

Verification / Validation

Some procedures utilize additional visual confirmation and validation of values obtained electronically in the form of strip charts or other printouts. Where possible verification is made using interrelated analytes, (e.g., the concentration of one analyte theoretically cannot exceed the concentration of another). Validation in gas

chromatography is accomplished through the use of two dissimilar columns or the use of one or more compound specific detectors.

Data quality indicators such as blank results, duplicate reproducibility (precision), matrix spike, and quality control sample recoveries (accuracy), and known sample or project histories are checked to verify result validity. Refer to the individual method SOPs for acceptability criteria.

Timely Reporting

Samples are typically tested consecutively as received unless holding times or special arrangements require expedited testing schedules. All testing is scheduled so that accepted holding times can be met.

Reporting Results

After sample analysis, analysts post test results to the LIMS. Prior to reporting, entered data are validated by a Supervisor or the Lab Manager. A final report is generated after all testing for a particular sample is completed, and reports are distributed to the client and any regulatory agency requiring copies.

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 an appropriate data qualifier. Failure to meet established analytical controls prompts corrective action. Corrective action may involve a review of the calculations, a check of the instrument maintenance and operation, a review of analytical technique and methodology, and/or reanalysis of quality control and field samples. If a potential problem develops that cannot be solved directly by the responsible analyst, the Laboratory Manager, area supervisors, or the QA Officer may examine and pursue alternative solutions. Resumption of work subsequent to extensive corrective action (i.e., outside the scope of the method or SOP) shall be determined by the Lab Manager or area supervisor. In addition, an assessment will be made in order to ascertain if contact with the client is necessary.

Uncertainty of Measurement

Anatek Labs attempts, when possible, to identify all the components of measurement uncertainty, and estimate uncertainty of measurements. For most analyses, this is accomplished by following well-recognized and established test methods, and meeting method and SOP-specified quality control measures (blanks, CCVs, matrix spikes, etc.) Successful analysis of quality control samples helps to establish the certainty of an analytical measurement. To reduce the uncertainty of measurement, results are generally not reported below the lower limit of quantitation or above the upper limit of quantitation. If results outside these ranges must be reported, qualifiers, flags, or explanations are used to identify the increased quantitative uncertainty.

A method accuracy assessment may be generated from the results of spiked field samples (*matrix spike* or MS). Taking at least the five most recent spiked samples, calculate the mean and standard deviation of the recoveries. The accuracy assessment is expressed as the mean ± 2*standard deviation. For example, if the mean recovery is 90% and the SD is 10%, accuracy would be expressed as 70-110%. A similar statement may also be generated using *Laboratory Control Samples* (LCS).

Radionuclide analysis incorporates a measure of uncertainty into reported results. The uncertainty of a measurement is a factor of background, counting times, and instrument considerations, and is calculated according to equations in the analytical method, and reported alongside the analytical results.

Notification of MCL Violations

If analysis of a drinking water sample indicates nitrate, coliform or E. coli results in excess of EPA-established *Maximum Contaminant Levels* (MCLs) (or if other contaminants are identified at 4 x MCL), the client and the appropriate regulatory agency or agencies shall be notified within 24 hours of the validation of the analytical run. For other results exceeding the MCL, notification shall take place within 48 hours or two business days after validation of the sample result. This notification may be by phone, fax, or e-mail, depending upon the requirements of the regulatory agency.

Internal Quality Control

An Internal Quality Control program has been designed to ensure systematic in-house production of high quality analytical data. The objectives of this program are:

1. To provide a measure of the precision of analytical methods;
2. To maintain a continuing assessment of the accuracy, precision and completeness of individual analyses performed in the laboratory;
3. To identify methods that can be strengthened and provide a source of data to overcome these deficiencies and weaknesses;
4. To detect training needs within the analytical group;
5. To provide a permanent record of instrument performance as a basis for validating data and projecting repair and replacement needs;
6. To upgrade the overall quality of laboratory performance.

Precision

Precision is the ability of an analytical method or instrument to reproduce its own measurement. It is a measure of the variability or random error in sampling, sample handling and in laboratory analysis. The *American Society of Testing and Materials* (ASTM) recognizes two levels of precision: 1) ***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 2) ***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 Anatek Labs our "within batch" precision is measured through the use of replicate samples of QC analyses and is expressed as the *Relative Percent Difference* (RPD) between replicate measurements. The "Batch to Batch" precision is calculated from the variance observed in results from analysis of standard solutions of laboratory control samples from multiple analytical batches.

Accuracy

Accuracy is a measure of the closeness of an individual measurement (or an average of multiple measurements) to the true or expected value. Accuracy is determined by calculating the mean value of results from ongoing analyses of standard reference materials, standard solutions, and laboratory-fortified blanks. In addition, laboratory-fortified (matrix spike) samples are also measured; this indicates the accuracy or bias in the actual sample matrix. 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 said to be biased. Bias is the systematic error either inherent in a method of analysis (e.g., extraction inefficiencies) or caused by an artifact of the measurement system (e.g., contamination). Anatek Labs utilizes several quality control samples and independent calibration verification standards. Bias can be positive or negative, and several types of bias can occur simultaneously – accordingly, only the net, or total, bias can be evaluated in a measurement.

Completeness

Completeness is a measure of the amount of valid data that is obtained, compared to the amount that is expected. For the 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. Anatek's objective for completeness is 100%.

The specific types, frequencies and processes for quality control sample analysis are described in detail in method-specific standard operating procedures. These sample types and frequencies are described below. In addition, a number of other quality control processes that may impact analytical results are also described below.

Analytical Batch

The basic unit for analytical quality control is the analytical batch. The overriding principle for describing an analytical batch is that all the samples in a batch, both field samples and quality control samples, are to be handled exactly the same way, with the same reagents and standards and instrumentation, and all of the data from each analysis is manipulated in exactly the same manner.

The minimum requirements of an analytical batch are:

1. The number of (field) samples in a batch is not to exceed that specified in the Standard Operating Procedure for the procedure being employed (typically 20).
2. All (field) samples in a batch are typically of the same matrix.
3. The QC samples to be processed with the (field) samples typically include:
    a. *Method Blank* (aka Laboratory Reagent Blank)
    Function: Determination of laboratory contamination
    b. *Laboratory Control Sample* (LCS) (aka *Laboratory Fortified Blank* – LFB)
    Function: Assessment of method performance
    c. *Matrix Spiked (field) Sample* (MS) -when sufficient sample is supplied (aka *Laboratory Fortified Sample Matrix* - LFSM)
    Function: Assessment of matrix problems
    d. Duplicate – either second Matrix Spiked (field) Sample or Duplicate (field) Sample when sufficient sample is supplied (aka Laboratory Duplicate) or LFB Duplicate
    Function: Assessment of batch precision
4. A single lot of any particular reagent is used to process the batch of samples.
5. Each operation within the analysis is performed by a single analyst/technician/chemist or by a team of analysts/technicians/chemists.
6. (Field) samples are assigned to batches commencing at the time that sample processing begins. For example: for analysis of metals, sample processing begins when the samples are digested. For analysis of organic compounds, it begins when the samples are extracted.
7. The QC samples are to be analyzed in conjunction with the associated field samples prepared with them.
8. Batch QC refers to the QC samples that are analyzed in a batch of (field) samples.
9. Specific project, program or method SOP requirements may be exceptions to these definitions. If project, program or method SOP requirements are more stringent than these laboratory minimum requirements, then the project, program or method SOP requirements will take precedence.

Method Blank (a.k.a. Laboratory Reagent Blank)

The method blank is either analyte-free water or analyte-free soil (when available), subjected to the entire analytical process. When analyte-free soil is not available, anhydrous sodium sulfate, organic-free sand or an acceptable substitute may be used instead. The method blank is analyzed to demonstrate that the analytical system itself is not contaminated with the analyte(s) being measured. The method blank results should be below the levels specified in the method – often less than the *Method Reporting Limit* (MRL) or ½ MRL or less than the *Method Detection Limit* (MDL) or some factor of the MDL for the analyte(s) being tested; otherwise, corrective action must be taken. At least one method blank is included with the analysis of every analytical batch as stated in the method Standard Operating Procedure.

Calibration Blanks

For some methods, *calibration blanks* are prepared along with calibration standards in order to create a calibration curve. Calibration blanks are free of the analyte of interest and, where applicable, provide the zero point of the calibration curve.

Continuing Calibration Blanks

Continuing calibration blank (CCB) samples are solutions of analyte-free water, reagent, or solvents that are analyzed in order to verify the system is contamination-free when continuing calibration standards are analyzed. Not every method requires CCBs. The frequency of CCB analysis is either once every ten (10) samples or as indicated by the method, whichever is greater.

Calibration Standards

Calibration standards are solutions of known concentration prepared from primary standard solutions that are, in turn, prepared from stock standard materials. Calibration standards are used to calibrate the instrument response with respect to analyte concentration. Standards are analyzed in accordance with the requirements stated in the

particular method being used. Per TNI guidelines, linear calibration curves should have at least 5 non-zero points; quadratic fit curves should have a minimum of 6 non-zero ponts. Refer to SOP ALI-08 for policies regarding standards.

Initial (or Independent) Calibration Verification Standards

Initial (or independent) calibration verification standards (ICVs) are second-source standards that are analyzed after a calibration and prior to sample analysis to verify the calibration curve. ICVs should be run every time a new calibration is prepared. The ICV standards are prepared from materials obtained from a source independent of that used for preparing the calibration standards. ICVs are also analyzed in accordance with method-specific requirements.

Continuing Calibration Verification Standards (CCV)

Continuing Calibration Verification standards (CCVs) are midrange standards that are analyzed in order to verify that the calibration of the analytical system is still acceptable. Many modern method revisions require low-level (minimum reporting level or MRL) CCVs to verify method performance at the reporting limit. The frequency of CCV analyses and acceptance criteria for accuracy are indicated in the reference method and the Standard Operating Procedure.

Internal Standards

Internal Standards (IS) consist of known amounts of specific compounds that are added to each sample following sample preparation or extraction. Internal standards are generally used in procedures that may be affected by changes in instrument conditions or changes caused by certain matrix effects. Calibration curves and sample results are calculated based upon the ratio of the instrument response to the internal standard response. The integrated area of each sample's internal standard response compared to the initial calibration average or most recent CCV should vary by no more than the limits specified in each method.

Surrogates

Surrogates are organic compounds that are 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 surrogates is added to method blanks, calibration and check standards and samples (including duplicate, matrix spike samples, duplicate matrix spike samples and laboratory control samples) prior to extraction and analysis in order to monitor the method performance on each sample. The percent recovery is calculated for each surrogate and recovery is a measurement of the overall method performance. The percent recovery must meet the limits set forth in the SOP or determined from control charting.

Matrix Spikes (a.k.a. Laboratory Fortified Sample Matrix)

Matrix spiked samples (also referred to as Laboratory Fortified Sample Matrix [LFSM] samples) are field samples to which a known amount of the target analyte (or analytes) has been added. The samples are then prepared and analyzed in the same analytical batch in exactly the same manner as routine samples. 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:

Percent 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.

Matrix spiked samples are prepared and analyzed at the levels and frequency noted in the Standard Operating Procedure for the particular analysis. When matrix spike recoveries fall outside of method or control-charted acceptance limits, the analytical results should be qualified as potentially affected by the matrix.

Laboratory Duplicates and Matrix Spike Duplicates

Duplicates are additional replicates of samples that are subjected to the same preparation and analytical scheme as the original sample. Depending on the method of analysis, either a duplicate sample aliquot or a matrix spiked sample and duplicate matrix spiked sample (MS/MSD) are analyzed. The relative percent difference between duplicate analyses or between an MS and MSD is a measure of the reproducibility of a given method and analytical batch. The relative percent difference (RPD) for these analyses is calculated as follows:

$$\text{Relative Percent Difference} = (S1 - S2) \times 100 / S_{avg}$$

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_{avg} = the average of observed analyte concentrations in the sample and its duplicate, or in the matrix spike and its duplicate matrix spike.

Duplicates or MS/MSD analyses are performed at the level and frequency outlined in the Standard Operating Procedure for the analysis being performed.

Duplicates or MS/MSD's are selected on the basis of volume or matrix. Samples with enough volume are selected unless a matrix problem is suspected in which case a sample with enough volume and an appropriate matrix is selected.

Laboratory Control Samples (a.k.a. Laboratory Fortified Blanks or Quality Control Samples)

The laboratory control sample (LCS) is an aliquot of analyte-free matrix to which known amounts of the target analyte(s) is (are) added. A standard reference material of known matrix type, containing certified amounts of target analytes, may also be used as a LCS. The LCS sample is prepared and analyzed in the same analytical batch and in exactly the same manner as the other routine samples. Stock solutions used for LCS's are purchased or prepared independently of calibration standards. The percent recovery (%Rec) 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 and precise measurements at the required reporting limit. Comparison of batch-to-batch LCS analyses enables the laboratory to evaluate batch-to-batch precision and accuracy. Acceptance criteria for LCS analyses are either specified in the analytical method or obtained through the use of control charts. A LCS is prepared and analyzed at a minimum frequency specified in the Standard Operating Procedure for the specific method being employed. If an insufficient quantity of sample is available to perform a laboratory duplicate or duplicate matrix spikes, occasionally a duplicate LCS (LCSD) will be prepared and analyzed. Laboratory Control Samples are also referred to as Laboratory Fortified Blanks (LFB) or *Quality Control Samples* (QCS), depending upon the method.

Interference Check Samples

An *interference check sample* (ICS) is a solution containing interfering elements of known concentration that can be analyzed to verify background and inter-element correction factors in metals analyses.

Post Digestion Spikes

Post digestion spikes are samples prepared for metals analyses that have an analyte spike added to determine if matrix effects may be a factor in the results. The spike addition should produce a method-specified minimum concentration above the instrument detection limit. A post digestion spike is analyzed with each batch of samples, and recovery criteria are specified for each method.

Source and Preparation of Standard Reference Materials

All analytical measurements generated at Anatek Labs are performed using materials and/or processes that are traceable to a Standard Reference Material. Standard Operating Procedures are utilized to trace all quantitative and qualitative determinations to certified reference materials. All metrology equipment (analytical balances, thermometers, etc.) is calibrated using materials traceable to the National Institute of Standards and Technology (NIST) and maintained on a schedule to ensure accuracy.

All Sampling containers provided to the client by the laboratory are assured to be free of interfering contaminants by:

1. The container is purchased as pre-cleaned with certificates of analysis available for each bottle type; or
2. The container is cleaned by the laboratory using Standard Operating Procedures; or
3. The specific bottle type and manufacturer has been proven through study to be free of interfering materials; and/or
4. A blank is prepared with a surrogate bottle using laboratory reagent water at the time of sample collection to provide information on possible interferences or contamination resulting from the sample container.

Consumable materials routinely purchased by the laboratory (e.g., analytical standards) are purchased from nationally recognized, reputable vendors. Consumable primary stock standards are obtained from certified commercial sources or from sources referenced in a specific method. Supelco, Ultra Scientific, AccuStandard, Chem Services, Inc., Absolute Standards, Aldrich Chemical Co., J.T. Baker, Spex, E.M. Science, Fisher Scientific, etc. are examples of the vendors used by Anatek Labs. All reference materials that are received are recorded by the technical staff in the appropriate logbook(s) and are stored under conditions that provide maximum protection against deterioration and contamination. The logbook entry includes such information as an assigned logbook identification code, the source of the material (i.e., vendor identification), solvent (if applicable) and concentration of analyte(s), reference to the certificate of analysis and an assigned expiration date. In addition, the date that the standard is received in the laboratory is marked on the container. When the material container is opened for use the first time, the date of opening is recorded on the container. Stock solutions and/or calibration standard solutions are prepared fresh as often as necessary according to Standard Operating Procedures. After preparation, all standard solutions are properly labeled listing analyte concentration, solvent, date, preparatory analyst and expiration date; these entries are also recorded in the appropriate logbook(s). Prior to introduction into the analytical system / process, all in-house prepared 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 instrument calibration and subsequent quantitative purposes. In addition, an independent source of reference material (QC sample, old PT, etc.) is also used to check the calibration standards for signs of deterioration.

Practical Quantitation Limits (PQL)

The *Practical Quantitation Limit* (PQL) is defined as minimum concentration of a substance that can be definitively quantified by a method. In general, the practical quantitation limit is the lowest calibration standard concentration. Results reported below the PQL (and above the MDL – see below) are qualified on the final report as estimated concentrations.

Practical quantitation limit is also referred to in some methods or regulations as the *Limit of Quantitation* (LOQ), *Minimum or Method Reporting Limit* (MRL), or *Reporting Limit* (RL).

Method Detection Limits (MDL)

The *Method Detection Limit* (MDL) is defined as the minimum concentration of a substance that can be measured and reported with 99% confidence that the analyte concentration is greater than zero and/or is distinguishable from a blank sample. Method detection limits are determined for most analyses performed at Anatek Labs. Refer to Appendix H for specific information on the development of MDLs.

The MDL is also referred to in some methods or regulations as *Minimum Detection Limit, Limit of Detection* (LOD) or *Detection Limit* (DL).

In general, Anatek Labs reports results to the lowest calibration point (PQL). Some clients or projects will request reporting to the MDL. Results between the MDL and the PQL are qualified on the final report as estimated concentrations, or 'J-flagged.'

Control Charting

Control charts are used to establish laboratory-specific, performance-generated acceptance limits for many analytical methods. The generation of control charts is routinely performed at Anatek Labs. Refer to Appendix G for specific information on the generation and use of control charts.

Quality Document Control

All Standard Operating Procedures and Quality Assurance Plans are maintained under the control of the QA Officer. The QA Officer is responsible for maintaining all official/authorized versions of all Standard Operating Procedures and Quality Assurance Plans. The master version of each Standard Operating Procedure is maintained by the QA Officer. Copies of SOPs are available to analysts and other personnel via PDF links on each computer workstation. This QA Plan is maintained in the possession of the QA Officer and a copy is distributed to the Laboratory Manager. All original signatures are maintained on the QA Officer's master copy. Any copies or versions of these documents that are distributed outside the laboratory are not controlled or updated.

Additional quality systems documents (bench sheets, facilities maintenance forms, etc.) are tracked in a Master List of Quality Systems Documents, which records the revision number and effective date of approved forms.

All Instrument Activity Logbooks (IALs) and manuals are maintained by the analysts using the equipment. IALs are periodically inspected by the QA Officer to ensure compliance with standard operating procedures (refer to ALI-15). When full, IALs are archived and retired with the piece of equipment.

Analytical and support records, both electronic and hard-copy, are retained in accordance with Anatek Labs data archiving SOPs.

Standard Operating Procedures (SOPs) and Laboratory Notebooks

Anatek Labs maintains a database of SOPs for use in both technical and administrative functions. SOPs are written following the format and content requirements described in the SOP for preparation of SOPs (ALI-01). Each SOP has been reviewed and approved by a minimum of two authorities, the Laboratory Manager and the QA Officer. All SOPs undergo a documented annual review to make sure current practices are described. The QA Officer maintains a comprehensive list of current SOPs. The document control process ensures that only the most currently prepared version of SOP is being used for guidance and instruction. The QA Manual, SOPs, standards preparation logbooks, run logbooks, etc., are all considered crucial to consistent operations at Anatek Labs and all analysts are instructed on the proper usage of each. Anatek Labs maintains a current file, accessible to all laboratory staff, of the promulgated methodology (EPA, Standard Methods, etc.) used to perform analyses as well as this QA Plan and applicable Standard Operating Procedures. (For specific IAL procedures refer to SOP ALI-15.)

Deviation from Standard Operating Procedures

Anatek Labs recognizes that occasionally a deviation from a Standard Operating Procedure may be necessary. In such cases, a written record of the deviation is retained with the sample data and if the deviation affects the data integrity an appropriate data qualifier comment is noted on the analytical report. An example of this would include a special preparative step or procedure not normally performed but perhaps mandated by special matrix concerns.

Modified Procedures

Anatek Labs strives to perform published methods as described in the referenced documents. If there is a material deviation from the published method, the method is cited as a "Modified" method in the analytical report. Modifications to the published methods are listed in the standard operating procedure. Standard operating procedures are available to analysts and are also available to our clients for review, especially those for "Modified" methods. Client approval is obtained for the use of "Modified" methods prior to analysis.

Policy on Manual Integration

Automated integration data reduction software is generally accurate when performing peak integration for chromatographic analyses. However, instances occur where the instrument software does not yield the proper integration and the analytical data is inaccurate. Some examples include, but are not limited to, peak splitting, co-eluting interferences, peak detection failure, peak tailing, and failure to separate peaks. Accurate measurements require an analyst to review peak integration and evaluate if adjustments need to be made.

Manual integration is never appropriate when performed for the purpose of meeting method QC criteria or compliance requirements, avoiding rework or instrument maintenance. Inappropriate manual integrations include peak shaving, peak enhancement, and baseline manipulation.

Violation of this policy is subject to disciplinary action up to and including termination of employment.

Integration Procedure and Review

All data are generated and reduced following the procedures specified in the methods and/or SOPs. Chromatograms are evaluated for chromatography performance criteria, including:

Baseline noise (3 to 1 signal to noise ratio)
Peak resolution
Peak tailing (good column performance should produce symmetrical peaks with minimum tailing for most compounds)
Peak splitting
Co-elutions
Negative spikes in baselines

Corrective action must be taken when the chromatography has deteriorated. Corrective actions include:

Trimming head of column
Guard column replacement
Cleaning detectors and/or ion source
Cleaning injector ports, replacing ferrule, liner, gold seal or washer
Identifying leaks
Replacing the column
Changing trap
Change suppressor
Change eluent
Change regenerant for IC systems

The analyst must review all automatic integrations for all parameters in the method. This review must include:

Relative retention time/retention time shifts
Identification of peaks
Mass spectrum primary ion abundance – secondary ions maximize within one scan of primary ion (for GC/MS analyses)
Peak shape
Interference
Consistency
Verification that baseline is clearly visible
Inspection of auto and manual integration for proper technique and necessity of manual integration

When auto integration is determined to be incorrect (e.g., peak splitting, co-eluting interferences, peak detection failure, peak tailing, and failure to separate peaks), the peak(s) must be manually integrated to correct the area response. Integration must be consistent throughout the analytical run for samples, QC samples, blanks, and calibration standards.

Quality control will include reviewing chromatograms and verifying that manual integrations, when performed, are appropriate and analytically sound.

System and Performance Audits

Laboratory Evaluations and Audits are conducted under the authorization of the QA Committee and all findings and recommendations are submitted to the QA Committee for decisive action. System Audit requests are generated

internally and externally. Internal audits are generally scheduled at the frequency noted under the type of review, however, concerns brought to the attention of the QA Committee may necessitate an unscheduled systemic review at the discretion of the QA Committee. External audit requests are referred to the QA Committee for authorization and scheduling of external auditors to review systems.

The following evaluations are performed at Anatek Labs:

Management System Reviews (MSRs)

Management System Reviews (MSRs) are external audits conducted at Anatek Labs. Idaho Department of Health Bureau of Laboratories audits Anatek Labs to assess the adequacy of the overall QA Plan. FL DOH (for NELAP) and ID Bureau of Laboratories perform rigorous on-site inspections of Anatek's QA Plan, adequacy of facilities, Quality Control Records, Performance Evaluations, Standard Operating Procedures and Analyst abilities, and submit audit reports to Anatek Labs. These reports and any corrective actions plans are maintained at Anatek Labs. Washington Department of Ecology also completes an inspection for WA wastewater and soil/solid certification. Anatek Labs facilities are available for customer or regulatory agency inspection of Management Systems as well. Anatek's QA Committee reviews all MSR reports and recommendations. If reports indicate the necessity for corrective action, the QA Committee or its designee will prepare and implement a Corrective Action Plan. The Corrective Action Plan will itemize the specific action necessary to correct the deficiency and define the time frames and responsible parties for implementation and follow-up.

Technical System Audits (TSAs)

Technical System Audits (TSAs) are both internal and external audits conducted at Anatek Labs. Florida Dept. of Health (NELAP), Idaho Dept. of Health, WA Dept. of Ecology, and Arizona Department of Health Services evaluate Anatek Labs's technical systems. These agencies review calibration records, sampling and measurement procedures, general lab cleanliness, support systems, equipment and facilities, maintenance and repair records, control charts and general operation of the lab. The inspecting agencies prepare audit reports for Anatek Labs and these reports and all responses and corrective action plans are maintained at Anatek Labs. Additionally, Anatek Labs staff performs internal TSAs annually. The QA Officer performs an annual inspection of Standard Operating Procedures, quality systems, calibration and maintenance records, and employee training records. The RSO conducts an annual review of the Radiation Safety Plan. TSA audit reports are prepared by the external auditor or QA and given to the QA Committee or the analyst as appropriate (reference SOP ALI-16). If a report indicates the necessity for corrective action a Corrective Action Plan will be prepared and implemented according to SOP ALI-07. The Corrective Action Plan will itemize the specific action necessary to correct the deficiency and define the time frames and responsible parties for implementation and follow-up. The results from all corrective action plans will be compiled and forwarded to management and/or the QA Committee as necessary.

Proficiency Testing / Performance Evaluation

Proficiency Testing (PT) studies (also referred to as *Performance Evaluation* – PE) are performed according to regulatory requirements for NELAP and the various testing regimens employed at Anatek Labs. Anatek Labs participates in at least two *Water Supply* (WS), two *Water Pollution* (WP) and two solids/soils (RCRA – *Resource Conservation and Recovery Act*) Performance Evaluations annually. All PE Sample materials are procured from a NIST/NVLAP approved provider. Acceptable results for each analyte and method used to perform regulatory testing are demonstrated semi-annually. In the event that an unacceptable result is received for a particular analyte, corrective actions are employed. Blind studies may be initiated by the lab to verify performance. Additionally double-blind studies may be conducted when initiated by customers.

Data Quality Audits (DQAs)

Peer review of acceptable blank results, QA/QC sample recovery, matrix spike and matrix spike duplicate recoveries, reproducibility of duplicate samples, and verification of sample calculations is performed on a minimum of 10% of analytical batches (in practice, almost all data packets are reviewed). Errors or deviations from acceptable criteria are noted and data is returned to the generating analyst for correction. In the event that QA/QC criteria for a particular sample or batch of samples cannot be met, all associated sample reports are noted accordingly and may include other relevant discussions. If numerous problems are found with a particular method or analyst, more data packets will be reviewed.

IT Systems Auditing

Information Technology (IT) systems auditing of Anatek Labs is conducted both internally and externally. The external auditing is conducted by IDOH, WA DOE and FL DOH. The agencies review Anatek's IT SOPs, IT documentation, access security and backup/restore plans during the inspections. Internal audits are performed at least once a year by Anatek QAU with assistance from IT personnel. The internal audits will inspect the network security, network throughput performance, server storage available, backup/restore plan testing and general documentation of the IT systems. An IT systems auditing report is prepared by the external auditor or QAU and given to the QA Committee. If a report indicates that corrective actions are necessary, a Corrective Action Plan will be prepare and implemented by IT personnel. The Corrective Action Plan will specifically address the areas of deficiency and the actions to be taken.

Corrective Action

Corrective action is initiated when deviations or non-conformances with laboratory or regulatory practices are identified. Some examples include unacceptable PT results, internal or external audit findings, data or record review findings, and customer complaints.

Corrective action may take several forms. Some findings (for example, matrix spike recoveries that fail recovery limits) may only require an explanation on the data or the final report, while other findings will initiate a documented Corrective Action Report. Corrective action reports identify the problem noted, an investigation, a root cause analysis of the problem, any actions taken to correct or prevent the problem, and follow-up activities.

Customer complaints will be directed to the Laboratory Manager, QA Manager, and/or section supervisors. Every reasonable effort should be made to address (and correct, if necessary) customer complaints. If the lab is found to be at fault, a corrective action form should be initiated and completed.

Preventative Action

Anatek Labs and its personnel strive to improve the laboratory procedures, including analysis, record-keeping, and customer service. Preventative action is a proactive process to identify opportunities for improvement rather than a reaction to the identification of problems or complaints. When improvement opportunities or preventative actions are identified, action plans will be developed, implemented, and evaluated for effectiveness. All Anatek employees are encouraged to look for and identify potential improvements to lab safety, efficiency, and customer service.

Training & Personnel Qualifications

All personnel involved in any function affecting data quality will have sufficient training and technical expertise to effectively execute their job requirements. The laboratory evaluates all prospective job applicants for scientific knowledge and experience as noted in the job descriptions for the position considered.

New employees receive documented training on the Quality Assurance Plan, laboratory safety, standard operating procedures, and data integrity, as well as method-specific training. A record of specialized training received by or given by the staff is kept in the Personnel Training folders.

In addition to prior work and educational experience, Anatek Labs actively encourages its employees to expand and refine their job skills and knowledge through participation in educational programs. Time off is granted to attend seminars and training sessions put on by instrument manufacturers, regulatory agencies, professional business and scientific organizations, etc. Additionally Anatek Labs conducts in-house training on related topics. Anatek Labs also encourages continuing education through a tuition reimbursement program.

Demonstration of Capability (DOC)

Analysts perform an *Initial Demonstration of Capability* (IDOC) when performing a new method or a method they have not performed in a 12-month period. For most methods, mean recovery and standard deviation from four replicates of a quality control sample are compared to method or SOP acceptance criteria for the IDOC. Demonstrations of capability are verified annually, either by an O*n-going Demonstration of Capability* (ODOC), performed similarly to the IDOC, or by successful performance of a blind proficiency testing sample.

Facilities, Equipment, and Services

Anatek Labs was founded in 1992. Anatek Labs is a full service environmental testing laboratory serving the Inland Empire and the Pacific Northwest. Anatek Labs operates facilities in Moscow, Idaho and Spokane, Washington.

A listing of major analytical equipment used at Anatek Labs can be found in Tables 1a & 1b of the Appendices this document.

Calibration Procedures and Frequency

All equipment and instruments used at Anatek Labs are operated, maintained, and calibrated according to the manufacturer's guidelines and recommendations, as well as to criteria set forth in the applicable analytical methodology. Personnel who have been properly trained in these procedures perform maintenance and calibration. Documentation of calibration information is maintained in data archives (see SOP ALI-14, Data Archiving) or Instrument Activity Logs (IALs). Brief descriptions of the calibration procedures for our major laboratory equipment and instruments are described below. More information is contained in laboratory SOPs.

Analytical Instrumentation

Each instrument utilized at Anatek Labs is calibrated against traceable standards. Standard Operating Procedures are used to ensure traceability of stock reference materials. Standard Operating Procedures also specify required instrument settings, calibration concentrations and frequency, instrument linear ranges, specific required QA/QC measures and a number of other related technical issues.

Preventative Maintenance

Preventative maintenance is a crucial element of Anatek Labs's Quality Assurance program. Qualified in-house personnel maintain instruments, such as GC/MS systems, spectrometers, analytical balances and gas and liquid chromatographs. All instruments are operated and maintained according to the instrument operating manuals. All routine and special maintenance activities pertaining to the instruments are recorded in instrument activity logbooks (IALs). The IALs contain extensive information about the instruments used at the laboratory.

When an instrument is acquired at the laboratory, the following information is noted in a maintenance notebook assigned to the new equipment:

1. The equipment's serial number;
2. Date the equipment was received;
3. Date the equipment was placed into service;
4. Condition of equipment when received (new, used, reconditioned, etc.); and
5. Prior history of damage, malfunctions, modification or repair (if known).

Preventative maintenance procedures, frequencies, etc. are available for each instrument. These may be found in the various SOPs for routine methods performed on an instrument and may also be found in the operating or maintenance manuals provided with the equipment at the time of purchase. Responsibility for ensuring that routine maintenance is performed lies with the Laboratory Manager and area Supervisors. The maintenance may be performed by a Supervisor or Technical Director, assigned to a qualified chemist, or contracted to the manufacturer or an outside repair service.

When performing maintenance on an instrument (whether preventative or corrective), additional information about the problem (attempted repairs, etc.) is also recorded in the instrument activity log. Typical logbook entries include the following information:

1. Details and symptoms of the problem;
2. Repairs and/or maintenance performed;
3. Description and/or part number of replaced parts;
4. Source(s) of the replaced parts; and/or
5. The analyst's initials and date.

Temperature Record Keeping

Temperatures are monitored and recorded for all of active temperature-regulating devices including ovens, incubators and refrigerators. An electronic monitoring system is used to track temperatures in a number of refrigerators and freezers in Moscow. The following are units that are documented daily (during operations) and the associated acceptable average temperature limits:

Sample Archive	$0 – 6^0$C
Drinking Water Storage	$0 – 6^0$C
Drinking Water VOC Storage	$0 – 6^0$C
Non Drinking Water Storage	$0 – 6^0$C
Waste Water VOC Storage	$0 – 6^0$C

All thermometers are checked annually against a National Institute of Standards and Technology (NIST) traceable thermometer.

Analytical Balances

Analytical balances are serviced on an annual basis by a professional metrology organization. New certificates of calibration for each balance are issued to the laboratory on an annual basis. The calibration of each analytical balance is verified daily. As needed, the balances are recalibrated using the manufacturer's recommended operating procedures. Records are kept that contain the recorded measurements, identification and location of equipment, acceptance criteria and the initials of the technician who performed the checks.

Water Purification System

There are a variety of water purification systems used at Anatek Labs. A filtration system is in place to provide deionized water throughout the laboratory. The system is monitored and provides a purity of at least 1 MΩ (up to approximately 18 MΩ). When purity falls below 1 MΩ, the system is serviced by Culligan (Moscow) or King Soft Water (Spokane) and new filters are installed. Additionally there is a filter system that provides 18 MΩ purity water. The specifications, preventative maintenance schedules and other information for particular water purification systems are explained in detail in the applicable Standard Operating Procedure.

Glassware Washing

Glassware washing and maintenance play a crucial role in the daily operation of a laboratory. The glassware used at Anatek Labs undergoes a rigorous cleansing procedure prior to every usage. Refer to SOP ALI-03 and method specific SOPs for specific glassware cleaning procedures.

Services and Supplies

Anatek Labs purchases services and supplies from reputable vendors, and ensures that supplies meet or exceed standards established in the analytical methods. A list of approved vendors is maintained, and updated annually.

Waste Disposal

All samples received at Anatek Labs remain in the ownership of the submitting party. Unless analysis of the samples demonstrates hazardous/regulated levels of contaminants, liquid samples are routinely disposed in the sanitary sewer after adjustment to a pH specified by the local wastewater treatment facility. Solid samples are disposed of using the solid waste sanitation services. Samples demonstrated to be inappropriate or hazardous for disposal by routine means are returned to the client for disposal/treatment at the original sampling location or

retained in a manner consistent with mineral acid, solvent or other hazardous materials storage and disposal activities within Anatek Labs

All mineral acids, solvents and other hazardous materials used in the daily operation of the laboratory are collected in designated areas on-site until sufficient material is collected for cost-effective disposal at a licensed disposal facility.

Subcontracting of Laboratory Services

Analytical services may be subcontracted when the requested analyses cannot be performed by Anatek Labs. Subcontracting of laboratory services is done only with the knowledge and approval of the client.

The acceptability of subcontracting laboratories is assessed using the following criteria:

1. The subcontracting laboratory is certified for the analysis requested if results are for regulatory purposes;
2. The subcontracting laboratory has an approved/audited Quality Assurance Plan and/or an established reputation for providing quality services;
3. The subcontracting laboratory agrees to perform and provide specific Quality Control measures outlined by the project manager or sample submitter;
4. The subcontracting laboratory agrees to retain records for a period of time no less than outlined by the project manager or sample submitter.

Termination or Transfer of Business

In the event Anatek Labs goes out of business or ownership is transferred, available clients will be contacted, and customer records will be dealt with according to client instructions and state and regulatory requirements. For those clients who cannot be contacted, customer records will be destroyed in the event the lab goes out of business or transferred in the case of new ownership.