Mississippi State Chemical Laboratory

Quality Manual

Written per ISO/IEC 17025:2017

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Table of Contents

Laboratory Quality Management System

1.0 Introduction

The Mississippi State Chemical Laboratory (MSCL) was authorized by Sections 57-21-1 et seq., Mississippi Code of 1972 as a regulatory agency. The MSCL works to ensure quality labeling and safety of fertilizers, pesticides, animal feeds, and petroleum-related products sold in the State of Mississippi. Analyses are performed to support the regulatory actions of the Mississippi Department of Agriculture and Commerce and its Bureau of Plant Industry as well as other regulatory agencies in the State. The MSCL provides chemical analyses to industry, farmers, and citizens of the State in a fee-based program. The Laboratory is an ancillary agency housed on the Mississippi State University's campus, as outlined in *QP-103 Organizational Structure*.

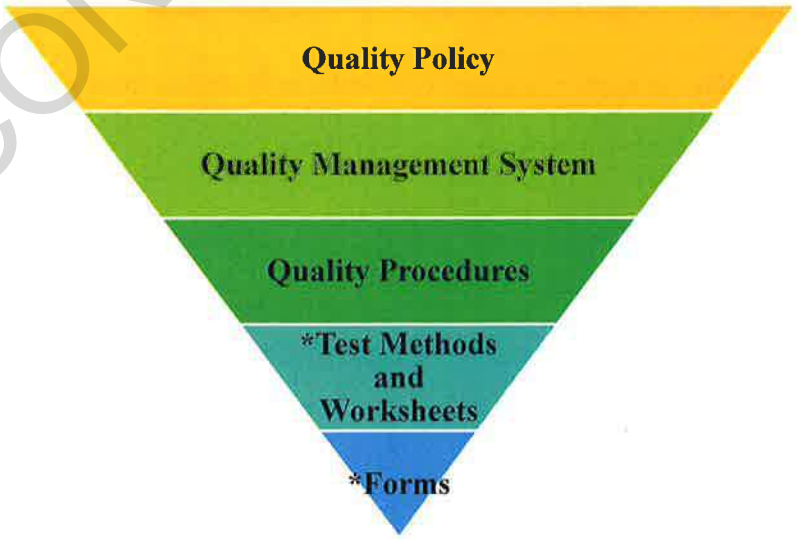
The MSCL is an **ISO/IEC 17025** accredited laboratory. The **ISO/IEC 17025** is an International Standard designed for the accreditation of Testing and Calibration Laboratories. It includes quality management system requirements along with technical requirements to ensure that each laboratory is equipped to perform particular tests and calibration activities. The MSCL's accreditation is validated by **Perry Johnson Laboratory Accreditation, Inc**.

The MSCL is divided into four divisions

- Chemical Regulatory Division **(Miss Code Ann. § 57-21-11a)**. This division provides analytical data for regulatory control programs in foods, animal feeds, fertilizers, economic poisons, and similar programs legally authorized.
- Petroleum Products Division **(Miss Code Ann. § 57-21-11b).** This division shall conduct testing on petroleum and related products.
- Industrial and Agricultural Services Division **(Miss Code Ann. § 57-21-11c).** This division shall provide applied scientific and analytical data to industries and individuals residing in or doing business in the State.
- Research Division **(Miss Code Ann. § 57-21-11d).** This division shall conduct self-supported, grant, or contract research.

2.0 Document Structure

This Quality Manual describes the quality management system for the Mississippi State Chemical Laboratory. This manual provides guidance for MSCL's Quality Policy, Quality Management System, Quality Procedures, Test Methods, Worksheets, and Forms to meet the requirements of ISO/IEC 17025:2017. It describes the minimum requirements for all areas and how ISO Standards are met.



*See Master List for Details of Test Methods, Worksheets, and Forms

3.0 Quality Policy

Mission Statement

The Mississippi State Chemical Laboratory (MSCL) is dedicated to providing high-quality analytical data that upholds the integrity, accurate labeling, and safety of fertilizers, animal feeds, human foods, pesticides, and petroleum products within the State of Mississippi.

Vision Statement

Our vision is to position MSCL as the leading authority in technical excellence and the most trusted analytical resource for our customers. To achieve this, we are committed to advancing our technical capabilities, fostering a culture of innovation, and delivering exceptional service. We are dedicated to continuous improvement and operational excellence.

Objectives of the Laboratory

- Provide strong leadership and a clear vision to guide the Laboratory's mission.
- Prioritize the health and safety of our employees.
- Enhance customer service and satisfaction by maintaining strong relationship with our customers and delivering exceptional services.
- Foster a culture of continuous improvement through our management system.
- Ensure that all analytical processes and results adhere to deadlines without compromising quality.
- Perform all operations in a cost-effective manner, optimizing resources while maintaining high standards.
- Uphold the highest standards of quality and compliance with ISO/IEC 17025:2017 and AOAC Guidelines.

Management System

The Laboratory's management system, detailed in this Quality Manual and referenced documents, is designed to guide staff in adhering to best practices and producing reliable and high-quality outputs. For detailed definitions and terminology, refer to *QP-100 Glossary*. The system's requirements apply comprehensively to all technical work performed by the Laboratory.

Commitment to Quality

MSCL is committed to delivering services and data of the highest quality, consistently meeting or exceeding customer requirements and expectations. This commitment is integral to supporting the Laboratory's mission, vision, and strategic objectives. All personnel are required to implement and comply with the policies in the Quality Manual, follow referenced procedures, and adhere to ISO/IEC 17025:2017 standards. Each employee plays a crucial role in maintaining quality and is responsible for the effective implementation and continuous improvement of the management system based on their technical and managerial responsibilities.

Quality Excellence

The technical and quality management teams are dedicated to upholding the highest standards of professional practice and strict adherence to ISO/IEC 17025:2017. All staff members are expected to remain vigilant for potential issues or sources of error that could impact the quality of technical work. Identified problems or errors must be promptly reported to Laboratory Management to ensure timely resolution and prevent recurrence, in line with our strategic focus on maintaining the highest quality standards.

Quality Policy Authorized By:

Erika Womack, PhD
State Chemist
Laboratory Director

4.0 General Requirements

4.1 Impartiality

4.1.1 It is the policy of the Laboratory that all laboratory activities are to be undertaken impartially and properly managed to safeguard that impartiality. Laboratory management is fully committed to impartiality.

4.1.2 Management ensures that employees always conduct themselves in an impartial and ethical manner and that they are free from any internal or external undue pressures, as defined in *QP-101 Impartiality*.

4.1.3 The management and staff do not engage in any inappropriate outside activities that would compromise their ability to generate quality and legally defensible data, as defined in *QP-101 Impartiality*.

4.1.4 Should a risk to the Laboratory's impartiality be identified, it will be addressed with *QP-123 Risk Management*.

4.2 Confidentiality

4.2.1 The Laboratory protects the confidential information and proprietary rights of its customers during all Laboratory activities and when issuing and storing hard copy or electronic reports, as defined in *QP-102 Confidentiality*.

5.0 Structural Requirements

5.1 Legal Entity and Management Responsibility

Under Mississippi's amended food law of 1997, the MSCL has been given primary responsibility for providing chemical, physical, and microbiological analytical services in support of manufactured and retail food regulatory programs. Additionally, the MSCL has the responsibility to respond to chemical contamination emergencies in the State in order to ensure a safe food supply.

5.2 Compliance with Management System Documents

The management system described within this document and the referenced documents, covers all Laboratory activities provided within the Laboratory. It is the intention of the Laboratory to comply with all requirements of our management system and ISO/IEC 17025:2017, and to satisfy the needs of its customers, regulatory authorities, and organizations providing accreditation. The Laboratory does not conduct any testing outside of its permanent facility.

5.3 Organizational Structure and Job Descriptions

The organization and management structure of the Laboratory is defined in *QP-103 Organizational Structure*. The job descriptions of all Laboratory personnel are defined in *QP-104 Responsibilities, Authorities, and Interrelationships* and F-003 under Areas of Responsibility. The State Chemist/Quality Assurance Manager ensures that the management system is implemented and followed at all times.

5.4 Authority and Resources for Laboratory Personnel

All Laboratory personnel have the authority and resources needed to conduct their assigned Laboratory activities, including the implementation, maintenance, and improvement of the management system, to identify all deviations (nonconformities) in the management system, and to initiate corrective actions for those deviations. All Laboratory personnel are to report to management on the performance of the management system, any need for its improvement, and to ensure the effectiveness of the Laboratory's activities.

5.5 Management System Communication and Integrity

Laboratory management ensures that appropriate communication takes place within the Laboratory about the effectiveness of the management system, the importance of meeting customers' expectations, and other requirements. Laboratory management also ensures that there are no contradictions (lack of integrity) within the management system when changes are made.

6.0 Resource Requirements

6.1 Personnel

6.1.1 It is the policy of the Laboratory to ensure that all personnel who could influence the Laboratory activities are to act impartially, be competent, and work in accordance with the Laboratory's management system.

6.1.2 The Laboratory's managerial and technical personnel, irrespective of other responsibilities, have the necessary authority and resources needed to meet the requirements assigned to their positions including the implementation, maintenance, and improvement of the Laboratory's management system, to identify nonconformities, to initiate appropriate corrective actions, to report on its performance, and to ensure the effectiveness of Laboratory activities.

6.1.3 The competency requirements for each function influencing the results of Laboratory activities, including qualification, training, skills, and experience are defined in *QP-104 Responsibilities, Authorities, and Interrelationships* and F-003 Personnel Qualification/Authorization and evaluated according to *QP-105 Training*.

6.1.4 Management communicates the duties, responsibilities, and authorities of all Laboratory personnel and retains records of their training, competency, and authorizations, as well as ensures that the integrity (lack of contradictions) of the management system is maintained when changes to the management system are planned and implemented.

6.1.5 The Laboratory generally uses personnel who are permanently employed. Contracted or part-time employees are subjected to all policies and procedures on training and demonstration of competency.

6.2 Facilities and Environmental Conditions

6.2.1 The Laboratory is housed in the Hand Laboratory at Mississippi State University. It has designated areas for centralized functions, *e.g.*, offices, Laboratory activities, sample receiving and storage, glassware washing, chemical and reagent storage, and instrumentation.

6.2.2 The monitoring and recording of the temperature in refrigerators and freezers, is described in *QP-106 Facility Monitoring*.

6.2.3 Access to all areas of the Laboratory is controlled by a security card-key access system. *QP-106 Facility Monitoring* addresses access control.

6.3 Equipment

6.3.1 The Laboratory has all the equipment it needs that is required for the correct performance of Laboratory activities. The Laboratory owns all its equipment.

6.3.2 The requirements for the acceptance, calibration, handling, transport, use, and maintenance of Laboratory equipment, instrumentation, and computers are found in *QP-107 Equipment* and the Test Methods.

6.3.3 All equipment that requires calibration shall be identified, where practicable, to allow the user to readily determine the status of calibration.

6.3.4 Manufacturer's manuals for each piece of equipment are in the proximity of the equipment. These documents are maintained according to *QP-122 Document Control*. It is the responsibility of each employee to read and understand the manual(s) for all equipment they use.

6.3.5 Equipment that gives suspect results or is not functioning properly is removed from service until it has been verified to perform correctly. Any data reported to customers from equipment found to be not functioning properly shall be addressed as specified by *QP-126 Corrective Action*.

6.3.6 Equipment sent outside the control of the Laboratory for calibration or repair is checked for function and calibration status before being placed back into service.

6.3.7 Intermediate checks used to maintain confidence in the calibration status of equipment are described in *QP-107 Equipment* and in the Test Methods. These checks serve to safeguard the equipment to ensure the acceptance of data.

6.3.8 Appropriate records are kept of all equipment that can influence Laboratory activities, as defined in *QP-107 Equipment*, the Test Methods, and *QP-114 Records Management*.

6.4 Metrological Traceability

6.4.1 The Laboratory has established metrological traceability of its reference standards (*e.g.,* masses and reference thermometers) and measuring equipment (*e.g.,* balances and pipettors) by using ISO/IEC 17025 accredited calibration laboratories, whose calibration certificates are endorsed with the recognized accreditation body's symbol and certificate number as defined in *QP-108 Metrological Traceability*.

6.4.2 The Laboratory has established metrological traceability of its measuring instruments (*e.g.,* gas chromatographs, and inductively coupled plasma spectrometers) using reference materials obtained from a reference material producer accredited to ISO Guide 34 or ISO 17034 by a recognized accreditation body when applicable, whose certificates of analysis are endorsed with the recognized accreditation body's symbol and certificate number as defined in *QP-108 Metrological Traceability*.

6.5 Externally Provided Products and Services

6.5.1 The Laboratory only uses quality critical products and services that are obtained from carefully selected and monitored external providers. *QP-109 Externally Provided Products & Services* defines the procedures used for evaluating, selecting, and monitoring these external providers.

6.5.2 The Laboratory retains all records for these processes according to *QP-114 Records Management*.

7.0 Process Requirements

7.1 Review of Requests, Proposals and Contracts

7.1.1 The Laboratory ensures that customer requirements, including the methods to be used, are adequately defined and understood; that the Laboratory has the capability and resources to meet the requirements, and that the appropriate test method is selected and capable of meeting the customer's requirements. *QP-110 Requests, Proposals, and Contracts* is used to conduct these reviews. Any differences between the request or proposal and the contract are resolved before any work commences. Each contract must be acceptable both to the Laboratory and the customer. Appropriate records of all reviews are kept.

7.2 Method Selection, Verification and Validation

7.2.1 Method selection is completed using *QP-110 Review of Requests, Proposals, and Contracts*.

7.2.2 Method verification of standard test methods is completed prior to method use as defined in *QP-111 Method Verification and Validation*. Records of these verifications are kept.

7.2.3 Method validation is conducted on non-standard methods, Laboratory-developed methods and standard methods used outside their intended scope and modifications of standard methods as defined in *QP-111 Method Verification and Validation*. Records of any method validations are kept.

7.3 Homogenization and Subsampling

7.3.1 The Laboratory does not conduct any field sampling. The Laboratory conducts appropriate homogenization and subsampling of customer submitted samples as defined in *QP-112 Subsampling*.

7.4 Sample Handling

7.4.1 All test samples received by the Laboratory are handled and protected in such a way as to ensure their integrity. *QP-113 Sample Handling* outlines the procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of test samples, including all provisions to protect the integrity of the test sample, and the interests of the Laboratory and the customer.

7.4.2 Test samples are systematically identified as they arrive at the Laboratory as defined in *QP-113 Sample Handling*. The identification is retained throughout the life of the sample in the Laboratory. The system is designed and operated so as to ensure that samples cannot be confused physically or when referred to in records. The system accommodates a subdivision of groups of samples and the transfer of samples within the Laboratory.

7.4.3 Upon receipt of the test sample, any abnormalities or departures from normal or specified conditions, as described in the relevant test method, are recorded. When there is any doubt as to the suitability of a sample for testing, or when the sample does not conform to the description provided, or the test required is not specified in sufficient detail, the Laboratory consults the customer for further instructions before proceeding and keeps a record of the discussion.

7.4.4 *QP-113 Sample Handling* also outlines the procedures and appropriate facilities for avoiding deterioration, loss or damage to the test sample during storage, handling, preparation, and testing; instructions provided with the sample are followed. When samples must be stored or conditioned under specified environmental conditions, these conditions are maintained, monitored, and recorded.

7.5 Records Management

7.5.1 The Laboratory ensures that all quality and technical records, as well as all data generated during testing activities, are properly maintained for a minimum of two years.

7.5.2 *QP-114 Records Management* is used to identify, collect, index, access, file, store, maintain, protect, backup, and dispose of quality and technical records. Quality records include reports from internal audits and management reviews as well as corrective actions and continual improvements. All records, other than quality records, are technical records.

7.5.3 Records are made available to demonstrate conformity to requirements and the effective operation of the management system. Records from and concerning customers, as well as records concerning external suppliers of products and services are maintained. All records, including test reports, are safely stored, held secure and in confidence to the customer. Records are maintained in the designated archival area. Electronic records are protected, backed-up, and unauthorized access and amendment to these records are not allowed.

7.6 Measurement Uncertainty

7.6.1 Estimates of measurement uncertainties are determined and recorded for all in-scope quantitative test methods, except when the methods preclude rigorous calculations. In those cases, the Laboratory attempts to identify all the components of uncertainty and make the best possible estimation.

7.6.2 *QP-115 Measurement Uncertainty* provides the details of estimating measurement uncertainty. Sources contributing to the uncertainty may include, but are not necessarily limited to sampling, sample homogeneity, subsampling, the reference standards, and reference materials used, the methods and equipment used, the environmental conditions, and the sample being tested.

7.7 Quality Control

7.7.1 The Laboratory monitors the validity (accuracy and precision) of test results by the inclusion of quality control measures in the performance of tests and by participation in Proficiency Testing.

7.7.2 *QP-116 Quality Control* and the Test Methods (TM's) describe the usual processes that involve the analysis of a Method Blank (MB), a Quality Control Sample (QCS), a Matrix Spike (MS), and a Sample Duplicate (SD) for each batch containing 20 samples or less.

7.7.3 The establishment of QCS acceptance criteria is based on historical measurements and control charts are used to evaluate the performance of the entire analytical system. Any QCS data found to be outside the control chart limits is addressed using *QP-120 Nonconforming Work* and *QP-126 Corrective Actions* and the resulting sample data are not reported to customers until the situation has been resolved.

7.7.4 *QP-117 Proficiency Testing Plan* describes the Laboratory's participation in various Accredited Proficiency Testing Schemes.

7.8 Reporting Results

7.8.1 The results of testing are provided to customers in test reports as specified in *QP-118 Reporting Results*. Each test report contains all the information requested by the customer and is intended to meet the requirements of PJLA ISO/IEC 17025:2017 with AOAC Working Document Sections 7.8.1 through 7.8.3. If the customer does not want all the required information to be reported and that requirement is part of the contract with the customer, it is readily available in the Laboratory.

7.8.2 The Laboratory does not provide opinions and interpretations of reported data.

7.9 Complaints

7.9.1 The Laboratory ensures that all complaints received from customers and other parties are properly addressed. Complaints resulting from nonconformities are processed according to *QP-119 Customer Feedback*. Records are maintained of all complaints and their follow-ups.

7.9.2 Records of all nonconformity complaints include the following:

a) Details of the complaint.
b) Necessary correction.
c) Root cause investigation.
d) Corrective action.
e) Follow-up verification of effectiveness.
f) A formal notice to the complainant at the end of the complaint process.

7.10 Nonconforming Work

7.10.1 The Laboratory ensures that all nonconforming testing work is properly contained and addressed with corrections and corrective actions.

7.10.2 *QP-120 Nonconforming Work* is used to contain and control any aspects of testing work, or the results of this work, when they do not conform to the test methods or the agreed upon requirements of the customer. Quality Control Sample failures and Proficiency Testing (PT) failures are the way nonconforming work is generally identified.

7.10.3 The procedure ensures that:

a) The responsibilities and authorities for the management of nonconforming work are designated.
b) Actions including halting of work and withholding test reports, as necessary, are taken when nonconforming work is identified.
c) An evaluation is made of the significance of the nonconforming work.
d) Correction is made immediately.
e) Where necessary, the customer is notified, and the work is recalled.
f) The responsibility for authorizing the resumption of work is defined.

7.11 Control of Data and Information Management

7.11.1 The Laboratory has access to all the data and information needed to perform its testing activities. The Laboratory ensures that all related instructions, manuals, and reference data related to Laboratory activities are readily available to personnel.

7.11.2 The Laboratory uses both computerized and non-computerized data management systems. The commercial laboratory information management systems (LIMS) software manual provides all the instructions for logging samples and generating customer reports. Any recording system failures are addressed with *QP-126 Corrective Actions*.

7.11.3 *QP-114 Records Management* includes procedures for managing both hard and soft copy data and records, including password access control and backup systems.

7.11.4 *QP-121 Software Validation and Data Review* includes procedures for the validation of Laboratory-developed software and a two-level review of quality control data, as well as calculations and data transfers.

7.11.5 The Laboratory does not use any external providers of LIMS.

8.0 Management System Requirements

8.1 Management System Documentation

8.1.1 The management system of the Laboratory has been established to formalize the quality practices and Laboratory activities employed to meet the scope, mission, and quality objectives of the Laboratory.

8.2 Document Control

8.2.1 Controlled copies of all management system documents (Quality Manual, Quality Procedures, Test Methods, equipment manuals, reference documents, *etc.*) used in the Laboratory are provided to Laboratory personnel as appropriate to their job responsibilities.

8.2.2 *QP-122 Document Control* provides instructions on document approval and issue, identification, reviewing, updating documents, and handling obsolete documents. Hand amendments of documents are not allowed.

8.3 Risk Management

8.3.1 The Laboratory considers the risks and opportunities associated with critical testing activities.

8.3.2 *QP-123 Risk Management* provides instructions for conducting risk assessments, risk identification, analysis, and treatment. The goal of this process is to ensure that the management system of the Laboratory achieves and enhances its goals and objectives, reduces unacceptable impacts and failures, and provides for its continual improvement.

8.3.3 All actions to address risks and opportunities are proportional to the potential impact on the accuracy and precision of test results.

8.4 Continual Improvement Process

8.4.1 The Laboratory continually improves the effectiveness of its management system through the use of the quality policy, quality objectives, customer feedback, analysis of quality control and other monitoring data, audit and assessment results, corrective actions, and management reviews.

8.4.2 *QP-124 Continual Improvement Process* provides the details of the Laboratory's implementation of this continual improvement philosophy, including the process for analyzing and using customer feedback and other data to improve the management system, Laboratory testing activities, and customer service.

8.5 Customer Communications

8.5.1 The Laboratory strives to ensure that there is always good communication with our customers before, during, and after projects are completed. *QP-119 Customer Feedback* provides the details of that communication, including facilitating customer audits and seeking customer feedback. Note: Excluded *QP-125 Customer Complaint* is merged with *QP-119 Customer Feedback.*

8.6 Corrective Actions

8.6.1 Corrective actions are initiated whenever unintended deviations (nonconformities) or nonconforming testing work has been identified, as defined in *QP-126 Corrective Actions.*

8.6.2 This procedure includes implementing corrections, conducting root cause analysis, selection and implementation of corrective actions, and monitoring the effectiveness of those corrective actions.

8.6.3 The Laboratory retains records as evidence of the nonconformities, root cause(s), corrective actions taken, and their results.

8.7 Internal Audits

8.7.1 Internal audits are conducted every calendar year to demonstrate compliance of the Laboratory with its management system and ISO/IEC 17025, as defined in *QP-127 Internal Audits.*

8.7.2 Independent and competent auditors conduct all internal audits.

8.7.3 Corrections and corrective actions are initiated for all nonconformities identified during these audits.

8.8 Management Reviews

8.8.1 The Management team reviews all aspects of the management system on a calendar year basis following the internal audits, according to the processes defined in *QP-128 Management Reviews.* The Management Review Process (WS-110) can be used as guidance.

8.8.2 All findings from management reviews are addressed using *QP-124 Continual Improvement Process.* Records of all reviews are kept.

Laboratory Quality Procedures

QP-100 Glossary

1. **SCOPE:**

   1.1. Purpose: This Glossary contains most of the terms used in the Laboratory's Management System. Document-specific terms can be found in particular documents.

   1.2. For the purposes of this manual, the following documents and their corresponding definitions apply; ISO/IEC 17000:2004; ISO/IEC Guide 99:2009; ISO 9000:2015; and ISO/IEC 17025:2017.

2. **OWNER:** State Chemist/Quality Assurance Manager

3. **DEFINITIONS:**

Note: Words printed in *italics* indicate those which are glossary entries.

Key References	Description
Accreditation	Formal recognition of a laboratory by an independent, science-based organization that the *Laboratory* is competent to perform specific tests.
Apparatus	Critical device used in *Test Methods*.
Arrangements	The most broadly defined type of document, could be as simple as a *Job Description* or a *Policy*.
Audit	A systematic, independent, *Documented Process* for obtaining audit evidence which can be *Records*, statements of fact, or other relevant information and assessing them objectively to determine the extent to which specified requirements are fulfilled; "Are we doing what we say?"
Internal Audit	Examines overall compliance with internal policy or regulatory requirements.
Horizontal Audit	Examines one element in a process on more than one item.
Vertical Audit	Examines more than one element in a process, on one item.
Authorities	The decisions a person makes in their job classification.
Authorized	The approval of a person to conduct a particular laboratory task.
Calibration	An operation that establishes a relation between the quantitative values and *Measurement Standards* with measurement uncertainties.
Calibration Record	The *Record* generated from *Calibration*.
Competent	Ability to apply knowledge and skills to achieve intended results; the ability to get the correct result.
Complaint	Expression of dissatisfaction by any person or organization in a laboratory, relating to the activities or results of that laboratory, where a response is expected.
Confidentiality	The property that information is not made available or disclosed to unauthorized individuals, entities, or processes; the protection of customers' confidential information and proprietary rights.
Continual Improvements	Action to identify needed improvements to the *Management System*.

Key References	Description
Contract	The written agreement between the customer and the *Laboratory* to conduct testing.
Control Chart	A graphical plot of quality control sample or other quality control results over time which include upper and lower warnings and control limits; control chart limits are defined below in Intermediate Precision.
Control Chart Rules	Rules used to establish whether an analytical system is "in control" or "out of control" and whether *Corrections* and *Corrective Actions* are to be taken, *e.g.*, quality control results that exceed the *Control Chart* limits are "out of control" and require *Corrections* and *Corrective Actions*.
Correction	Action to eliminate a detected nonconformity; the immediate action taken to correct a problem, usually to allow data to be reported to a customer; examples include making an adjustment, fixing a mistake, taking immediate remedial action, repeating analyses, recalibrating equipment.
Corrective Action	Action to eliminate the cause of a detected *Nonconformity*; the long-term action to investigate an identified problem using root cause analysis with the expectation that there will be a change to a document in the Management System that will prevent the identified problem from recurring and as a result improving the *Management System*.
Customer Feedback	Information coming directly from customers about the satisfaction or dissatisfaction they perceive about the *Laboratory's* service.
Customer Report	The final presentation to the customer of the results obtained from the test methods performed.
Data	Original or derived information obtained during the performance of a test method or the conduct of a study.
Decision Rule	Rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement.
Deficiency	See *Nonconformity*.
Departure	See *Nonconformity*.
Deviation	*Departure* from what is considered normal; a generic use of the deviation term – a corrective action would **NOT** be required [PJLA ISO/IEC 17025:2017 with AOAC Working Document Sections 6.2.3, 7.4.3, 7.8.2.1(n)]
Contract Deviation	A change to an agreement with the customer. Usually, this change is intentional. A *Corrective Action* would **NOT** be required [PJLA ISO/IEC 17025:2017 with AOAC Working Document Sections 7.1.4 and 7.1.5]
Planned Deviation	Intentional changes – a *Corrective Action* would **NOT** be required. [PJLA ISO/IEC 17025:2017 with AOAC Working Document Sections 7.2.1.7 and 7.3.3.(h)]
Test Deviation	An intentional and temporary change to a test method. This deviation requires a document to be prepared, approval by the document owner; technical justification to demonstrate the ability to get the correct result, and approval from the customer (this could also be a *Contract Deviation*). A *Corrective Action* would **NOT** be required [PJLA ISO/IEC 17025:2017 with AOAC Working Document Sections 6.2.3 and 7.4.3].

Key References	Description
Unintentional Deviation	An unplanned change to, or non-compliance with approved quality procedures. See *Nonconformity* – a *Corrective Action* would be required for PJLA ISO/IEC 17025:2017 with AOAC Working Document Section 5.6(c) and normally for Section 6.4.9 if data had been reported.
Document	A piece of written, printed, or electronic matter that tells a person in the *Laboratory* what to do or how to do it.
Document Control	The act of ensuring that documents (and their revisions) are proposed, reviewed for accuracy, approved for use by authorized personnel, distributed properly and maintained in such a way as to ensure the use of the correct version of the document at the location where the prescribed activity is performed.
Documented Process	A detailed description of how to execute a process outlining the exact steps needed to complete a task from start to finish.
Environmental Conditions	Laboratory conditions, such as temperature, humidity, biological sterility, and electrical supply that would negatively affect the ability to get correct results.
Five Whys	A technique for discovering the root cause of a problem and showing the relationship of causes by repeatedly asking the question, "Why?"
Goals	The output of the procedure for the identification of training needs. Goals and training needs are synonymous.
Identify and Identified	A record of a finding, for example a risk.
Impartiality	Presence of *Objectivity*.
Instructions	Detailed description of how something should be done.
Instruments	Measuring equipment or measuring instruments, *f*, Strain Gauges.
Interferences	Physical or chemical properties in the sample that would negatively affect the ability to get correct results.
Inter-laboratory Comparison	Organization, performance, and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions.
Intermediate Precision	The precision of an analytical procedure that expresses the closeness of agreement between a series of measurements obtained from multiple sampling of the same homogeneous sample under the prescribed conditions; intermediate precision expresses within laboratories variations
Interrelationships	The vertical and horizontal connections with other laboratory staff.
Intra-laboratory Comparison	Organization, performance, and evaluation of measurements or tests on the same or similar items within the same laboratory in accordance with predetermined conditions.
Job Descriptions	The definition consists of job responsibilities, authorities, and interrelationships.
Laboratory	Mississippi State Chemical Laboratory (MSCL). Body that performs one or more of the following activities
List	A sequential record.
Management Review	A self-evaluation of the *Laboratory's* management system documents and testing activities for the purpose of improving the *Quality Management System*.

Key References	Description
Management System	A set of documented, written, processes, instructions, arrangements, responsibilities, and authorities to ensure that a laboratory can fulfill all tasks required to achieve its objectives. This system consists of the documents described in QM-003.
Measurand	The quantity intended to be measured, *e.g.*, amount-of-substance; in chemistry, "analyte" or the name of a substance or compound, are terms sometimes used for "measurand." This usage is erroneous because these terms do not refer to quantities.
Measurement	Process of experimentally obtaining one or more quantity values that can reasonably be attributed to a quantity.
Measurement Accuracy or Accuracy	The closeness of agreement between a measured quantity value and a true quantity value of a measurand.
Measurement Bias	The estimate of a systematic measurement error.
Measurement Error	The measured quantity value minus a reference quantity value.
Measurement Precision	The closeness of agreement between indications or measured quantity values obtained by replicate measurements on the same or similar objects under specified conditions.
Measurement Procedure	The detailed description of a measurement according to one or more measurement principles and to a given measurement method, based on a measurement model and including any calculation to obtain a measurement result.
Measurement Standard	Measurement standard designated for the calibration of other measurement standards for quantities of a given kind in a given organization or at a given location. *e.g.*, a traceable 1 kg mass is a reference standard.
Measurement Traceability	The property of a result of a measurement whereby the result can be related to a reference (standard or material) through a recorded, unbroken chain of calibrations, each contributing to the measurement uncertainty.
Measurement Uncertainty	Parameter characterizing the dispersion of the quantity values being attributed to a measurand.
Nonconformance	See *Nonconformity*.
Nonconformity	The failure to properly follow policies, procedures, instructions, or the nonfulfillment of a specified requirement.
Objective Evidence	The facts that either prove compliance or show nonconformance.
Objectivity	A conflict of interest does not exist or is resolved so as not to adversely influence subsequent activities of the *Laboratory*. Other terms include "freedom from conflict of interests", "freedom from bias", "lack of prejudice," "neutrality," "fairness," "open-mindedness," "even-handedness," "detachment," or "balance."
Obsolete Document	A document that is no longer in use but describes the process from time "A" to time "B".
Opportunity For Improvement	A preventive action that is a proactive process to identify opportunities for improvement rather than a reaction to a problem or complaint.
Organizational Charts	The organizational structure of the *Laboratory* management and staff.

Key References	Description
Plan	A written document that usually defines "how" and "when" something is going to be done, *e.g.*, continual improvements, and action items from management reviews.
Policy	The rule, the "what", or an overarching plan (direction) for achieving a laboratory's goals.
Precision	See *Measurement Precision.*
Procedure	The step-by-step instructions, the "how", or the steps in a process and how these steps are to be performed for the process to fulfill specified requirements.
Proficiency Testing	Evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons.
Program	A written document that usually defines "what", "how", "when" and "who" for something to be done, *e.g.*, equipment calibration.
Purchasing Documents	Purchase orders, requests, requisitions, or releases.
Qualified	See *Competent.*
Quality Control	Those activities that are performed during the analysis to fulfill the requirements for quality; normally a quality control sample, that is in the sample matrix with known values, is taken through the full method as opposed to just the final determinative step.
Quantity	Property of a phenomenon, body, or substance, where the property has a magnitude that can be expressed as a number and a reference, *e.g.*, amount-of-substance concentration of ethanol in wine sample.
Records	The proof that documents in the *Laboratory's Management System* have been followed – the assessor/auditor believes that if there is no record, the task has not been done.
Reference Material	A material, sufficiently homogeneous and stable with reference to specified properties, which has been established to be fit for its intended use in measurement, *e.g.*, a consumable material with known quantities of trace metals.
Reference Standard	See *Measurement Standard.*
References	External or internal documents that were used to develop the test method or are closely associated with the test method.
Request	An inquiry from the customer to the *Laboratory* relative to testing activities.
Responsibilities	What a person does in their job classification.
Root Cause Analysis	A problem-solving process or the process of asking the "why" question relative to the identified problem to determine the bottom-line causal factor(s) and to use that analysis to improve the process.
Schedule	A written document that defines "when" something is to be done, *e.g.*, internal audits or management reviews.
Scope and Applicability	Defines the parameter being analyzed and the matrix or matrices of the samples; also refers to any restrictions with respect to applicability.
Shall	Imperative or "must" – a requirement in ISO/IEC 17025.
Should	Strong recommendation or "guideline" – a note in ISO/IEC 17025.

Key References	Description
Software	A general term used to describe a collection of computer programs, procedures, and documentation that perform some data-related task on a computer system.
Specify and Define	Terms used in ISO/IEC 17025
Systematic Measurement Error	The component of measurement error that in replicate measurements remains constant or varies in a predictable manner.
Test Method	All of the critical activities to be performed to obtain analytical results; same as standard operating procedure.
Test Result Critical	An item which would affect the quality of the test or test result.
University	Mississippi State University.
Validation	A *Verification*, where the specified requirements are adequate for an intended use (*e.g.*, a procedure, ordinarily used for the measurement of mass concentration of nitrogen in water may be validated also for measurement in another matrix). The confirmation by examination and the provision of objective evidence that the requirements for a specific intended use are fulfilled (ISO/IEC 17025)
Validation Records	The confirmation by examination and provision of objective evidence that the requirements for a specific intended use are fulfilled. Or, to put it simply, "Does the test method meet the intended use of the customer?".
Verification	The provision of objective evidence that a given item fulfills specified requirements, *e.g.*, confirmation that performance properties of a measuring system are achieved.

QP-101 Impartiality

1. **SCOPE:**

   1.1. This procedure applies to all Laboratory and testing activities conducted within the Laboratory.

   1.2. To ensure that all Laboratory personnel are free from internal and external commercial, financial, and other pressures and influences that may adversely affect the quality of their work and to ensure impartiality in all Laboratory activities.

2. **OWNER:** State Chemist/Quality Assurance Manager

3. **DEFINITIONS:**

   3.1. Impartiality: presence of objectivity, where decisions and actions are made without bias, favoritism, or conflict of interest, ensuring fairness and neutrality.

   3.2. Objectivity: conflicts of interest do not exist or are resolved so as not to adversely influence subsequent activities of the Laboratory; other terms include "freedom from conflict of interests," "freedom from bias," "lack of prejudice," "neutrality," "fairness," "open-mindedness," "even-handedness," "detachment," "balance."

4. **PROCEDURE:**

   4.1. The Laboratory policy requires all personnel to abide by the University Operating Policies and Procedures (www.policies.msstate.edu), as well as this procedure.

   4.2. New employees are required to attend an orientation program where the details of these requirements are reviewed. Records of such training shall be kept.

   4.3. Laboratory management shall review any changes to the Laboratory's Quality Manual and related Quality Procedures when they are changed or modified and provide training on the identified updates. Records of such training shall be kept.

   4.4. All test reports shall be reviewed by a second qualified person prior to issuance to ensure impartiality.

   4.5. Employees are not permitted to discuss testing activities with customers without written permission from management to ensure freedom from conflicts of interest.

   4.6. Employees shall not falsify records, prepare fraudulent reports, or make false claims.

   4.7. Employees shall not accept gifts or gratuities from customers in an attempt to influence the MSCL's decisions or results, as per Mississippi State University operating policy.

   4.8. Employees shall not conduct non-Laboratory business on Laboratory time or use Laboratory facilities or equipment to conduct outside interests unless prior approval has been obtained.

   4.9. Employees shall not solicit business on their own behalf from a customer or any other entity.

   4.10. Employees shall not work for another entity without approval from the State Chemist.

   4.11. Employees shall not have personal financial dealings with an individual or company that does business with the Laboratory which might influence decisions made on the Laboratory's behalf.

   4.12. Employees shall not allow associates, family, or friends to influence business decisions to their own benefit, but only to the best interest of the Laboratory.

   4.13. Employees shall not make any decision in order to provide gains or benefits to the employee and/or others.

   4.14. If actual or perceived internal or external undue pressures exist, employees are required to submit a written notification (*e.g.*, email or formal letter) to the Director(s), Laboratory Managers, or Quality Assurance Division.

4.15. Should employees deliberately compromise the quality and integrity of their work, the individual will be held accountable for such conduct as defined in the University Operating Policies and Procedures.

4.16. Use F-021 MSCL Risk Assessment Form to identify and minimize the potential risk to laboratory's impartiality.

4.17. It is possible that the Mississippi State University President, Provost and Executive Vice President, Vice President and Associate Vice President of Research could direct the State Chemist to comply with an action that may affect the quality of results or that may present a potential conflict of interest. If such a situation were to occur, the State Chemist would discuss the issue with the Mississippi State University President, Vice President, and Associate Vice President of Research. The State Chemist may refer the issue to the State Attorney General or to the University Legal Counsel.

4.18. Annually, MSCL employees will complete the Personnel Qualification and Authorization Form (F-003), documenting that they have read and understand the Impartiality procedure.

4.19. Conflict-of-interest agreements are completed as required by Mississippi State University's Office of Research Compliance & Security.

4.20. Conflict-of-interest training is required annually for all employees of the Laboratory.

NOTE: By means of this policy, procedure, and the communication of the Management System to all employees, management ensures that employees are never instructed or forced to alter or falsify data. To ensure confidence in Laboratory operations, a formal Management System has been implemented. Technical competence is ensured through ongoing quality control and equipment calibration. Impartiality is assessed through internal and external audits. Judgment is ensured through the hiring of qualified personnel and by continuously refining, upgrading, and improving their skills. Operational integrity is reviewed by management on a regular basis during internal audits to verify compliance with the Laboratory's Management System and at management review meetings to ensure continued suitability and effectiveness of Laboratory policies and procedures. Any problems are acted on immediately through the corrective action procedures.

QP-102 Confidentiality

1. **SCOPE:**

   1.1. This procedure applies to all testing activities conducted within the Laboratory.

   1.2. To ensure that our customers' information and proprietary rights are properly protected, including the transmission and storage of their electronic results, and not made available or disclosed to unauthorized parties.

2. **OWNER:** State Chemist/Quality Assurance Manager

3. **DEFINITIONS:**

   3.1. Confidentiality: The property that information is not made available or disclosed to unauthorized individuals, entities, or processes; the protection of customers' confidential information and proprietary rights.

4. **PROCEDURE:**

   4.1. Employees and other personnel, including contractors, personnel of external bodies, or individuals acting on behalf of the Laboratory, are not to disclose customer confidential or proprietary information to anyone without the explicit written consent of the customer and Laboratory management, except when required by law.

   4.2. The majority of test results are for the use of external customers. These test results are only to be released to our customers or their designated representative. Release of test results to someone outside of the Laboratory requires the expressed written permission of the customer and Laboratory management, except when required by law.

   4.3. When the Laboratory is required by law or contractual arrangements to release confidential information of the customer, unless prohibited by law, the customer shall be notified in writing of the information provided.

   4.4. Any information about the customer obtained from sources other than the customer (*e.g.*, a complaint or an accreditation body) shall be confidential to the Laboratory and not shared with the customer, unless agreed by the source. The identity of the source of information shall be also kept confidential.

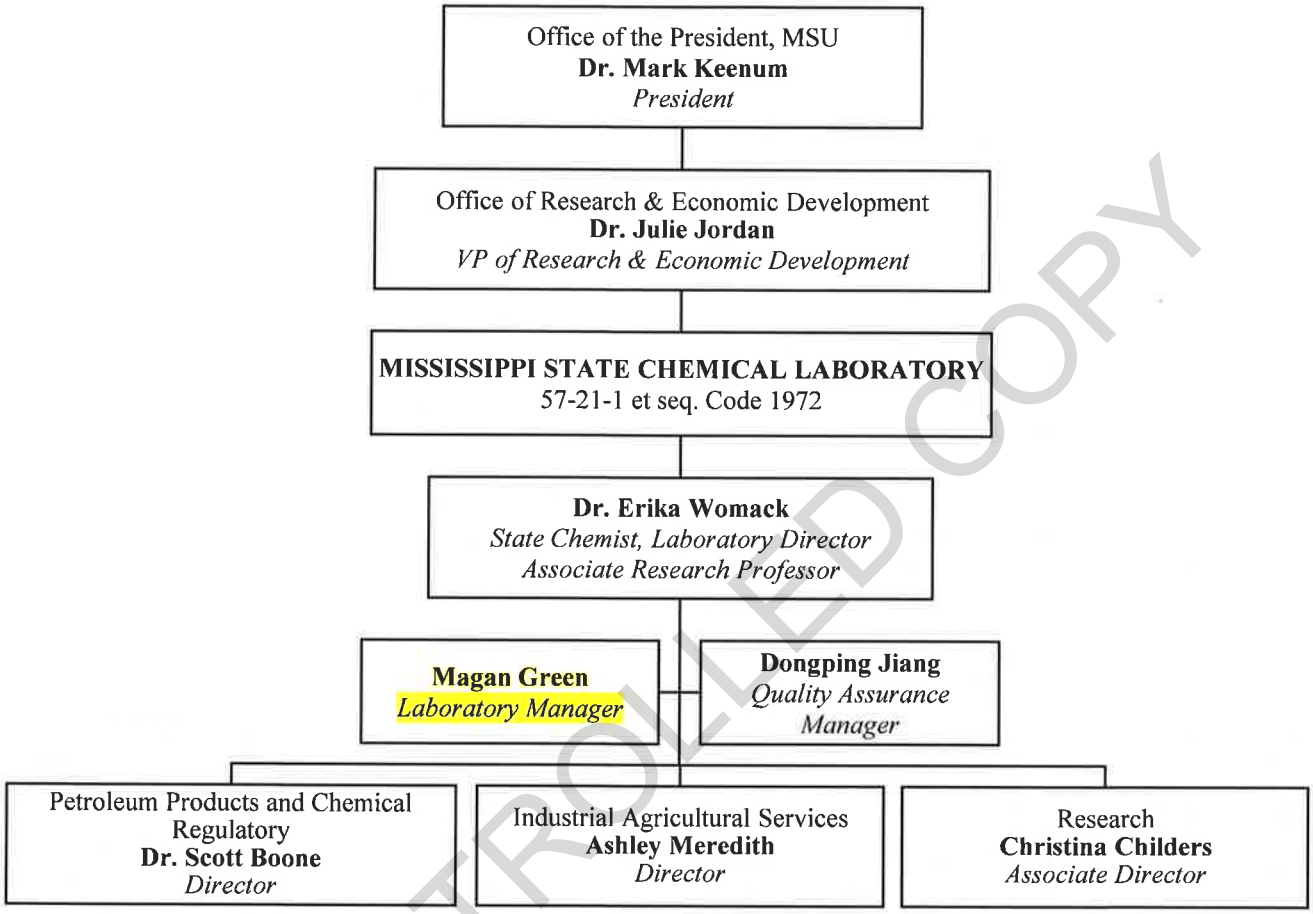
   4.5. Test results shall be maintained in a secure database that is accessed only through the use of personnel with appropriate permissions and passwords.

   4.6. Employees are not to use privileged information or data from any customer for any purpose beyond the scope of employment.

   4.7. Employees shall ensure that during customer audits, other customers' information shall not be viewed or evaluated in any manner. This is best accomplished by not allowing access to such information and always escorting the customer's auditor during their entire visit.

   4.8. Test results submitted to customers electronically, either by email or by fax shall be accompanied by the following statement: "This communication is intended only for the individual or entity to which it is directed. It may contain information that is privileged, confidential, or otherwise exempt from disclosure under applicable law. Dissemination, distribution, or copying of this communication by anyone other than the intended recipient, or a duly designated employee or agent of such recipient, is prohibited. If you have received this communication in error, please notify us by telephone at (662) 325-3324 or via e-mail at mscl@info.msstate.edu and delete this message and all attachments thereto. Thank you."

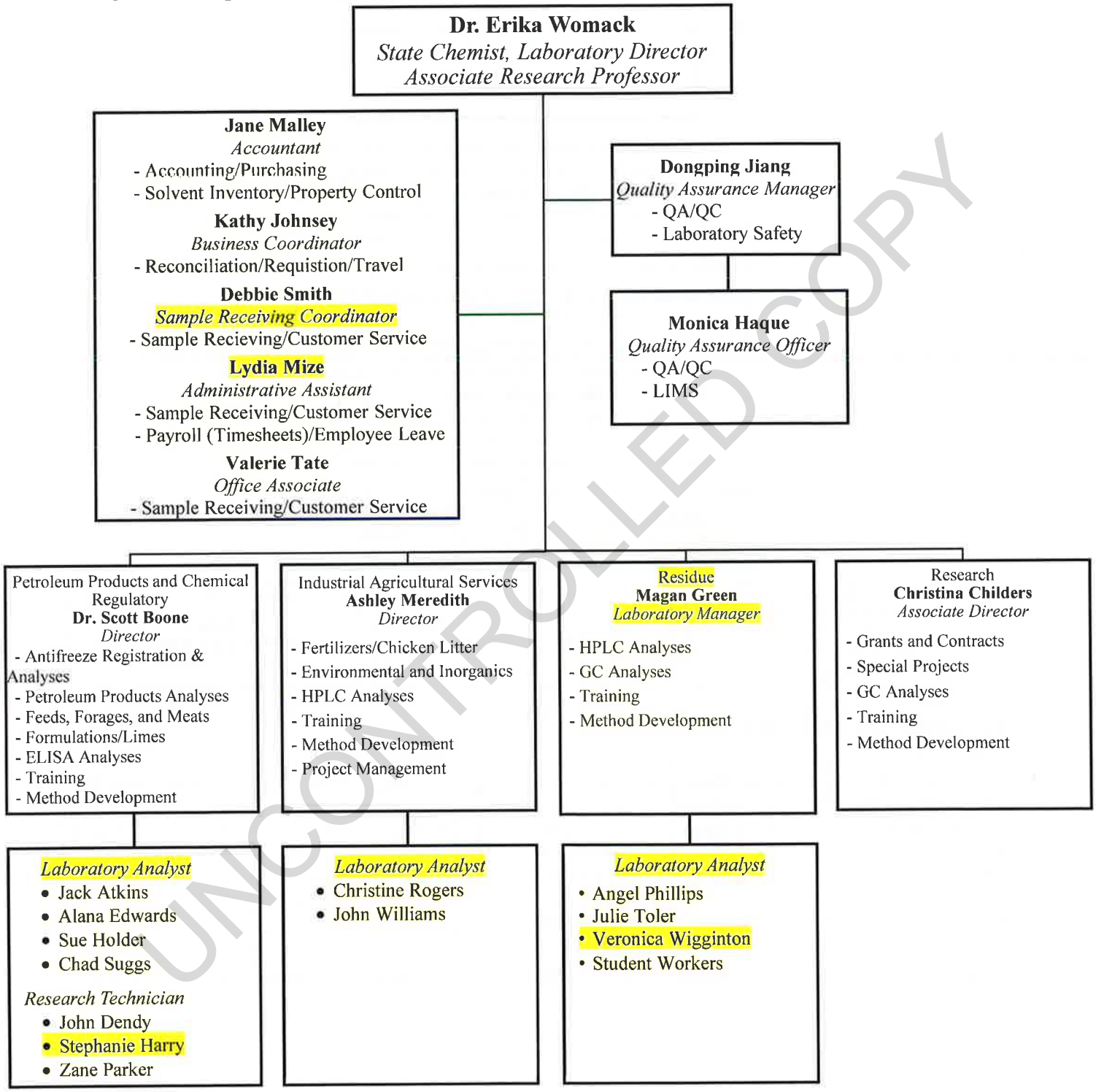
QP-103 Organizational Structure



Managerial Reporting Lines:

Erika Womack	Dongping Jiang	Scott Boone	Magan Green	Ashley Meredith
• Kathy Johnsey • Jane Malley • Lydia Mize • Debbie Smith • Valerie Tate	• Monica Haque	• Jack Atkins • John Dendy • Alana Edwards • Stephanie Harry • Sue Holder • Zane Parker • Chad Suggs	• Angel Phillips • Julie Toler • Veronica Wigginton • Student Workers	• Christine Rogers • John Williams

QP-104 Responsibilities, Authorities, and Interrelationships



Note: The Laboratory has designated secondary and tertiary deputies for all supervisory roles. These deputies are shown in the following table:

Operation/Division	Principal	1st Back-up	2nd Back-up
Regulatory *Petroleum Products*	Scott Boone	Erika Womack	Ashley Meredith
Regulatory *Feeds, Forages, and Meats*	Scott Boone	Christina Childers	Jack Atkins
Regulatory *Environmental Chemical*	Scott Boone	Ashley Meredith	Magan Green
Research *Grants and Contracts*	Christina Childers	Erika Womack	Scott Boone Ashley Meredith
Industrial and Agricultural Services	Ashley Meredith	Christina Childers	Scott Boone
Quality Assurance	Dongping Jiang	Monica Haque	Christina Childers
Business Office	Erika Womack	Jane Malley	Kathy Johnsey
State Chemist	Erika Womack	Scott Boone	Ashley Meredith
Sample Receiving/Login	Debbie Smith	Valerie Tate	Lydia Mize
LIMS	Monica Haque	Erika Womack	Angel Phillips

QP-105 Training

1. **SCOPE:**

   1.1. This procedure applies to all personnel within the Laboratory.

   1.2. To ensure that personnel, whose job activities affect test data, are competent and qualified based on appropriate education, experience, and/or demonstrated skills.

   1.3. To establish procedures for recognizing training requirements and delivering training within the Laboratory.

   1.4. To ensure that records of the training, competency, and authorization of all technical personnel are maintained.

2. **OWNER:** State Chemist/Quality Assurance Manager

3. **DEFINITIONS:**

   3.1. Awareness: to acquaint personnel with the responsibilities, procedures, and objectives related to generating the required quality of testing activities (WS-054 New Employee ISO 17025 Training Checklist; WS-055 The MSCL Manager's Onboarding Checklist; WS-056 The MSCL New Employee Onboarding Checklist; WS-057 The MSCL New Student Worker Onboarding Checklist).

   3.2. Identification of training needs: to establish the goals for initial and ongoing training of all personnel.

   3.3. Training: the preparation of personnel to perform their work effectively (WS-035, Personnel Qualifications and Training).

   3.4. Competence: the demonstrated ability to apply knowledge and skills effectively to achieve acceptable results.

4. **PROCEDURE:**

   4.1. Identification of Training Needs

      4.1.1. *QP-104 Responsibilities, Authorities, and Interrelationships* will be used for the identification of training needs (education, experience, training, knowledge, skills) and to evaluate an employee's competencies.

      4.1.2. New employee's skills will be compared to *QP-104 Responsibilities, Authorities, and Interrelationships* and training goals will be identified The review of a new employee's resume or employment applications may also be used for this purpose.

      4.1.3. To ensure ongoing qualification and capability of all personnel to meet job requirements by identifying and addressing any disparities between job descriptions and the actual work experience, skills, and education of the employee.

      4.1.4. If a gap is identified between the requirements of the job position versus the actual skills and education of any employee, a training matrix will be prepared by management or supervisor to ensure that any required training is scheduled.

      4.1.5. As appropriate, the person will be required to demonstrate the necessary skills prior to his or her authorization to perform the related tasks.

      4.1.6. Form F-013 Test Method Approved Analysts details the responsible directors, laboratory managers, and authorized/trained personnel for each in-scope test method and will be updated when applicable.

   4.2. Provision of Required Training

      4.2.1. All new employees receive orientation, which covers a review of the Laboratory's quality policy, objectives, and relevant Management System documents. New employees are made aware of the relevance and importance of their activities and how they contribute to the

achievement of quality objectives of the Management System. (WS-054 New Employee ISO 17025 Training Checklist; WS-055 The MSCL Manager's Onboarding Checklist; WS-056 The MSCL New Employee Onboarding Checklist; WS-057 The MSCL New Student Worker Onboarding Checklist).

4.2.2. Training on test activities is conducted in each division. The general approach is to describe the process in detail by reading the procedures and clarifying the process with the new employee, by demonstrating the process, by observing the new employee while performing the process and finally by requiring the new employee to pass an appropriate performance test related to the process. Training is recorded in F-007, MSCL Training Form. A portion of a method training is also recorded in F-007 if applicable.

4.2.3. The effectiveness of the training provided is assessed in one of several ways which include on the job observation of employee work activities, obtaining correct results on Quality Control Samples, Proficiency Test Samples, and other samples with certified values. Effectiveness can also be evaluated by conducting employee performance reviews or monitoring the causes of nonconformities to determine trends that are associated with an employee's job skills, work performance, or job knowledge that may indicate that additional training is required. If a trend is identified, training is scheduled to ensure continued satisfactory job performance. Training is recorded in F-007, MSCL Training Form.

4.2.4. The Quality Division provides annual training for employees to ensure their continued knowledge and familiarization with the Management System policies and procedures. The quality objectives and quality policy are reviewed with employees on a regular basis.

4.2.5. Laboratory management formally authorizes personnel to carry out specific laboratory activities: test method development, modification, verification, and validation, as well as the analysis of test results, report review, authorization of test results, and handling of complaints.

4.2.6. Training files shall contain records of training, education, skills, experience, as well as the competency and authorization of the person to perform certain activities. Dates for the competency and authorization are also kept. Employees will submit a completed F-003 Personnel Qualification/Authorization Form and F-012 Annual Performance Goals annually with the MSCL Annual Evaluation. F-012 will be kept with personnel records.

QP-106 Facility Monitoring

1. **SCOPE:**

   1.1. This procedure applies to all testing activities conducted within the Laboratory.

   1.2. To ensure that Laboratory testing areas are suitable to avoid trace system contamination from exposure to high level standards/formulations.

   1.3. To ensure that the available equipment and environmental conditions in the Laboratory facilitate the ability to produce valid results, and necessary conditions are monitored and documented.

2. **OWNER:** State Chemist/Quality Assurance Manager

3. **DEFINITIONS**

   3.1. Monitoring: determining the status of a system, process, product, service, or activity; synonymous with auditing.

      3.1.1. Monitoring is generally a determination of the status of an object carried out at different stages or at different times.

4. **PROCEDURE**

   4.1. Laboratory areas

      4.1.1. Laboratory areas are separated to decrease the likelihood of trace system contamination from high level standards or samples.

      4.1.2. Neat standards are weighed in a separate room with balances for dilutions and have sinks for cleaning.

      4.1.3. Formulations and formulation analysis are kept in separate laboratory spaces from trace systems.

      4.1.4. The Laboratory does not perform laboratory activities at sites or facilities outside of its control.

   4.2. Temperature Monitoring

      4.2.1. The Laboratory continuously monitors temperature in refrigerators and freezers, as shown in WS-071, Monitoring Temperature of the Refrigerators/Freezers & Thermometer Verification.

      4.2.2. The temperatures of the devices are defined in the Test Methods.

      4.2.3. The reference thermometer is calibrated every 2 years, using an accredited ISO/IEC 17025:2017 calibration laboratory. Certificate of Calibration are properly endorsed with the accreditation body's symbol and certificate number and maintained using *QP-114 Records Management.*

      4.2.4. Any exceedances in temperature are evaluated. If the exceedances affected the quality of test results, the full process in *QP-126 Corrective Actions* is followed.

   4.3. Facility access

      4.3.1. The Laboratory uses a security card-key access system for all exterior doors.

      4.3.2. Permissions are established in this system for all Laboratory personnel, as well as for the contracted maintenance service personnel.

         4.3.2.1. New personnel are given access permissions.

         4.3.2.2. Permissions are removed for any personnel no longer employed by the Laboratory.

QP-107 Equipment

1. **SCOPE:**

   1.1. This procedure is applicable to all personnel operating equipment.

   1.2. Applicable to all Laboratory equipment, as defined below.

2. **OWNER:** State Chemist/Quality Assurance Manager

3. **DEFINITIONS:**

   3.1. General service equipment: equipment not used for measurement, but can affect the test results (*e.g.*, ovens, furnaces, hotplates, stirrers, non-volumetric glassware).

   3.2. Volumetric equipment: equipment used for measurement that will affect the test results (*e.g.*, volumetric flasks, volumetric pipets, burets, syringes, mechanical pipets).

   3.3. Measuring equipment: equipment used for measurement that will affect the test results (*e.g.*, balances, thermometers, gas chromatographs, meters, spectrophotometers).

4. **PROCEDURE:**

   4.1. General service equipment

      4.1.1. Check for proper functioning and whether the equipment is fit for purpose.

      4.1.2. If everything is acceptable, put into use or continue use.

      4.1.3. If anything is not acceptable, repair or replace.

   4.2. Volumetric equipment

      4.2.1. Prior to initial use and ongoing use:

         4.2.1.1. Check for damage upon receipt.

         4.2.1.2. Conduct an initial and ongoing verification using a dispense and weigh technique.

         4.2.1.3. If this verification is acceptable, put into use or continue use.

         4.2.1.4. If the verification is not acceptable, repair or replace.

   4.3. Measuring equipment

      4.3.1. Prior to initial use:

         4.3.1.1. Conduct an Installation Qualification to ensure that the equipment meets Laboratory's or OEM's specifications (see PJLA ISO/IEC 17025:2017 with AOAC Working Document Section 6.4.4) and ensure that appropriate records of this process are maintained (see PJLA ISO/IEC 17025:2017 with AOAC Working Document Section 6.4.13c).

         4.3.1.2. If the specifications are met, the equipment may be placed into service.

      4.3.2. Prior to ongoing use:

         4.3.2.1. Calibrate or verify the calibration of the equipment as required.

         4.3.2.2. See Test Methods and *QP-108 Metrological Traceability* for details on calibration, verification, and maintenance.

      4.3.3. Equipment that cannot be properly calibrated or verified for use shall be taken out of service and either repaired or replaced.

   4.4. Equipment Qualification

4.4.1. When new equipment is installed, the Laboratory may elect to purchase Installation Qualification (IQ) and Operation Qualification (OQ) from the manufacturer or installer. This information is kept with the equipment records.

4.4.2. Alternatively, for new or used equipment the Laboratory may determine independently that quality and technical specifications have been met. Equipment is not used until this has been completed and users have been trained in its operation.

4.5. Equipment Maintenance and Performance

4.5.1. An equipment maintenance schedule, including preventative maintenance recommended by the manufacturer, is established for the servicing of Laboratory equipment.

4.5.2. Records of the maintenance are kept demonstrating that the procedure is being followed (*e.g.*, in the instrument logbook).

4.5.3. Equipment is maintained according to manufacturer's recommendations. In the absence of manufacturer's instructions, Laboratory developed instructions are provided.

4.5.4. Refer to the specific Equipment Manual of each instrument for information on minimum maintenance requirements for quality critical equipment.

4.5.5. General service equipment is maintained only with cleaning and operational checks unless stated otherwise in Equipment Manuals, Test Methods, or worksheets.

4.5.6. Use of outside contractors to perform repairs or maintenance is at the discretion of Laboratory management.

4.5.7. Initial calibration or verification (intermediate check) procedures are prepared for all quality critical Laboratory equipment used to perform testing. In lieu of preparing a separate procedure, if the calibration/verification procedure is described in equipment manuals, test methods or worksheets, no additional instructions are required.

4.5.8. Records of calibration and verification are maintained in a logbook or file.

4.5.9. Minimum calibration and verification schedules for some Laboratory equipment are found in Equipment Manuals, Test Methods, and/or worksheets. For other quality critical equipment with no listed schedule, a calibration/verification schedule is developed and maintained.

4.5.10. Calibration and verification of some equipment systems is addressed in the Equipment Manuals, Test Methods, or worksheets. Traceability is maintained along with specific method performance criteria, which includes a reference standard or reference material.

4.5.11. Instruments which fail a calibration or verification parameter

4.5.11.1. All results between passing calibration and passing verification can be reported.

4.5.11.2. All results between passing and failing calibration or verification and after failing calibration or verification will be held until appropriate corrections are implemented.

4.6. Out of Service Equipment

4.6.1. Quality critical equipment that is not in use and has not been calibrated or verified, shall be clearly tagged as being out of service. For example, a sign on it can state, "Calibration Void Do Not Use", "Out of Service Do Not Use", or "Instrument Out of Service Calibrate/Verify Before Use."

4.6.2. Quality critical equipment is not returned to service until acceptable performance checks and verifications have been performed and recorded in the instrument's logbook. An exception may be made if the equipment failure is not directly related to its analysis function, such as a problem with peripheral equipment.

4.6.3. Equipment that is not operating properly is tagged, taken out of service, and clearly marked to show that it is out of service.

4.6.4. Out of service equipment must be calibrated or verified prior to placing back into use.

4.6.5. When, for whatever reason (*e.g.*, repair or calibration), equipment goes outside the direct control of the Laboratory, the Laboratory shall ensure that the function and calibration status of the equipment and its software are checked and shown to be satisfactory before the equipment is returned to service.

4.7. Handling, Use, Storage, and Transport of Equipment

4.7.1. Each instrument or piece of equipment has step-by-step instructions for its start-up, operation, and shutdown described in the manufacturer's manuals or per Laboratory procedure.

4.7.2. Equipment is operated by personnel specifically authorized to perform the test method and operate the associated equipment.

4.7.3. Sensitive equipment is transported or moved according to manufacturer's instructions. Equipment is not returned to service until performance checks and verifications have been performed and recorded.

4.8. Original computer software is write-protected and, in most cases, password-protected to prevent unauthorized program adjustments.

QP-108 Metrological Traceability

1. SCOPE:

1.1. This procedure applies to the calibration of all quality critical equipment using reference standards and reference materials that are traceable to the International System of Units or through an appropriate reference material producer.

2. OWNER: State Chemist/Quality Assurance Manager

3. DEFINITIONS

3.1. Metrological Traceability: property of a measurement result whereby the result can be related to a reference (standard or material) through a documented, unbroken chain of calibrations, each contributing to the measurement uncertainty.

3.2. Calibration: An operation that establishes a relation between the quantity values and measurement standards with measurement uncertainties.

3.3. Verification: The provision of objective evidence that a given item fulfills specified requirements, *e.g.*, confirmation that performance properties of a measuring system are achieved.

4. PROCEDURE

4.1. Equipment

4.1.1. All quality critical measuring equipment in the Laboratory are labeled with a unique identification.

4.1.2. The inventory records contain the following information:

4.1.2.1. Item and its software.

4.1.2.2. Manufacturer and model.

4.1.2.3. Serial number or other unique identification.

4.1.2.4. Location.

4.1.3. The label or tag found on or near the equipment contains the following information, if applicable:

4.1.3.1. unique identification.

4.1.3.2. date of last calibration.

4.1.3.3. date of the next calibration.

4.1.4. Equipment that is scheduled to be calibrated daily or with each use is not required to be tagged with calibration dates. See *QP-107 Equipment* qualification and maintenance.

4.1.5. Small items with insufficient space to record the information on the label (*e.g.*, thermometers) need only be identified with their unique identification number.

4.2. Reference Standards and Reference Materials

4.2.1. The calibration of reference standards (*e.g.*, weights) shall be performed by an ISO/IEC 17025:2017 accredited calibration laboratory and the Certificates of Analysis of their calibrations shall be endorsed with the Accreditation Body's symbol and Certificate Number.

4.2.2. Reference materials are to be obtained from ISO Guide 34 Reference Material Producers, where relevant and available. The Certificates of Analysis of these materials shall be endorsed with the Accreditation Body's symbol and Certificate Number.

4.2.3. Reference standards and reference materials are to be stored, handled, and transported according to manufacturer's specification. Their information including the receiving date, manufacturer's

expiration date or laboratory determined expiration date, name, description, manufacturer's lot number, and laboratory identifier is recorded in the master list where practicable.

4.2.4. Reference Material shall be labeled with the date received and expiration date.

4.2.5. Disposal of Reference Standards and Materials. The master list shall be reviewed monthly for expired standards and materials. Within 30 days of expiration the standards or materials are either disposed of or recertified by the company, demonstrating that they are still suitable for use.

4.2.6. When commissioning test information is not available, the equipment logbook should be endorsed: "Equipment in use at implementation of records."

4.3. Reagent

4.3.1. Reagents prepared in the lab are generally assigned for one-year expiration date. A shorter expiration date might be assigned based on the experimental data. When expired reagents are identified, they are disposed of according to the Mississippi State University hazardous waste disposal procedures.

4.3.2. Expired reagents and expired reference standards and materials are prohibited to use in the lab unless recertified.

QP-109 Externally Provided Products & Services

1. **SCOPE:**

   1.1. This procedure applies to all personnel within the Laboratory.

   1.2. To define the process for the selection, purchasing, receipt, and verification of test result critical equipment, services, and supplies used in the Laboratory.

2. **OWNER:** State Chemist/Quality Assurance Manager

3. **DEFINITIONS:**

   3.1. Selection: identification of the most appropriate equipment, service, or supply.

   3.2. Purchasing: to procure the appropriate equipment, service, or supply.

   3.3. Receipt: accepting and evaluating the quality of the equipment, service, or supply.

   3.4. Quality Check: confirmation of the reliability of purchased services and supplies; must be free of contaminants or interferences and demonstrate acceptable performance.

   3.5. Test Result Critical (TRC): an item which would affect the quality of the test or test result.

4. **PROCEDURE:**

   4.1. Selection of TRC equipment, products, and supplies

      4.1.1. TRC supplies shall be identified and established based upon previous testing experience within the Laboratory. Any addition of new suppliers/supplies will be tested with Quality Control Samples (QCS) and blanks to verify quality using the same analytical method for the analytes.

      4.1.2. The individual Test Methods shall include the specifications and requirements of all TRC services and supplies. Such materials shall be identified with a *TRC* identifier following the specifications in those methods.

      4.1.3. The specifications for Reference Standards and Reference Materials are found in *QP-108, Metrological Traceability*.

      4.1.4. Any changes, additions, or deletions of TRC services and supplies shall be approved by a member of the Management Team.

   4.2. Selection of TRC Services

      4.2.1. Director(s), Laboratory Managers, or Quality Assurance Division shall identify any specific requirements for Subcontract Laboratories, Equipment Calibration Services, Accreditation Bodies, and Proficiency Test Providers.

      4.2.2. Where relevant and available, Subcontract Laboratories shall be an ISO/IEC 17025:2017 Accredited Laboratory and their Scope of Accreditation shall be kept on file as evidence of their competence.

      4.2.3. Where relevant and available, Equipment Calibration Services shall be conducted by an ISO/IEC 17025:2017 Accredited Calibration Laboratory and their Scope of Accreditation shall be kept on file as evidence of the competence.

      4.2.4. Accreditation Bodies used by the Laboratory shall be recognized through a Mutual Recognition Agreement with the International Laboratory Accreditation Cooperation (ILAC).

      4.2.5. Where relevant and available, Proficiency Testing Providers shall be accredited by organizations that have demonstrated their competency in accordance with ISO/IEC 17043.

   4.3. Purchasing of TRC services and supplies

      4.3.1. When placing an order for services or supplies, the appropriate Purchase Requisition Form (F-006) shall be completed and submitted for approval to the appropriate supervisor or designee.

4.3.2. The Purchase Requisition shall be compared to the Test Methods to ensure that the appropriate services or supplies are being ordered (refer to WS-038, Approved Vendor List for approved in-scope TRC suppliers).

4.3.3. A member of the Management Team (or designee) will submit the Purchase Requisition to the Purchasing Agent, who will then place the order with an approved supplier where practicable (WS-038 Approved Vendor List).

4.4. Receiving TRC supplies

4.4.1. Upon receipt of the purchased supplies, the receiving persons will verify the contents to the Packing Slip and will then initial and date Packing Slip to show receipt and correctness of contents. The Business Office compares the Packing Slip to the Purchase Requisition.

4.4.2. The purchased TRC supplies shall be inspected for signs of tampering, opening, or damage, and they will be verified, by label, to match the specific catalogue number (and if specified, "Grade") of requested materials.

4.4.3. The supplies will be distributed to the appropriate division for approval/use.

4.4.4. TRC supplies shall be labeled with the lot number, date of receipt, and expiration date, where practicable. All Certificates of Analysis (COA) of reference materials are to be initialed and retained; if the COA is not included with the delivery, the supplier is contacted and the appropriate COA requested.

4.4.5. Non-TRC materials may be subject to incoming inspection to determine if they meet specifications.

4.5. Quality Check of TRC supplies

4.5.1. The analyst performing the tests shall confirm by the label of purchased materials that TRC supplies are being used for the tests and record the lot/batch number of the TRC supplies onto the proper form/tracking/reagent/material sheet.

4.5.2. TRC supplies will be evaluated and verified during use, or before use, if applicable, by assessing the quality control data. Acceptable QCS and any Method Blanks will verify the quality of all supplies being used.

4.5.3. The QCS and blanks will serve to assure that the supplies meet the quality needed and serve to check for uncommon errors from the manufacturer to prevent a delay in the critical testing and to meet customer needs. If a blank fails to meet the quality needed to perform the tests, the analysis of samples will cease, and the failing material will be identified and replaced.

4.5.4. In the case where a TRC supply is produced within the Laboratory, the blanks in each set will serve as a check for quality needed to perform the tests and meet the desired results.

4.6. Storage of TRC supplies

4.6.1. Storage of supplies shall follow manufacturer's instructions and the Laboratory safety guidelines.

4.7. Inventory of TRC Items

4.7.1. Analysts shall check the expiration date of the TRC supplies prior to use. If the supply is expired, it is not to be used. It shall be removed and scheduled for disposal.

4.8. TRC Discrepancies

4.8.1. All discrepancies shall be reported to the appropriate supervisor, who will notify the purchasing agent. The Business Office will record all discrepancies on F-015 Vendor and Supplier Incident Report and file with the Quality Division.

4.8.2. Discrepancies include damaged/opened packages, mislabeled supplies, or failure to meet quality parameters defined by the Laboratory.

4.8.3. A correction will be issued for any nonconformance based upon TRC discrepancies (*QP-120 Nonconforming Work*) and the supplier will be notified.

4.9. Receiving TRC Services

4.9.1. Tests results from Subcontract Laboratories are reviewed for accuracy and completeness. If quality control data was requested, it shall be reviewed to determine compliance with acceptance criteria.

4.9.1.1. If all is acceptable, the Laboratory will include the subcontracted data in their customer reports.

4.9.1.2. If everything is not acceptable, the Laboratory will submit a formal complaint to the Subcontract Laboratory.

4.9.2. Calibration Certificates of equipment shall be evaluated for accuracy, completeness, and the appropriate endorsement and certificate number.

4.9.2.1. If all is acceptable, the Laboratory will retain the certificates in the appropriate file.

4.9.2.2. If everything is not acceptable, the Laboratory will submit a formal complaint to the calibration laboratory.

4.9.3. Should there be any problems or inappropriate deficiencies during on-site assessments, the accreditation body shall be contacted for an appropriate resolution. If such resolution cannot be achieved, a formal complaint will be submitted.

4.9.4. Proficiency Test results shall be reviewed for accuracy and completeness.

4.9.4.1. If all is acceptable, the Laboratory will accept the results.

4.9.4.2. If everything is not acceptable, the Laboratory will submit a formal complaint to the Proficiency Test Provider.

4.10. Suppliers of TRC Services and Supplies

4.10.1. The Laboratory shall maintain a record of all suppliers of TRC equipment, services, products, and supplies.

4.10.2. An individual incident that occurs with vendors and suppliers will be reported on F-015 Vendor and Supplier Incident Report and filed with the Quality Division. All of these reports will be reviewed and used as supporting documentation when completing WS-081, Annual Vendor Evaluation during annual Management Review. Records of these evaluations (WS-081) shall also be maintained.

4.10.3. Initial Evaluation of Suppliers

4.10.3.1. All current suppliers will be given a grade.

4.10.3.2. This grade is added as a column to our Vendor File.

4.10.4. Ongoing Evaluation of Suppliers

4.10.4.1. Should there be a problem with a supplier, the grade will be reduced, and the Vendor File will be updated. The vendor should be sent a complaint.

4.10.4.2. Should there be another problem with that same supplier, the grade will be reduced further, and the Vendor file will be updated. The vendor should be sent another complaint.

4.10.4.3. Should there be another problem with that same supplier, the supplier will be eliminated from our Vendor File. The vendor should be informed that they are no longer an acceptable supplier.

4.10.5. Records of the evaluations of these suppliers will also be maintained.

QP-110 Requests, Proposals and Contracts

1. **SCOPE:**

   1.1. This procedure applies to all personnel responsible for arranging testing activities to be conducted within the Laboratory.

   1.2. This procedure ensures that all the customer requirements are met by:

      1.2.1. Defining, documenting, and ensuring complete understanding of the methods to be used.

      1.2.2. Verifying the Laboratory's capability and capacity to meet the customer requirements.

      1.2.3. Selecting and validating the appropriate Test Method (TM) to meet the customer's requirements.

2. **OWNER:** State Chemist/Quality Assurance Manager

3. **DEFINITIONS:**

   3.1. Review: to evaluate, to examine, to understand.

   3.2. Request: an inquiry from the customer to the Laboratory, relative to testing activities.

   3.3. Proposal (tender): a response from the Laboratory to the customer, relative to capability and capacity to perform the requested testing.

   3.4. Contract: the written agreement between the customer and the Laboratory to conduct testing.

4. **PROCEDURE:**

   4.1. Sample Submission Form or equivalent agreement

      4.1.1. The appropriate Sample Submission Form (SSF) is provided by the Laboratory to all customers.

      4.1.2. The SSF or equivalent agreement shall be completed prior to analysis.

         4.1.2.1. Should the SSF or equivalent agreement not be properly completed, the Laboratory's Sample Receiving staff or designee(s) contact the customer for revisions/completion.

         4.1.2.2. No activity shall be initiated until the SSF, or equivalent agreement, is properly filled out.

   4.2. Review of Customer Request

      4.2.1. The analysis requested by the customer on the SSF is reviewed by designated Laboratory personnel to ensure that the intended use of the test data by the customer is clearly understood where practicable. If a requested test is inappropriate or out of date, the customer will be notified by the reviewer.

      4.2.2. The TM(s) is clearly identified on the Laboratory Information Management System (LIMS) Sample Login Report. The reviewer's initials and dates are also recorded on the Login Report.

      4.2.3. The TM(s) is then compared with the Laboratory's Scope of Accreditation prior to analysis.

         4.2.3.1. If the TM(s) is on the Laboratory's Scope of Accreditation, the capability of the Laboratory is thus identified by the signing of the Login Report.

   4.3. Review of Laboratory Capability and Capacity

      4.3.1. The availability of adequate technical personnel is assessed by the Management Team by reviewing the employee work schedules for the time period during which the test(s) are to be conducted.

      4.3.2. A member of the Management Team will discuss the work to be done with all involved employees, including laboratory analysts, to determine the availability of necessary equipment and employee work schedules.

4.3.3. The Laboratory does not routinely use external providers. If an external laboratory is needed, requirements of PJLA ISO/IEC 17025:2017 with AOAC Working Document Section 6.6 shall be applied and the customer notified of activities to be outsourced. The customer must approve of any activities to be outsourced before proceeding.

4.3.4. The Laboratory does not supply statements of conformity except in cases of regulatory feed samples with limits specified by the state law.

4.4. Preparation of Formal Quotes

4.4.1. The Laboratory will prepare a formal quote for the customer, identifying the TM(s) (if requested), the expected turn-around-time, and the total cost. This proposal also includes the submitter's name, phone number, and/or email address, when provided.

4.4.2. Prior to the submittal of this quote to the customer, the Quality Assurance Manager or a member of the Management Team will review the quote for completeness and identify any additional terms and conditions.

4.4.3. The quote is then sent to the customer via email or fax.

4.5. Review of Contract

4.5.1. The customer is notified by the Laboratory of any changes to the contract. If the customer requests any changes or revisions, these may be made and agreed to by the Quality Assurance Manager or member of the Management Team.

4.5.2. If the quote is not acceptable to the customer, the Laboratory resolves any issues prior to initiation of any work. If these issues cannot be resolved, the MSCL declines the contract and does not conduct the test(s).

4.5.3. If work commences and any deviations to the contract are made, the customer is notified. The review process is repeated, and all affected personnel are notified. Deviations are recorded on the SSF or communicated via email.

QP-111 Method Verification and Validation

1. SCOPE:

1.1. This procedure applies to the development of methods, verification of standard methods, validation of non-standard test methods, and modifications to standard methods.

2. OWNER: State Chemist/Quality Assurance Manager

3. DEFINITIONS:

3.1. Verification: provision of objective evidence that a given item fulfills specified requirements, *e.g.*, confirmation that performance properties of a measuring system are achieved (ISO/IEC 17025:2017 – Terms and Definitions).

3.2. Validation: a verification, where the specified requirements are adequate for an intended use, *e.g.*, a measurement procedure, ordinarily used for the measurement of mass concentration of nitrogen in water, may be validated also for measurement in another matrix; confirmation by examination and the provision of objective evidence that the requirements for a specific intended use are fulfilled (ISO/IEC 17025:2017).

3.3. Standard Method: a method that is traceable to a recognized validated method, (i.e., Official Methods of the AOAC International, EPA Methods, ASTM methods).

3.4. Non-Standard Method: methods not taken from authoritative or validated sources.

4. PROCEDURE:

4.1. The validation or verification of standard and non-standard methods is done prior to using them for reporting data.

4.2. Use the form F-008 Request for Method Development, Validation, Verification, or Modification.

4.3. Conduct the defined experiments, refer to TM-019 Standard Operating Procedure for Method Development, Verification, Validation and Modifications; WS-072 Test Method Verification; WS-052 Test Method Validation; WS-073 Test Method Modification; and WS-074 Statistical and Analytical Measurements for the detailed procedures.

4.4. Record the data, use F-009 Method Validation/Verification/Modification Summary for method approval, and include the statement of fitness for the intended use in the validation data packet.

4.5. Validation of computer software and spreadsheets.

4.5.1. All computer software is checked to ensure that it records and processes data correctly by manufacturer or lab personnel when applicable.

4.5.2. All spreadsheets are validated by checking the calculations and locking for edit when practicable.

5. ADOPTION OF THE METHOD:

5.1. The laboratory representative who is authorized to adopt the method and the date the authorization was granted is recorded on F-008, Approval/Review.

6. MODIFICATIONS OF VALIDATED METHODS

6.1. If changes are made to a validated method, the influence of the changes will be evaluated and, if determined, a new method validation or verification will be performed if deemed necessary.

7. RECORDS:

7.1. Records generated by this process are maintained per *QP-114 Records Management*. Note: The procedure used, the experimental records, and the statement that the method is fit for the intended use may have to be kept longer than the 2-year retention time required by Conformity Assessment Bodies (CAB).

QP-112 Subsampling

1. **SCOPE:**
   1.1. This procedure applies to samples received in the Laboratory for analysis.
   1.2. To establish requirements for sample homogenization and subsampling.
2. **OWNER:** State Chemist/Quality Assurance Manager
3. **DEFINITIONS:**
   3.1. Homogenization: process to obtain a finely mixed/chopped sample for analysis that represents the entire customer sample submitted to the Laboratory.
   3.2. Subsample: a portion taken from a sample; a laboratory sample may be a subsample of a bulk sample or a population; similarly, a test portion may be a subsample of a laboratory sample.
   3.3. Subsampling: process by which a smaller, representative sample(s) (to create a test portion) is taken from a larger sample.
   3.4. Test portion: (also called test unit, aliquot, analytical unit); that quantity of a material of proper size actually used for measurement of the property of interest.
   3.5. Riffling: the division of a sample into representative portions of the material.
4. **MATERIALS:**
   4.1. Disposable or glass sample beakers/containers with lids, or resealable plastic bags.
   4.2. Bowl chopper/food processor/grinding mills/genogrinder/mortar and pestle, capable of finely mixing/chopping/crushing sample.
   4.3. Sieve/knives/scissors as needed to mix/chop the sample.
   4.4. Stainless steel, glass, or plastic containers for mixing.
   4.5. Stainless steel, plastic scoops, brushes, or PTFE spatulas.
5. **PROCEDURE:**
   5.1. Homogenization
      5.1.1. Sample specific homogenization will be on a case-by-case basis or as directed by the client or the technical SOP.
      5.1.2. Care must be taken when mixing the sample to include all the liquid, solids, and any other portions of the sample.
      5.1.3. Sample homogenization should be completed expeditiously to minimize loss of moisture due to evaporation.
      5.1.4. All mixing/chopping/grinding is to be performed using clean and dry equipment at room temperature.
      5.1.5. Do not open more than one sample at a time before homogenization.
      5.1.6. Large samples should be split into smaller and mixed/chopped individually or as directed by client or Test Methods. After mixing/chopping each portion, they should be transferred to a container large enough for the entire sample to be mixed carefully and thoroughly.
      5.1.7. Mixing/chopping tissue samples may be easier when samples are close to freezing.
      5.1.8. Dry ice can be added when homogenizing samples under certain conditions (*e.g.*, fruits and vegetables).

5.1.9. Powders, even those that are apparently homogeneous, should be mixed thoroughly by tumbling gently on different axes immediately before subsampling.

5.1.10. Turbid liquid samples are mixed either by shaking or with a magnetic stirrer while subsampling.

5.1.11. Liquid samples that partition into immiscible layers can be sampled by the following technique: a vertical sample may be taken using a hollow glass tube (with non-tapered sides), lowering the tube to the bottom of the container, closing off the top of the tube, and transferring the sample to another container for testing.

5.1.12. Clear liquid samples are required to be mixed well by shaking and inverting for approximately 10-60 seconds prior to subsampling.

5.1.13. Feed samples should be homogenized on a mill (*e.g.*, Wiley, Retsch, or Pulva) or by mortar and pestle, based upon sample.

5.1.14. Fertilizer samples should be homogenized on a mill (*e.g.*, Retsch ZM 200 or Pulva) or by mortar and pestle, based upon sample.

5.1.15. Lime samples should be homogenized by mixing, crushing with mortar and pestle (when necessary), and subsampling for sieve, and CCE analysis.

5.1.16. Forage samples and chicken litter should be homogenized using the Wiley mill or equivalent.

5.2. Subsampling

5.2.1. Sample specific subsampling will be on a case-by-case basis or as directed by the client or the Test Method.

5.2.2. Subsampling prior to mechanical homogenization will be determined on a case-by-case basis or by direction of client or Test Method.

5.2.3. The subsample is removed from original container, placed into a labeled container specific for storage or analysis. Both the original and subsample container are labeled with the same identification number or LIMS ID.

5.2.4. Subsampling should be conducted in a timely manner after homogenization.

5.2.5. Remove an appropriate test portion of the homogenized sample and weigh or aliquot by volume as specified in the appropriate Test Method.

QP-113 Sample Handling

1. **SCOPE:**
   - 1.1. This procedure applies to all personnel within the Laboratory.
   - 1.2. To ensure that samples are handled properly from receipt to disposal.
2. **OWNER:** State Chemist/Quality Assurance Manager
3. **DEFINITIONS:**
   - 3.1. Test samples: samples received from customers that are to be tested.
4. **PROCEDURE:**
   - 4.1. Transportation and Receipt of Test Samples
     - 4.1.1. It is the responsibility of the customer submitting test samples to the Laboratory to ship or deliver the samples in a manner that retains their integrity. The customer is also expected to properly fill out the appropriate Sample Submission Form (SSF) along with the test sample(s). The recommended sample container, preservation, storage & holding time are listed in WS-118 The MSCL Sample Submission Guide.
     - 4.1.2. Upon receipt of test samples, Laboratory personnel determine if the integrity of the sample has been maintained during transit and that all necessary information has been supplied by the customer.
     - 4.1.3. The samples received are verified against the descriptions on the SSF for consistency.
     - 4.1.4. The condition of the test items is observed.
     - 4.1.5. Discrepancies or abnormalities for Sections 4.1.2 – 4.1.4 shall be recorded or attached to the SSF and resolved with the customer before continuing the sample receipt process.
     - 4.1.6. The SSF is given the next LIMS sequential identification number(s).
     - 4.1.7. Regulatory samples must be collected and submitted by a Mississippi Department of Agriculture and Commerce employee.
   - 4.2. Sample Identification
     - 4.2.1. Samples are identified using an electronic LIMS, which gives each new sample a sequential sample identification number.
     - 4.2.2. Samples are logged into the LIMS according to the appropriate worksheets (*e.g.* Sample Login (WS-029) and Samples Under Scope (WS-031).
     - 4.2.3. The LIMS Manual provides instructions on sample identification.
   - 4.3. Sample Handling, Protection and Storage
     - 4.3.1. Samples are stored as received or required by the Test Methods, (room temperature, refrigerated, or frozen) unless dictated otherwise by the customer. Samples are handled and protected to avoid contamination.
     - 4.3.2. Samples are kept inside the confines of the secure laboratory area, limiting access to authorized personnel only.
     - 4.3.3. Visitors to the Laboratory are always accompanied by laboratory staff and do not have access to the test samples.
   - 4.4. Sample Reporting
     - 4.4.1. MSCL does not collect samples. The Report of Analysis informs the customer that samples are reported as received.

4.5. Sample Retention and Disposal

4.5.1. After all testing has been completed the samples are returned to storage, unless the entire sample is used for analysis. It is suggested to record "consumed in analysis" in the data packet.

4.5.2. Unless an alternative arrangement is specified by the customer when samples are submitted to the Laboratory, the excess from samples not used for analysis will be retained by the Laboratory after reporting results for a minimum of 30 business days.

4.5.3. Samples ready for disposal are discarded according to the Mississippi State University hazardous waste disposal procedures with direction from the MSU Environmental Health and Safety Office or returned to customers if requested.

4.5.4. Prior arrangements must be made for testing beyond the retention time of 30 business days.

QP-114 Records Management

1. SCOPE:

1.1. To establish and maintain a uniform system for the identification, storage, protection, retrieval, retention, and disposition of hard copy and electronic records.

1.2. Applies to all records required to demonstrate competency, provide evidence and results for performed tasks and testing activities, for preventive actions, corrective actions, continual improvements, internal audits, and management reviews, for future reference or for the verification of the suitability and effectiveness of the *Management System*.

2. OWNER: State Chemist/Quality Assurance Manager

3. DEFINITIONS:

3.1. Record: the "proof" that demonstrates that the Laboratory's Management System documents have been followed; results achieved or evidence of activities performed.

3.2. Filing: method of filing records. (*e.g.*, one file contains one type of record).

3.3. Storage: overflow filing location.

3.4. Retention: required time for which records are to be kept. The minimum retention time is 2 years.

3.5. Disposition: method of dealing with records after the retention period expires.

3.6. Quality Records: evidence of activities related to corrective actions, continual improvements, internal audits, and management reviews.

3.7. Technical Records: all records other than Quality Records, including test data, traceability audit trails, metrological traceability, and customer reports.

4. PROCEDURE:

4.1. Quality Records

4.1.1. All hard copy records shall be made in ink only.

4.1.2. All quality records are identified, indexed, and filed according to the category (corrective actions, continual improvements, internal audits, or management reviews) as appropriate for prompt retrieval for a minimum of two years.

4.1.3. The use of correction fluid, tape, or multiple scribing to amend recordings is not permitted. Instead, a single line through the incorrect entry is allowed, provided that the original entry remains legible for review. Any changes made to hard copies must be initialed and dated. If forms or documents are received by the Laboratory with correction fluid or tape, personnel shall note the correction, initial, and date the change.

4.1.4. Electronic records are collected in the network system, while hard copy records are reviewed and filed by the person responsible for the tasks.

4.1.5. If the network system is not usable, hard copy records are generated and controlled as the quality record.

4.1.6. Records shall be readily available to employees and to the customer, as required by a contract. At a minimum, the current and last year's hard copy records are kept on file in an office environment. When appropriate, older records are kept in the Laboratory's archives.

4.2. Technical Records

4.2.1. The MSCL Sample Submission Form (SSF) must be completed according to WS-029 (Sample Login). This form includes chain of custody (COC) section, which is sufficient for cases where strict COC is requested by the customer, such as samples used in litigation or mandated by law).

4.2.2. Laboratory records should have clear audit trails for traceability. Audit trails of technical records should include analyst, date, analyst training, calibration, equipment specifics, reagents specifics, reports, results, LIMs transmissions, reviews, records, sample analysis, sample handling, sample preparation, and sample receiving.

4.2.3. All hard copy records shall be made using ink only.

4.2.4. All technical records are identified, indexed, and filed as appropriate for prompt retrieval up to the time of customer acceptance and retrieval for a minimum of two years or longer, as required by a customer's contract. (WS-024, Filing Technical Reports).

4.2.5. The Laboratory shall ensure that all observations, data, and calculations are recorded immediately as they are made. Each entry must be linked to the specific task it pertains to. When multiple testing options are available, the Laboratory must document which option was chosen.

4.2.6. The use of, correction liquid or tape, or multiple scribing through a recording is not allowed. A single line through an incorrect recording is allowed as long as the previous recording is legible for review. Amendments to technical record hard copies are to be initialed and dated. Changes should be easily tracked back to the original recording.

4.2.7. Technical records shall provide enough information for repetition of the original activity, and for identification of factors affecting the measured result and its measurement uncertainty.

4.2.8. Electronic records are collected in the network system, while hard copy records are forwarded to the person responsible for review and filing.

4.2.9. If the network system is not usable, hard copy records are generated and controlled as the technical record.

4.2.10. Records shall be readily available to employees and to the customer, as required. As a minimum, the current and last year's hard copy records are kept on file in an office environment. When appropriate, older records are kept in the Laboratory's archives.

4.2.11. Test data is validated through a second-level review by another technician and/or supervisor including: checks to determine accuracy of calculations, conversions, and data transfers; checks for transcription errors, omissions, and mistakes; checks to ensure QCS results are acceptable; and checks to determine consistency with expected values when applicable.

4.3. Electronic Records

4.3.1. All databases and Excel spreadsheets are protected against unauthorized access or amendment using unique usernames and passwords.

4.3.2. The environmental temperatures and conditions will be monitored if it affects the validity of the test results.

4.3.3. Changes to electronic data shall be done with audit trails in databases.

4.3.4. Archiving and backup is done to prevent data loss due to hard drive failure.

4.3.5. The networks are maintained by Mississippi State University.

4.4. Disposition of Records

4.4.1. Disposition is determined as necessary. Disposition methods may include:

4.4.1.1. continued retention of records, if retention period is not expired or as defined above;

4.4.1.2. destruction of records;

4.4.1.3. recycling (normally electronic media);

4.4.1.4. storing in a separate location, when retaining expired records for reference.

4.4.2. When records are archived, standard storage cartons are used and labeled appropriately to indicate its contents for easy retrieval. Cartons shall be stored in a dry, protected area in order to minimize damage, deterioration, or loss of records.

4.4.3. Records in electronic form are backed up regularly on electronic media and stored in a secure area.

4.4.4. After the established retention time of two years, or as required by a customer's contract, records may be shredded or discarded as trash. The same person responsible for maintaining the records shall dispose of the records.

QP-115 Measurement Uncertainty

1. SCOPE:

1.1. This procedure applies to all quantitative test methods within the scope of accreditation for the Laboratory.

2. OWNER: State Chemist/Quality Assurance Manager

3. DEFINITIONS:

3.1. Quantity: property of a phenomenon, body, or substance, where the property has a magnitude that can be expressed as a number and a reference.

3.2. Quantity value: value of a quantity.

3.3. Measurand: the quantity intended to be measured.

3.4. Uncertainty of Measurement: non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used.

3.5. Coverage Factor (k): the number that is multiplied by the standard uncertainty to give an estimate of uncertainty for a large portion of all values. For 95% confidence, $k = 2$ when using 20 data points.

3.6. Standard Uncertainty: measurement uncertainty expressed as a standard deviation.

3.7. Expanded Measurement Uncertainty: the combined standard uncertainty multiplied by the coverage factor k.

4. PROCEDURE

4.1. Identification of Method Type - The first step is to identify the method type. There are three types of tests defined in this procedure, each of which has different considerations relative to measurement uncertainty estimation:

4.1.1. Test methods that are reported on a qualitative basis or on a categorical or nominal scale;

4.1.1.1. These are methods where samples are classified using visual observation or other similar methods to determine, detect, or identify the target.

4.1.1.2. The requirement to calculate measurement uncertainty does not apply to test methods or studies where the end point is an opinion or diagnosis.

4.1.2. Well-recognized test methods are those methods that specify limits to the values of the major sources of uncertainty of measurement and specify the form of presentation of calculated results;

4.1.2.1. The requirement to calculate measurement uncertainty does not apply to these test methods. This category includes:

4.1.2.2. Rapid method kits that specify limits to the values of major sources (contributors) of uncertainty as well as well-recognized rapid methods where kits are used to determine qualitative results, (for example, a semi-quantitative kit assay that reports qualitative results, such as "presence" or "absence" based on a numeric value).

4.1.2.3. Semi-quantitative test methods where the determination is based on a continuous-scale measurement.

4.1.3. All other test methods, including chemical, environmental, or biological test methods based on published regulatory or consensus methods (examples: FDA, EPA, AOAC, ASTM, ISO) as well as those test methods needing major (or all) components of uncertainty identified.

4.1.3.1. In such cases measurement uncertainty estimates are to be generated based on appropriate techniques specified below.

4.1.3.2. Laboratory-developed methods require validation per PJLA ISO/IEC 17025:2017 with AOAC Working Document Section 7.2.2. As part of this validation, the significance of measurement components or the significance of the modifications of the measurement components from the standard test method must be considered so that the measurement uncertainty for the method can be estimated.

4.2. Estimating Measurement Uncertainty for Type 4.1.3 Methods (See Above)

4.2.1. Perform testing on the Quality Control Sample (QCS) periodically. QCS could be a reference material, and old PT sample or matrix spike sample.

4.2.2. When the QCS can be run through all method steps, the standard deviation (SD) from the QCS data shall be used as an estimate of combined measurement uncertainty. A relative standard deviation (RSD) may also be used. It is recommended that 20 or more individual sequential data points be obtained to estimate the standard deviation. This estimate should only include data from analysis runs that were determined to be "in control."

4.2.3. The estimate of expanded uncertainty shall be calculated using the formula:

Measurement Uncertainty for a Defined Matrix (QCS) = k * SD

Where k (the coverage factor) = 2 (for 95% confidence) when using 20 data points

4.2.4. If fewer than 20 QCS data points are available, the coverage factor k should be the appropriate t statistic for 95% confidence for the associated degree of freedom.

4.2.5. If QCS is a matrix spike sample, the percent recovery can be used to calculate the standard deviation. The combined measurement uncertainty can be estimated by using relative standard deviation (RSD). The unit of the measurement uncertainty should be reported as %.

5. RECORDS:

5.1. Records generated by this process are maintained per *QP-114 Records Management.*

5.2. Records for the estimation of uncertainty of measurement are kept for each quantitative test method within the Scope of Accreditation and may have to be kept longer than the 2-year retention time.

NOTE - It is important to understand the major factors of uncertainty and provide appropriate control for all such factors. Concurrent analysis of reference materials or control samples with the customers' samples can be performed in place of purely mathematical estimation of uncertainty. If possible, the control sample should be of identical or similar matrix as the matrices routinely tested by the test method. The uncertainty of the method can be estimated for the class of matrix and the variation described as the uncertainty in testing the specific matrix class at the average amount of the measurement result.

QP-116 Quality Control

1. **SCOPE:**

   1.1. This procedure applies to all personnel within the Laboratory.

   1.2. To ensure the accuracy and validity of test results.

2. **OWNER:** State Chemist/Quality Assurance Manager

3. **DEFINITIONS:**

   3.1. Quality Control Sample (QCS): a material with a matrix similar to the matrix of the test sample of known value and taken through the full test method. This can be a matrix spike, reference material, a previous proficiency test (PT) sample, etc.

   3.2. Control Chart: a presentation of QCS data over time to show current results against acceptance criteria and trends of data over time. Procedures are established to show when QCS data are in control and when they are not.

   3.3. Other quality control samples (*e.g.*, Method Blanks, Matrix Spikes, Matrix Spike Duplicates, Sample Duplicates) may be required as defined in the Test Methods.

4. **PROCEDURE:**

   4.1. Running a QCS sample

      4.1.1. A QCS shall be run concurrently with each batch of samples. A typical batch of samples includes 10 to 20 samples but is dependent on the specific technical method or worksheet.

      4.1.2. Data from running QCS shall be recorded on an appropriate control chart. If a reference material with a certified value and an acceptable range or standard deviation is used, the control limits should be established based on these values. After 20 data points have been added to the chart, these 20 sequential results are used to establish an in-house warning limit at two standard deviations and an in-house control limit at three standard deviations if necessary. The limits can be recalculated when applicable, such as instruments repaired or parts replaced.

      4.1.3. The current QCS data point is evaluated against the upper/lower warning and control limits. The process may be out of control if:

         4.1.3.1. Any result falls outside the upper or lower control limits.

         4.1.3.2. Two or more consecutive values fall outside the upper or lower warning limits on the same side of the mean.

         4.1.3.3. A series of seven or eight consecutive values fall all above or all below the mean.

      4.1.4. Control charts shall be monitored by analysts entering data, whenever practicable. All charts shall be reviewed on a routine basis by Director(s), Laboratory Managers, or Quality Assurance Division (*e.g.*, with sample data packet by Primary Reviewer and Secondary Reviewer). Documenting and reporting out of control situations shall be the responsibility of the analyst, if it is determined that the process is out of control by the analyst, Director(s), Laboratory Managers, or Quality Assurance Division, the data from customer samples shall not be reported, and the following steps are to be taken:

         4.1.4.1. Initiate a correction for QCS outside the acceptable ranges.

         4.1.4.2. Initiate a Corrective Action Request (CAR) (F-001) to determine the root cause of the problem and to initiate appropriate and effective corrective actions to prevent recurrence of the problem.

      4.1.5. Any laboratory employee may initiate a CAR. This can be done by contacting the Quality Assurance (QA) Division.

4.2. Running a Sample Duplicate

4.2.1. For some methods, a sample duplicate is analyzed for every 1 to 20 samples in a batch, or at the frequency requested by the client. The duplicate sample should be the first available sample, when applicable, in a batch.

4.2.2. The advisory duplicate relative percent difference (RPD) for a sample duplicate is ≤20%. For other methods, method precisions are periodically evaluated as specified in the Test Methods.

4.2.3. If running samples in triplicate is required by the Test Method, the advisory Relative Standard Deviation should be less than 5%.

$$RPD = \frac{|X_1 - X_2|}{(X_1 + X_2)/2} \times 100\%$$

where:

X_1 = Concentration of sample
X_2 = Concentration of duplicate

4.3. Refer to the individual Technical Methods for the acceptance criterion for the coefficient of determination (R^2) of the Calibration Curve, Initial Calibration Verification, Continuing Calibration Verification and Calibration Blank and/or Method Blank. The additional QCS can be added at the request of the client to meet their contract needs.

4.4. Using matrix spikes

4.4.1. Either an appropriate reference material, suitable matrix, or blank matrix that has been spiked with a known concentration of analyte shall be run concurrently with each batch of samples when applicable.

4.4.2. A typical acceptance for matrix spikes is 70 – 130%, but for large screens with many analytes, 50-150% is acceptable, or as directed by client or the Test Methods. Values will not be adjusted based upon the recovery. The recovery values will be reported to the client when requested.

4.5. For qualitative methods

4.5.1. Appropriate quality controls shall be included whenever possible in order to demonstrate that the analysis works. The suitability of the controls used shall be justified by the Laboratory.

4.6. Proficiency Testing

4.6.1. Where possible, the Laboratory shall participate in external PT programs that are suitable to the materials/analytes examined by the Laboratory and should include all tests/methods/techniques. The PT activities should cover a minimum of one activity per method/test type and/or technology per year and meet the Conformity Assessment Body (CAB) proficiency testing requirements. The Laboratory PT plan is documented using LF-81 (Four-Year PT Schedule).

4.6.2. Proficiency testing shall be conducted by the Laboratory following its standard working practices. Analysts shall adhere to the instructions specified in each PT program when practicable. For most PT programs, the *z*-score will be calculated for each individual result.

Results Obtained	Rating
$\|z\| \leq 2$	Acceptable
$2 < \|z\| < 3$	Questionable
$\|z\| \geq 3$	Unacceptable

If $|z| \geq 3$, then a CAR will be initiated by the QA division.

QP-117 Proficiency Testing Plan

1. **SCOPE:**

   1.1. To demonstrate the Laboratory's technical competency for all Test Methods on its Scope of Accreditation.

   1.2. To define the process for participating in appropriate Proficiency Testing (PT) Schemes and/or Inter-Laboratory Comparisons.

   1.3. To ensure that the Laboratory reports all PT and/or Interlaboratory Comparison data to the accrediting body (*e.g.*, PJLA) when required and to initiate corrective actions for all failures.

2. **OWNER:** State Chemist/Quality Assurance Manager

3. **DEFINITIONS:**

   3.1. Proficiency Testing (PT): the evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons.

   3.2. Inter-Laboratory Comparison (ILC): organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions.

   3.3. Sub-Disciplines: a sub-field of testing as defined on the Laboratory's Scope of Accreditation (*e.g.*, Gravimetric Chemistry, High Pressure Liquid Chromatography, Gas Chromatography, and ICP/OES are all separate Sub-Disciplines).

   3.4. Corrective Action: action to eliminate the cause of a detected nonconformity.

4. **PROCEDURE:**

   4.1. Overview: The Quality Assurance Manager will ensure that the Laboratory participates in relevant and available PT Programs and/or ILC Programs.

      4.1.1. Where relevant and available, the Laboratory shall participate in accredited PT programs.

      4.1.2. Where such programs are not available, the Laboratory shall conduct and participate in appropriate ILC programs.

      4.1.3. Where such ILC programs are not available, the Laboratory shall rely on its continuing QCS program data to demonstrate technical competency.

      4.1.4. The Laboratory shall demonstrate successful participation in at least one PT/ILC testing activity prior to receiving accreditation.

   4.2. Schedule: The Quality Assurance Manager shall build a 4-Year PT/ILC Plan that covers all test methods and matrices on their Scope of Accreditation.

      4.2.1. The PT/ILC Plan shall cover all current test method and matrices. Additional test procedures will be added to the PT/ILC Plan once they become accredited.

      4.2.2. The PT/ILC Plan shall ensure that the appropriate number of PT/ILC samples is analyzed each year, which is dependent on the number of sub-disciplines.

         4.2.2.1. Laboratories with four or fewer sub-disciplines are required to conduct one PT/ILC activity per year, every year.

         4.2.2.2. Laboratories with five or more sub-disciplines are required to conduct two PT/ILC activities per year, every year.

         4.2.2.3. The 4-Year PT/ILC Plan shall ensure that all sub-disciplines and matrices/materials are covered over a four-year period.

      4.2.3. The scope PT/ILC Plan are reviewed annually during the Management Review.

   4.3. Analyzing PT/ILC samples.

4.3.1.1. Proficiency testing and ILC testing is performed in accordance with the Laboratory's normal testing and reporting procedures, unless otherwise specified in the instructions from the PT Provider.

4.3.1.2. The Director or Laboratory Manager shall ensure that qualified personnel, for the relevant tests, run one PT/ILC sample per year.

4.4. Reporting PT and ILC data to accrediting body (*e.g.*, PJLA) according to its requirements.

5. RECORDS:

5.1. Records generated by this process are maintained per *QP-114 Records Management*.

QP-118 Reporting Results

1. **SCOPE:**

   1.1. Applicable to personnel reporting results.

   1.2. Applies to all data that is to be reported to customers.

2. **OWNER:** State Chemist/Quality Assurance Manager

3. **DEFINITIONS:**

   3.1. Report: a formatted record of the results of testing.

4. **PROCEDURE:**

   4.1. Final Customer Reports

      4.1.1. The method and form used to report results to the customer will vary. At a minimum, results for customer samples, in their final form, shall be approved by a secondary reviewer before being released to the customer.

      4.1.2. Test reports must conform to the requirements established in section 7.8 of the ISO/IEC 17025:2017 standard. In the case of a written agreement with the customer, the results may be reported in a simplified way.

      4.1.3. When the test report contains results of tests performed by subcontracted laboratories, these results shall be clearly identified as having been provided by a subcontractor.

      4.1.4. When an amendment to a test report that has been issued is necessary, a supplement to the test report shall be issued to the customer.

         4.1.4.1. Such amendments shall be uniquely identified as a supplement and shall contain a reference to the original test report.

         4.1.4.2. When it is necessary to issue a completely new report, this is clearly identified and shall include reference to the original report that it replaces.

      4.1.5. Interim (partial) test reports can be issued to the customer.

         4.1.5.1. Reports shall be uniquely identified as partial reports. (*e.g.*, Using the comment section on the report or adding a watermark)

         4.1.5.2. Upon completion of testing, a final test report shall be issued that is also uniquely identified and shall also contain a reference to any and all interim (partial) reports that it replaces.

      4.1.6. After accredited status is obtained, the accrediting body (*e.g.*, PJLA) name and/or symbol, and certificate number may be used on test reports.

         4.1.6.1. When the name and symbol is used, it is always accompanied by "accredited" and the symbol must maintain its form.

      4.1.7. The Laboratory may use the symbol or other reference to the accreditation body in organizational publications, websites, etc. if it clearly represents specifically the Laboratory's Scope of Accreditation.

         4.1.7.1. The symbol may not be used on personal business cards.

QP-119 Customer Feedback

1. SCOPE:

1.1. This procedure applies to all personnel and customers of the Laboratory.

1.2. To define the process for handling feedback from customers and other parties.

1.3. To ensure that all communications with the Laboratory's customers are helpful, positive, timely, and done in a cooperative fashion.

1.4. To ensure that the Laboratory seeks positive and negative feedback/complaints from customers to improve the Laboratory's Management System, test methods, and/or customer service.

2. OWNER: State Chemist/Quality Assurance Manager

3. DEFINITIONS:

3.1. Complaint: any problem for which objective evidence is available to demonstrate that a requirement has not been fulfilled; also referred to as a nonconformity, deviation, or deficiency.

3.2. Communication: interactions between Laboratory personnel and customers.

3.3. Feedback: information coming directly from customers about the satisfaction or dissatisfaction they feel about the Laboratory's service.

3.4. Evidence, objective evidence, or direct evidence: proof of conformity or proof of nonconformity; something observed or viewed in records; evidence is not what is heard, which is simply information.

3.5. Requirement: need or expectation that is stated and obligatory; an imperative or a "shall."

3.6. Conformity: fulfillment of a requirement; in compliance.

3.7. Nonconformity: non-fulfillment of a requirement; out of compliance; deviation; deficiency.

3.8. Customers: the persons or organizations to whom we provide test reports.

3.9. Other Parties: employees, external auditors, University personnel.

3.10. Inquiry: input from a customer or other party to which the Laboratory is expected to respond.

3.11. Corrective Action: action to eliminate the cause of a detected nonconformity.

3.12. Correction: action to eliminate a detected nonconformity.

3.13. Continual Improvement: needed improvements of the Management System or an action to eliminate the cause of a potential nonconformity.

4. PROCEDURE:

4.1. Handling Inquiries

4.1.1. Customers value the maintenance of good communication. Communication with the customer, especially in large assignments, shall be maintained throughout the work.

4.1.2. The Laboratory shall inform the customer of any delays or major changes in the performance of the tests.

4.1.3. Inquiries received from customers or other parties will be recorded, when applicable, and complaints will be recorded on the F-001 Corrective Action Request (CAR) form.

4.1.4. When handing a complaint, the customer's feedback must be carefully considered. The customer should be asked detailed questions to gather all relevant facts (*e.g.*, who, what, where, when, how).

4.1.5. The individual handling the feedback should summarize the customer's input by writing it down and informing the customer that the conversation is being documented. If the feedback is received via email, there is no need for a separate summary.

4.1.6. The situation should be addressed to determine if an immediate correction or corrective action is required. If an investigation is warranted and completed, the customer should be briefed, provided their contact information is available. Outcomes communicated to the customer should be delivered by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question, when possible.

4.2. Decision to Respond to Inquiry with Corrective Action or Continual Improvement

4.2.1. If there is a specific, written requirement for the particular situation or issue and evidence that the requirement has not been met, a corrective action is initiated on F-001 as defined by *QP-126 Corrective Action.*

4.2.2. If there is no specific, written requirement for the particular situation or issue, irrespective of evidence provided, a Continual Improvement may be considered. A decision with respect to whether a Continual Improvement is initiated is made by a member of the Management Team.

4.2.3. In any case listed above, the customer will be contacted and informed of actions taken or to be taken by the Laboratory.

4.3. Corrective Action

4.3.1. If a Corrective Action, as determined in Section 4.2.1 is required, the Corrective Action is initiated and completed.

4.3.2. Prepare a summary of the Corrective Action(s) taken and submit it to the customer, if requested.

4.4. Continual Improvement

4.4.1. If a Continual Improvement as determined in Section 4.2.2 is possible, seek approval from the Management Team before proceeding. If approval is given, Continual Improvement Form (F-019) is initiated.

4.4.2. Prepare a summary of any Continual Improvement(s) taken and submit it to the customer, if requested.

4.5. Customer Audits

4.5.1. Upon request and with prior notification, customers will be allowed to audit the Laboratory performing any tests that are reported to that customer.

4.5.2. The Laboratory shall ensure that the confidentiality of other customers' information is protected, as required in *QP-102 Confidentiality*.

4.6. Customer Feedback

4.6.1. Solicited Customer Feedback
A Survey Monkey link is located on the MSCL website and customers are encouraged to fill it out. Additionally, the link to the survey requesting feedback is included in the email when results are reported. This list and survey questions are reviewed and approved during

Management Review meetings. Customer responses, both positive and negative, are reviewed periodically during management meetings and during the annual Management Review.

4.6.2. Unsolicited Customer Feedback
Comments as to the performance of the Laboratory and customer service received through the normal course of business by any laboratory personnel should be submitted to management or QA division and saved as unsolicited feedback. All unsolicited customer feedback is reviewed periodically during Management Review.

4.6.3. All solicited and unsolicited customer feedback and summary of Management review on customer feedback are saved on a shared drive under Customer Feedback. The actions taken in response to customer feedback are monitored and evaluated periodically if applicable.

4.6.4. If there is a specific, written requirement for the particular situation or issue and evidence that the requirement has not been met, a Corrective Action is initiated.

4.6.5. If there is no specific, written requirement for the particular situation or issue, irrespective of evidence provided, a Continual Improvement may be considered. A decision with respect to whether a Continual Improvement is initiated is made by a member of the Management Team.

4.7. Analysis of Feedback

4.7.1. The data from customer feedback should be averaged across all customers but, if there is a significant problem identified with one customer, it should be addressed separately.

4.7.1.1. If low scores are obtained from the feedback, *QP-126 Corrective Actions* shall be implemented.

4.7.1.2. If the feedback scores are not the highest possible, *QP-124 Continual Improvement Process* shall be implemented.

4.7.1.3. The output of either Corrective Actions or a Continual Improvement Process shall result in a change or an improvement of the Laboratory's Management System, *e.g.*, in a QP, a test method, or in customer service.

QP-120 Nonconforming Work

1. **SCOPE:**

   1.1. This procedure applies to all personnel within the Laboratory.

   1.2. To define the process for managing nonconforming testing work.

2. **OWNER:** State Chemist/Quality Assurance Manager

3. **DEFINITIONS:**

   3.1. Nonconforming Work: testing work for which evidence exists that the result(s) are not acceptable. Best identified with Quality Control Sample (QCS) data, proficiency testing (PT) results, or test result critical (TRC) outcomes.

   3.2. Evidence (objective or direct): proof of conformity or nonconformity, observed or recorded. Evidence is is not hearsay.

   3.3. Requirement: a stated and obligatory need or expectation; an imperative or a "shall."

   3.4. Conformity: fulfillment of a requirement; compliance.

   3.5. Nonconformity: failure to properly follow policies, procedures, instructions, or fulfill a specified requirement.

   3.6. Correction: action to eliminate a detected nonconformity, such as making an adjustment, fixing a mistake, taking immediate remedial action, repeating analyses, or recalibrating equipment, usually to allow data to be reported to a customer.

   3.7. Corrective Action: action to eliminate the cause of a detected nonconformity, involving root cause analysis and changes to the Quality Management System (QMS) to prevent recurrence.

   3.8. Corrective Action Request (CAR): a formal request for the investigation and resolution of a problem.

4. **PROCEDURE:**

   4.1. Identification of nonconforming work.

      4.1.1. The most apparent indication of nonconforming work is a QCS failure, as QCS evaluates all steps in the test method. Nonconforming work can also be identified through unacceptable PT results or TRC discrepancies.

      4.1.2. Actions taken for nonconforming work are determined based on the Laboratory's risk levels associated with the specific area of nonconformance.

   4.2. Containment of nonconforming work.

      4.2.1. All Laboratory personnel involved in testing activities have the authority and are responsible for halting work and withholding test reports when nonconforming work is identified.

      4.2.2. The individual halting the work shall promptly report the situation to Director(s), Laboratory Managers, or Quality Assurance Division. Together, the individual halting the work, Director(s), Laboratory Managers, or Quality Assurance Division shall evaluate the significance and/or acceptability of the nonconforming work and the extent of the problem on current and any previous testing activities.

      4.2.3. A correction (*e.g.*, equipment maintenance, equipment calibration, restarting the test) shall be initiated and recorded in *e.g.*, Instrument Logbook, Tracking sheet or CAR form.

      4.2.4. Once the correction is implemented and verified as effective, the Quality Assurance Manager or designee shall authorize the resumption of testing work.

      4.2.5. The customer's samples will be rerun. If the QC data is acceptable, the results may be reported.

4.2.6. If previously reported data is affected by nonconforming work, the customer is notified, the original report is invalidated, and a new report will be issued.

4.3. Corrective Action

4.3.1. A corrective action or correction is initiated for all nonconforming work (*QP-126 Corrective Actions*). A corrective action requires completion of CAR form, F-001, while a correction may be documented with either a CAR, logbook, or tracking sheet.

4.3.2. A correction can also be initiated by the Primary Reviewer or Secondary Reviewer during report review for incorrect sample information, results, or invoice information entered.

4.3.3. CAR forms are retained as records of nonconforming work.

QP-121 Software Validation and Data Review

1. SCOPE:

1.1. Applicable to personnel developing or modifying software for the collection, processing, recording, storage, or retrieval of data.

1.2. Applicable to personnel conducting initial or second-level reviews of data prior to reporting results.

1.3. Applies to all data that is to be reported to customers.

2. OWNER: State Chemist/Quality Assurance Manager

3. DEFINITIONS:

3.1. Review: to critically evaluate and ensure the accuracy of data that is part of the test method.

3.2. Initial review: the review performed by authorized personnel independent of the original performance of the test.

3.3. Second-level review: the review performed by authorized personnel independent of the original performance and initial review of the test.

4. PROCEDURE:

4.1. Software development or modification and validation

4.1.1. The Laboratory personnel performing these activities shall be trained, competent, and authorized as defined in *QP-105 Training*.

4.1.2. Upon completion of the software development, the code or Excel calculational cells shall be retained.

4.1.3. The software shall be validated by comparing the software output to a manual process output and keeping appropriate records as defined in *QP-114 Records Management*.

4.1.4. Once validated, the software will be reviewed and approved as a controlled document according to *QP-122 Document Control*.

4.2. Initial review of test data and results

4.2.1. This review consists of the following (Refer to the worksheet WS-020):

4.2.1.1. Check that the appropriate test method was used.

4.2.1.2. Check that the appropriate equipment, reagents, and TRC supplies were used and identified on the applicable analytical worksheet.

4.2.1.3. Check that all analytical data is accurate and complete.

4.2.1.4. Check that all manual data transfers and manual calculations are correct.

4.2.1.5. Enter the Quality Control Sample (QCS) data onto the control chart.

4.2.1.6. Determine if the QCS data falls within acceptance criteria: if the QCS data is acceptable, proceed with reporting data and if not, initiate *QP-120 Nonconforming Work*.

4.2.1.7. If everything passes these criteria, initial and date the analytical worksheet; if not, identify the error(s) and correct as appropriate.

4.3. Second-level review of test data and results

4.3.1. This review consists of the following (Refer to the worksheet WS-020):

4.3.1.1. Check that the appropriate test method was used.

4.3.1.2. Check that all data from the analytical worksheet has been properly transferred to the final report.

4.3.1.3. Check that at least 10% of the analytical data is verified as accurate and complete (*e.g.,* chromatograms).

4.3.1.4. Check that at least 10% of the manual data transfers and manual calculations are correct.

4.3.1.5. Check that all the QCS data falls within the acceptance criteria and if not, ensure that *QP-120 Nonconforming Work* was initiated.

4.3.1.6. Verify that data is consistent with expected values if applicable.

4.3.1.7. If everything passes these criteria, initial or sign and date the final report; if not, identify the error(s) and correct as appropriate.

4.3.1.8. All sample reports are initialed and signed by hand before issuing to prevent release of unauthorized reports.

QP-122 Document Control

1. **SCOPE:**

   1.1. This procedure applies to all documents (internally generated or from external sources) that comprise the Laboratory's Management System.

   1.2. To ensure that all documents are reviewed and approved prior to their issue and distribution, identified on an appropriate master/distribution list, made available to employees, reviewed periodically, and handled in such a way as to preclude the use of invalid and/or obsolete documents.

2. **OWNER:** State Chemist/Quality Assurance Manager

3. **DEFINITIONS:**

   3.1. Document: Any information or instructions including policy statements, procedures, test methods, forms with instructions, schedules, equipment manuals, specifications, calibration tables, charts, textbooks, posters, notices, memoranda, software, drawings, and plans.

   3.2. Master List: A record of all documents which includes the Title, Revision Number or Revision Date, Effective Date and Location(s) or Holder(s).

      3.2.1. A protected copy of the Document Master List shall be readily available for all personnel on the commonly shared drive.

   3.3. Revision Number: the identification of the document to indicate a revision has been made (*e.g.*, 1.0 or 1.2).

4. **PROCEDURE:**

   4.1. Document Format and Identification

      4.1.1. The header of each controlled document will include document number, page identification, title, revision, effective date, and revision being replaced.

      4.1.2. Any controlled document should be paginated in the form "Page n of nn" or the number of pages should be shown on the cover sheet.

      4.1.3. The Quality Manual will be formatted as in QM-000.

      4.1.4. The Quality Procedures will be formatted as in this document (QP-000).

      4.1.5. The Test Methods will be formatted as in Test Method TM-000.

      4.1.6. Control Charts will be formatted as in CC-000.

      4.1.7. All forms, worksheets, and templates are formatted as in Forms (F-000), Worksheets (WS-000), and Templates (T-000).

      4.1.8. External Documents do not require any additional formatting.

   4.2. Document Control

      4.2.1. The Laboratory requires all personnel to abide by this procedure (QP-122).

      4.2.2. All personnel can prepare and/or review new or updated documents. A member of the Management team or the State Chemist must approve all new or updated documents. For the Quality Manual and Test Methods, the names and titles of the reviewer and approver are included in the document. Refer to *QP-104 Job Descriptions*, and position authorities.

      4.2.3. The document approver then updates the Master List to include the Title, Revision Number, Effective Date, and Location(s) or Holder(s). The Quality Assurance Manager or designee will email notification of change of the controlled document (*e.g.*, Quality Documents, Test Methods) to appropriate personnel.

4.2.3.1. The Quality Division is responsible for notifying personnel when new Quality documents such as Quality Procedures and Quality Manuals are ready to be issued. Quality Documents are to be signed out, via a sign out sheet, by laboratory personnel when they provide the older revision to the Quality Division. This can be done during a Laboratory-wide meeting. Upon receival, the person being issued the document must sign and date the first page.

4.2.3.2. Individual updated Test Methods are to be reviewed and signed by the responsible analyst and Management. Director(s), Laboratory Managers, or Quality Assurance Division is responsible for notifying the appropriate analysts when TMs have been updated. Analysts then can turn in old Test Methods to the QA division and in turn be issued the new revision. Upon receival, the person being issued the document must sign and date the first page.

4.2.4. One electronic copy of the obsolete document is moved to a secure record folder identified as "Archived Documents." All other hard or electronic copies are either marked as archived, obsolete, or destroyed.

4.2.5. Quality Documents in use shall not be printed or copied except by the Quality Division.

4.2.6. Requests for hard or soft copies of controlled documents shall be made to the Quality Division, who will then issue the document and update the Master List relative to the Location(s) or Holder(s).

4.3. Uncontrolled Documents

4.3.1. There are four instances where uncontrolled documents will be allowed:

4.3.1.1. Documents that are being used for training, but not used for conducting the task in that document. For example: References listed in Test Method such as test kit instructions.

4.3.1.2. Documents that are being revised, but not used for conducting the task in that document.

4.3.1.3. Documents that are being used for internal auditing, but not used for conducting the tasks in those documents.

4.3.1.4. Documents that are being sent to people outside of the Laboratory, but not used for conducting the task in that document. When sending documents to people outside of the Laboratory, the document will have a watermark clearly labeling it as an Uncontrolled Document.

4.3.2. In the above cases, the Laboratory will destroy all such documents after completion of training, revision, or auditing and will not be responsible for keeping documents sent to outside people.

4.4. Document Review

4.4.1. Documents shall be reviewed periodically (goal is every two years) and updated as necessary to ensure continuing suitability and compliance with applicable requirements.

4.5. Document Changes

4.5.1. Requests for changes to documents will be made to a member of the Management Team, who will evaluate the proposed changes and decide upon their appropriateness.

4.5.2. All changes to the text in revised documents will be identified with a "highlight" to facilitate training on the changes, where practicable.

4.5.3. Updated documents will be controlled as specified in Section 4.2 of this document.

4.5.4. Hand amendments to documents are not allowed without direction from the Quality Division.

4.6. Controlling Forms, Worksheets, and Templates

4.6.1. Forms, Worksheets, and Templates will be controlled by revision number (located in the Master List) only and can be printed out as needed.

4.6.2. The Master List will not include location information for printed forms, worksheets, and templates.

4.7. Controlling External Documents

4.7.1. External documents will be identified on the Master List by their title and any revision information (number, dates, *etc.*).

4.7.2. The Master List for these documents will not include the owner or approver, and only general information on their location (*e.g.*, common drive or next to instrument).

QP-123 Risk Management

1. SCOPE:

1.1. To ensure that all actual or perceived risks to laboratory activities are properly evaluated, addressed, and controlled.

1.2. Use F-021 (MSCL Risk Assessment Form) to evaluate and minimize any current or potential risks to laboratory operations.

2. OWNER: State Chemist/Quality Assurance Manager

3. DEFINITIONS:

3.1. Risk: effect of uncertainty on objectives; an effect is a deviation from the expected – it can be positive, negative, or both, and can address, create, or result in opportunities and threats.

3.2. Risk management: coordinated activities to direct and control an organization with regard to risk.

3.3. Risk source: element which alone or in combination has the potential to give rise to risk.

3.4. Event: occurrence or change of a particular set of circumstances; an event can be a risk source.

3.5. Consequence: outcome of an event affecting objectives.

3.6. Likelihood: chance of something happening; equivalent to "probability."

3.7. Control: measure that maintains and/or modifies risk; controls include, but are not limited to, any process, policy, device, practice, or other conditions and/or actions which maintain and/or modify risk.

4. PROCEDURE:

4.1. Risks to Impartiality

4.1.1. All personnel shall be continuously alert to any threats that would in any way compromise the impartiality of any laboratory activities, such as those arising from the following:

4.1.1.1. Ownership, governance, management, or personnel, including undue pressures and inappropriate outside activities (as described in *QP-101 Impartiality*).

4.1.1.2. Shared resources, finances, contracts, marketing, or commissions.

4.1.1.3. Customers or vendors.

4.1.2. When an actual or perceived risk to our impartiality is identified, the individual shall immediately initiate a corrective action, as defined in *QP-126 Corrective Actions*, and inform the Quality Division of that activity.

4.2. Risks to Confidentiality.

4.2.1. All personnel shall be continuously alert to any threats that would in any way compromise the confidentiality of customers' information or their proprietary rights.

4.2.2. When an actual risk to the confidentiality of customers' information or their proprietary rights has been identified, the individual shall immediately initiate a corrective action, as defined in *QP-126 Corrective Actions*, and inform the Quality Division and the customer of that activity.

4.3. Risks When Identifying Deviations (Nonconformities).

4.3.1. All personnel shall be continuously alert to any reasons where an identified deviation (nonconformity) would not be acted upon using *QP-126 Corrective Actions*.

4.3.2. Should such an event occur, the individual will immediately report it to State Chemist and Quality Division.

4.4. Risks When Reporting Statements of Conformity

4.4.1. The records generated by *QP-121 Software Validation and Data Review*, shall also be reviewed by the Director(s), Laboratory Managers, or Quality Assurance Division prior to submitting the test reports. Statements of conformity are provided to the customer when required or requested.

4.4.1.1. Records of those reviews shall be maintained by the Quality Division.

4.5. Risks When Addressing Incorrect and Reported Test Results

4.5.1. Upon this discovery, either through a customer complaint or by the Laboratory itself, the following activities shall be taken:

4.5.1.1. The Laboratory shall initiate a corrective action as defined in *QP-126 Corrective Actions* and advise the customer(s) of that action in writing.

4.5.1.2. The Laboratory shall also recall all the incorrect reports and attempt to correct the data and reissue corrected reports. The customer shall be advised if the attempts to correct the reports fail.

4.6. Risks When Handling Nonconforming Work

4.6.1. If a QCS fails to meet the control limits (± 3 standard deviations) on the control chart, the sample data shall not be reported to the customer and *QP-120 Nonconforming Work* shall be initiated.

4.6.2. If an instrument calibration fails to meet the acceptance criteria specified in the test method, the Laboratory shall stop the analysis activity and initiate the corrections defined in the test methods as required in *QP-120 Nonconforming Work*.

4.6.2.1. If the corrections facilitate an acceptable calibration, the samples and QCS shall be repeated and if all criteria have been met, data may be reported to the customers.

4.6.2.2. If the corrections do not facilitate an acceptable calibration, *QP-126 Corrective Actions* will be initiated.

QP-124 Continual Improvement Process

1. **SCOPE:**

   1.1. This procedure applies to all personnel within the Laboratory.

   1.2. To ensure the continual improvement of the Management System by recognizing and addressing needed improvements through the Continual Improvement Process.

   1.3. To ensure the Continual Improvement Processes are implemented and recorded.

   1.4. To ensure that continual improvement processes are effective in improving the Management System.

2. **OWNER:** State Chemist/Quality Assurance Manager

3. **DEFINITIONS:**

   3.1. Continual Improvement Process (CIP): action to identify needed improvements to the Management System. CIP Form (F-019) is used to record information about the needed improvement.

   3.2. Root Cause(s): the most basic cause(s) that can reasonably be identified that management has control to fix and, when fixed, will prevent the problem's recurrence.

   3.3. Root Cause Analysis (RCA): a problem-solving process or the process of asking the "why" question relative to the identified problem to determine the fundamental causal factor(s) and to use that analysis to improve the process.

4. **PROCEDURE:**

   4.1. Initiating a Continual Improvement Process.

      4.1.1. Reasons for a CIP may be (but not limited to) needed improvements to the Management System, potential nonconformities, management review action items, customer feedback, risk assessment, purchase of new or improved equipment, Laboratory redesign or remodeling, and suggestions from employees.

      4.1.2. Any Laboratory employee may initiate a CIP. This can be done by contacting the Quality Division.

      4.1.3. The requester should include as much detail as possible and provide clear statements for the improvement on the CIP form (F-019).

   4.2. Approval of the Continual Improvement.

      4.2.1. The Management Team will evaluate and decide on the merit and cost of a CIP. If the decision is affirmative, the process will proceed; if not, the process will stop.

   4.3. Root Cause Analysis.

      4.3.1. If it is determined that the recommended improvement is superficial, conduct a root cause analysis. Worksheet WS-034 Root Cause Analysis/CAR Identification and Implementation is suggested as a guideline to help determine root cause.

      4.3.2. Update the F-019 as necessary with the results of any root cause analysis.

   4.4. Develop a Continual Improvement Plan.

      4.4.1. The requester will develop a plan for the needed improvement and record that plan on the CIP form and submit to the Management Team for review. The Management Team will determine if approved and how to proceed.

   4.5. Implement the Continual Improvement Process.

      4.5.1. Implement the Continual Improvement Process Plan, evaluate the results, revise the action plan as necessary, monitor the revised plan, and summarize the results on the CIP form.

4.6. Evaluate the Effectiveness of the Continual Improvement Process.

4.6.1. Review and evaluate the outcome of the implementation to determine whether the CIP has been successful.

4.6.2. If the CIP is successful, the process will proceed; if not, the process will stop.

4.7. Update the Related Documents in the Management System or Create New Documents.

4.7.1. If the CIP is successful, the Management Team will either update the related documents in the Management System or create new documents to reflect the improvements identified.

4.7.2. Once completed, the CIP is closed.

QP-126 Corrective Actions

1. SCOPE:

1.1. This procedure applies to all personnel within the Laboratory.

1.2. To ensure the continual improvement of the Management System by recognizing and addressing nonconforming work and nonconformities through the corrective action process.

1.3. To ensure corrective actions are implemented and recorded.

1.4. To ensure that corrective actions taken are effective in preventing recurrence of those nonconformities discovered within the Management System.

2. OWNER: State Chemist/Quality Assurance Manager

3. DEFINITIONS:

3.1. Requirement: need or expectation that is written and obligatory; an imperative or a "shall".

3.2. Conformity: fulfillment of a requirement; in compliance.

3.3. Nonconformity: non-fulfillment of a requirement; out of compliance; departure; deficiency.

3.4. Nonconforming work: testing work for which evidence exists that the result(s) are not acceptable; best identified with Quality Control data and proficiency test data.

3.5. Evidence, objective evidence or direct evidence: proof of conformity or proof of nonconformity; something observed or viewed in records; evidence is not what is heard, which is simply information.

3.6. Correction: action to eliminate a detected nonconformity.

3.7. Root Cause(s): the most basic cause(s) that can reasonably be identified that management has control to fix and, when fixed, will prevent the problem's recurrence.

3.8. Root Cause Analysis (RCA): a problem-solving process or the process of asking the "why" question relative to the identified problem to determine the bottom-line causal factor(s) and to use that analysis to improve the process.

3.9. Primary Effect: any effect that we want to prevent from recurring (*e.g.*, nonconforming work, deficiency).

3.10. Actions: momentary causes that bring conditions together to cause an effect (action causes).

3.11. Conditions: causes that exist over time prior to an action (condition causes).

3.12. Corrective Action: action to eliminate the cause of a detected nonconformity and to prevent recurrence.

3.13. Corrective Action Request (CAR) Form: F-001 used to record information about the problem and its solution.

4. PROCEDURE:

4.1. Initiating a Corrective Action.

4.1.1. Reasons for CARs may be (but not limited to) Management System nonconformities, complaints, nonconforming work, quality control failures, proficiency test failures, and internal and external audit nonconformities.

4.1.2. Any laboratory employee may initiate a CAR which can be found on the Master List on the common drive. Personnel then can contact the Quality Division who then will assign the CAR an identification and add additional evidence if needed.

4.1.3. The requester should include as much detail as possible and provide objective evidence for the nonconformity on the CAR form.

4.2. Corrections

4.2.1. Appropriate corrections (immediate remedial actions) are taken to mitigate or to eliminate the nonconformity (*e.g.,* "put out the fire", remove the problem). Address the consequences when applicable.

4.3. Root Cause Analysis: Initiate an investigation to determine the root cause(s) of the problem. Worksheet WS-034 Root Cause Analysis/CAR Identification and Implementation is suggested as a guideline to help determine root cause. Multiple root causes could exist. Consider all causes including, but not limited to, physical causes, human causes, and organizational causes.

4.4. Identification and Implementation of Corrective Action(s).

4.4.1. Identify the potential corrective actions based on the identified root cause.

4.4.2. Select the most appropriate corrective action.

4.4.3. Update the appropriate procedures to include the corrective actions if necessary.

4.4.4. Determine if similar nonconformities exist or could potentially occur.

4.4.5. Evaluate any risk involved with implementation of the chosen corrective action.

4.4.6. Implement the corrective actions. The person(s) responsible for implementation of the CAR is(are) listed on the F-001. After completing the CAR, it should then be submitted to the director or laboratory manager to review and sign before it can be turned into the QA division.

4.5. Evaluate the Effectiveness of the Corrective Actions.

4.5.1. Follow-up audits are conducted to determine whether the corrective actions taken have prevented the recurrence of the problem.

4.5.1.1. If it has been shown that the problem has not recurred, the CAR is closed.

4.5.1.2. CARs will be monitored after completion (F-016 CAPA monitoring). If the problem has recurred, the root cause investigation (Section 4.3) must be re-initiated and the process from that step must be repeated.

4.6. Update risks and opportunities if applicable.

4.6.1. Apply and accept changes to the management system if necessary.

4.6.2. Update documents involved in the original problem. Follow *QP-122 Document Control* for issuing updated controlled documents including test methods.

QP-127 Internal Audits

1. **SCOPE:**

   1.1. To utilize internal audits to maintain and improve the Management System as defined in ISO/IEC 17025:2017. Performing internal audits is one method for verifying conformity with the Management System and contractual requirements and to identify opportunities for improvement.

   1.2. This procedure describes the methodology for the planning and execution of Internal Audits at the Laboratory.

2. **OWNER:** State Chemist/Quality Assurance Manager

3. **DEFINITIONS:**

   3.1. Audit: A systematic, independent, documented process for obtaining audit evidence which can be records, statements of fact, or other relevant information and assessing them objectively to determine the extent to which specified requirements are fulfilled; "Are we doing what we say?"

   3.2. Audit Criteria: A set of policies, procedures, or requirements used as a reference against which audit evidence is compared.

   3.3. Audit Finding: Results of the evaluation of the collected audit evidence against the requirements. The audit finding types are:

      3.3.1. Commendation: Noteworthy effort or achievement that recognizes superior performance or improvement and can be reported in the audit summary.

      3.3.2. Conformity: Fulfillment of a requirement (*e.g.*, policy, procedure, instruction).

      3.3.3. Nonconformity: Non-fulfillment of a requirement.

      3.3.4. Continual Improvement: A situation where the requirement is met, but the Management System could be enhanced to improve its effectiveness.

   3.4. Internal Audit Checklist (F-022): A list of audit questions or activities, based on the requirements of the Quality Manual and/or the audited procedures, to provide objective evidence of items reviewed during the audit. The checklists shall cover some or all of the requirements of ISO/IEC 17025:2017.

   3.5. Audit Program: The procedures, schedules, and personnel needed to conduct internal audits.

   3.6. Auditee: Individual or department being audited.

   3.7. Lead Auditor: Individual responsible for the Internal audit checklist, conducting the audit, and the audit report.

   3.8. Auditor: Person who possesses the training and qualifications as defined by this procedure to conduct an audit.

   3.9. Corrective Action: Action taken to eliminate the cause of the nonconformity.

   3.10. Corrective Action Request Form (CAR), (F-001): A form used to record nonconformities, root cause analysis, corrective actions, and follow-up activities.

   3.11. Continual Improvement Process (CIP), (*QP-124*): Needed improvements to the management system.

   3.12. Continual Improvement Process Form (F-019): A form that may be used to record a plan to address improvement opportunities identified during an audit.

   3.13. Opening Meeting: Meeting held prior to the audit in which the Lead Auditor presents the audit focus and scope to the Audit Team, including other auditors and auditees, via e-mail, phone, or in person.

   3.14. Closing Meeting: Meeting held at the end of the audit to summarize and accept the audit results. This meeting can be conducted through an email that is sent to the Audit Team and appropriate management

that lists number of findings and includes the completed Audit Checklist, (F-022 & F-029 when applicable), and Audit Report, (F-011).

4. PROCEDURE:

4.1. Internal Auditor Qualification and Competency

4.1.1. The initial qualification and competency as an Internal Auditor shall be achieved by completing at least the following requirement:

4.1.1.1. Annual training on common internal quality audit practices provided by a recognized training source (*e.g.,* APHL or PJLA webinar), and/or on-the-job training consisting of at least one internal audit under the supervision of a qualified auditor.).

4.1.2. To maintain Internal Auditor qualification status, auditors shall perform a minimum of one internal audit biennially.

4.1.3. Auditors should take into consideration the findings of previous audits, while conducting current audits.

4.1.4. The internal audit program is to ensure that the Laboratory's own requirements for its management system, lab activities, and laboratory information management systems are continuing to be met.

4.2. Internal Auditor Responsibilities

4.2.1. Whenever resources permit, Internal Auditors conducting internal audits shall be independent of those having direct responsibility for the activity being assessed.

4.2.2. Internal Auditors shall conduct Internal Audits as assigned in the MSCL Internal Audits Schedule.

4.2.3. Auditors are responsible for completing the auditor training and maintaining proficiency and qualifications as required in the Internal Auditor Qualification section of this document.

4.3. Internal Audit Process and Responsibilities

4.3.1. The Quality Assurance Manager is responsible for coordinating the internal audits of all elements of the Management System at least every two years, or annually when applicable (*e.g.*, Laboratory Information Management Systems), by following the general Internal Audit Schedule and building specific schedules for each element. The schedule may be adjusted as necessary through risk-based assessment.

4.3.2. Elements of the Management System are audited using an Audit Checklist, F-022, that is prepared by the Lead Auditor. This checklist may vary in content from time to time, depending on the audit focus.

4.3.3. The Lead Auditor shall prepare an audit plan in advance of the scheduled audits. A copy of this audit plan shall be distributed to the State Chemist/Quality Assurance Manager and the audit team members who will be involved in the audit. The audit plan, which may be a simple email, should include the names of auditors, auditees, observers, audit schedule (date, time, and location), and the elements that will be audited.

4.3.4. An Internal Audit report (F-011) is prepared by the Internal Auditor and contains the following:

- Section Audited
- Audit Dates
- Name of the auditor and principal auditee(s)
- Audit scope, based on risk-based assessment
- Description of how processes were audited when applicable
- Audit observations and findings
- Recommendations and opportunities for improvement

- Corrections or CARs issued when applicable

4.3.5. A Corrective Action Request (CAR) is issued without undue delay if nonconformity for a requirement is identified.

4.3.6. A Continual Improvement Process Form, F-019 may be used to address Opportunities for Improvement identified during the audit.

4.3.7. The Internal Auditor shall consult with the audit team for concurrence on each nonconformity prior to CAR issuance.

4.3.8. Responses to CARs shall be processed as outlined in *QP-126 Corrective Actions*.

4.3.9. Responses to CIPs shall be processed as outlined in *QP-124 Continual Improvement Process*.

4.3.10. After completion of the audit, the Lead Auditor compiles all audit results into a closing email and is submitted to relevant management and the Audit Team for review and/or implementation.

4.3.11. All internal audits are reviewed annually during Management Review.

4.4. Audit Files

4.4.1. Audit Files are quality records and are maintained.

4.4.2. The Audit file shall, as a minimum, contain the following items:

- Completed Internal Audit Report (F-011)
- Completed Internal Audit Checklist (F-022 & F-029 when applicable)
- Auditor notes, e-mails, pictures, scanned files, or other evidence when applicable
- CARs and CIPs, if any

4.4.3. Audit Files shall be stored in a secured area according to *QP-114 Records Management*.

QP-128 Management Reviews

1. **SCOPE:**

   1.1. This procedure applies to all management team personnel within the Laboratory.

   1.2. To define the process for conducting management reviews of the *Management System*.

2. **OWNER:** State Chemist/Quality Assurance Manager

3. **DEFINITIONS:**

   3.1. Management Review: a self-evaluation of the *Laboratory's Management System* documents and testing activities for the purpose of improvement and the identification of risks.

   3.2. Management System: a set of documented, written, processes, instructions, arrangements, responsibilities, and authorities to ensure that a laboratory can fulfill all tasks required to achieve its objectives.

   3.3. Continual Improvement Process, *QP-124* to be made to the *Management System*.

   3.4. Finding: what was found.

   3.5. Action Item: what is being planned; action items will be handled with *QP-124 Continual Improvement Process* according to a defined deadline.

4. **PROCEDURE:**

   4.1. Overview

      4.1.1. The State Chemist/Quality Assurance Manager, with input from the Management Team, shall review the *Management System* documents (policies, procedures, work instructions) to assure their continuing suitability and effectiveness and to identify and implement any necessary changes or improvements. The Management Review summary will be recorded in F-014 Document Review and Quality Effectiveness.

   4.2. Schedule

      4.2.1. The Management Team meets a minimum of once a month to review and address the effectiveness of the *Management System*. The review includes: (*e.g.*, Corrective Action Request, Continual Improvement Process, Internal Audits, Nonconforming Work, Opportunity for Improvement, and Customer Complaints). The Management Review is scheduled annually.

   4.3. Participants

      4.3.1. The State Chemist/Quality Assurance Manager shall convene the Management Team.

      4.3.2. The Management Team includes the State Chemist, Associate State Chemist, the Quality Assurance Manager, Director, and Laboratory Manager. Other key personnel may be present as needed.

   4.4. Responsibilities of the participants

      4.4.1. The Management Review Process (WS-110) can be used as guidance when preparing the annual Management Review Summary Report.

      4.4.2. The State Chemist or designee shall chair and conduct the meeting according to the agenda.

      4.4.3. Members of the Management Team will make presentations on their specific areas of responsibility and evaluate the information presented in accordance with the questions identified in the Management Review Process.

      4.4.4. The State Chemist or designee will assign specific persons to address the findings and Action Items from this review and establish deadlines for their completion.

4.4.5. The Quality Assurance Manager or designee will prepare the final Management Review records. These records will be distributed to all participants. Records will be managed according the *QP-114 Records Management*.

4.4.6. The Management Review Process, (WS-110), provides guidance on the issues to be addressed, the questions to be asked, and the records to be prepared.

4.5. Response to management review findings and identified action items.

4.5.1. The responsibilities for handling individual action items will be assigned to specific individuals.

4.5.2. The Continual Improvement Process, using the form (F-019), will be initiated for all the appropriate action items within a timely manner after the review meeting and with the activity to be completed by due date.

Reviewed and Approved

Reviewed By:

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Dongping Jiang, Quality Assurance Manager — **Date** 8/5/24

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