Prepared by: Date:

Reviewed by: Date:

Approved by: Date:

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# Purpose

The Laboratory Manual provides a central authoritative source for the approved and mandatory laboratory procedures, policies, and quality assurance practices to be used by OTSC scientists in the course of their daily work.

# Scope / Field of Application

Laboratory analysis is a critical part of the Office of the Texas State Chemist’s (OTSC) regulatory activities. The Laboratory Manual (LM) is the essential source for communicating to the laboratory staff the manner in which business is to be conducted within a regulatory framework. Adherence to this manual by OTSC laboratory staff is necessary to ensuring both quality and consistency. This laboratory manual is OTSC’s primary resource for laboratory information; however, other documents may supplement specific topics. Recognizing the Laboratory Manual may not cover all situations and variables arising from the laboratory setting, any significant departures must have the concurrence of management and must be appropriately documented.

# Responsibilities

*State Chemist and Director* – Responsible for all laboratory activities (AAS) and field programs (FFCS) including administration of the laws assigned to this office, food safety surveillance and monitoring, and preparedness programs performed by OTSC. The Director will provide evidence of his commitment to the implementation of the Laboratory Quality Manual by ensuring that the plan is achievable within the specified budget, monitoring progress of the management team in fulfilling their obligations, verifying that reports are submitted within the specified time frame, and reviewing internal audit reports and other activities as outlined in SOP M0039, Management Review Procedure. The Director commits the needed resources to fulfilling the Laboratory Quality Manual and communicates the importance of the program to FFCS and AAS management, chemists, investigators, and staff.

*Associate Directors* – In the absence of the State Chemist directs the operations of the Office of the Texas State Chemist AAS and/or FFCS and reports to the State Chemist progress of the laboratory and/or field office. The Associate Directors monitor activities within these units, verifies that corrective actions are taken when necessary and ensures accurate and thorough record keeping is performed.

*Quality Assurance Manager* – The quality assurance manager is responsible for ensuring the laboratory accurately performs laboratory procedures and provides quality data. The QA Manager monitors activities for all sections of the State Chemist Office Laboratory. This includes, but is not limited to, the development of QA Programs for the Texas State Chemist Office, the preparation of standard operating procedures (SOPs), the incorporation of proficiency test programs, the performance of audits (internal and external) and facilitation of training.

*Laboratory Operations Manager –* Responsible for the direction and supervision of the analysis of regulatory samples, monitoring the throughput of contracts and outside customer requests. Responsibilities also include the review of data and procedures, and the maintenance of the laboratory information management system (LIMS).

*Lead Chemists, Team Leaders, and Team Members –* In addition to duties defined in their individual position descriptions, the Lead Chemist and Team Leaders are responsible for conveying the needs and concerns of the team to lab management and communicating management needs to the team. (However, the team members are free to contact management directly if needed.) The team leader meets with the team to determine how best to accomplish the FFCS Plan of Work while adhering to the Quality system described in this manual. The team is responsible for ensuring necessary repair and preventive maintenance is scheduled and performed on instrumentation and equipment.

Deputies for key personnel are appointed to fulfill the key personnel’s duties in their absence.

Management is responsible for providing resources to ensure that current and/or increased workload requirements are met. This includes making adjustments as a result of employee absence. Only fully trained employees are utilized to fulfill the duties of personnel who are absent. If sufficient human resources are not available, management will identify the best possible solution to meet operational requirements.

# OTSC Laboratory Quality Policies

**1.0 Introduction and Table of Contents**

This Laboratory Manual of Quality Policies has been prepared to meet the requirements for laboratory accreditation of the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025 (2005).

**Section Topic**

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**2 Controlled Distribution of Quality Manual**

**3 Quality Policy Statement**

**4 Management Requirements**

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**5 Technical Requirements**

**5.1 General**

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**5.10 Reporting the Results**

**Revision History**

**2.0 Controlled Distribution of the Quality Manual**

The OTSC Manager of Quality Assurance is responsible for maintaining the official master copy of the OTSC Laboratory Manual which contains the OTSC Quality Manual. General distribution of this manual is accomplished using a computer network. Annual review is coordinated by the Quality Assurance Manager.

**3.0 Quality Policy Statement**

The management within our organization is responsible for the quality and integrity of all data generated by this office. The management, collectively, assures this quality through adherence to our Laboratory Manual, Quality Assurance Plan, and through the development and adherence to Standard Operating Procedures. The quality policy statement is stated in Subsection 4.2.2.

**4.0 Management Requirements**

**4.1.1** The Office of the Texas State Chemist is an office within the Texas Agricultural Experiment Station which is part of the Texas A&M University System.

**4.1.2** The intent of OTSC is to operate the Agricultural Analytical Services laboratory according to the following requirements:

 Texas A&M AgriLife Research TAMAR policies

 OTSC policies

 ISO/IEC 17025

Accreditation body policies on advertising, metrological traceability, and

 proficiency testing

 Federal and State laws and regulations

 Customer contracts

**4.1.3** The Office of the Texas State Chemist operates one laboratory at

 445 Agronomy Road

 College Station, TX  77843-2114

**4.1.4** The Agricultural Analytical Services Laboratory is part of the Office of the Texas State Chemist and Texas A&M AgriLife Research. The Texas Feed and Fertilizer Control Service is the regulatory branch of the Office of the Texas State Chemist. The Agricultural Analytical Services Laboratory reports analytical results directly to the Texas Feed and Fertilizer Control Service electronically via its Laboratory Information System (LIMS)

**4.1.5 a.** The laboratory has managerial and technical staff with the authority to discharge their duties as reflected in the prepared job descriptions by the laboratory. This authority includes the implementation, maintenance, and improvement of the management system, the authority to identify departures from the management system and procedures, and the authority to initiate preventative and corrective actions. Management authorities are defined in the TAMAR Position Authorization/Description (PAD). The resources needed to discharge these duties are identified in Section 5.2 to Section 5.6.

**4.1.5 b.** Management ensures that employees conduct themselves in an ethical manner and do not have conflicts of interest. An “External Employment and Consulting Application and Approval” form HR202A is completed by non-faculty and a “Texas A&M AgriLife Research, Texas Cooperative Extension, and College of Agriculture and Life Sciences Request for Consulting and Outside Professional Employment for Faculty and Extension Agents” form AG-406 is completed and approved for employees seeking outside employment.

**4.1.5 c.** Following review and authorization by laboratory management, reports of laboratory data are transmitted and filed in accordance with official policies. The majority of data are reported to internal customers only. Furthermore, the OTSC building and laboratory is a controlled access facility.

**4.1.5 d.** Adherence to the highest ethical standards is critical to accomplishing the mission of the Office of the Texas State Chemist. Being an employee of a state regulatory office requires a familiarity with and an observance of the Texas A&M University System Policy 07.01 “Ethics Policy, TAMUS Employees”. All employees are required to take ethics training through Texas A&M every two years.

**4.1.5 e.** The Agricultural Analytical Services laboratory is part of the Office of the Texas State Chemist which is part of the Texas A&M AgriLife Research. The organization and the relationship among the laboratory staff is reflected in the OTSC organizational chart which may found on the TAMAR and OTSC web pages or by contacting the OTSC administrative secretary. The Quality Manager reports directly to the State Chemist and Director.

**4.1.5 f.** Job responsibilities for laboratory personnel are documented in the management system procedures. A TAMAR Position Authorization/Description (PAD) is maintained for all employees by the OTSC Senior Administrative Coordinator.

**4.1.5 g.** The laboratory staff performing analytical procedures have access to consensus standards, instrument manufacturers’ manuals, and laboratory standard operating procedures (SOPs) for reference. Demonstration of competence for technical personnel is documented and used as evidence of desired familiarity with laboratory methods. Chemists do not perform analytical work on regulatory samples until qualified (see SOP P0001).

**4.1.5 h.** The Laboratory Operations Manager is responsible for the technical operation of the laboratory and for ensuring laboratory staff follow quality system procedures. Resources for training and laboratory methods are described in sections of this manual and in laboratory SOPs.

**4.1.5 i.** The Quality Assurance Manager is responsible for the laboratory’s quality system and its implementation and has direct access to the State Chemist who is responsible for decisions concerning policy and resources.

**4.1.5 j.** Deputies for key personnel are appointed to fulfill the key personnel’s duties in their absence.

In the absence of the State Chemist and Director, the deputy is the Associate Director or an employee designated by the State Chemist and Director.

In the absence of the Quality Assurance Manager or the Laboratory Manager, the deputy is the Deputy Quality Assurance Manager or an employee designated by the Director.

**4.1.6** Effective communication from management occurs through the use of but not limited to memos, newsletters, electronic presentations, emails, or verbally to laboratory personnel regarding the effectiveness of the management system. Monthly meetings of the management team facilitate the exchange of information between office divisions while quarterly laboratory staff meetings provide for direct communication of quality issues.

**4.2 Management System**

**4.2.1 The laboratory management system is outlined in the following documents:**

 Quality Manual

 Quality procedures

Technical procedures

 Work Instructions

 Forms and records

 References

This management system is established to address the requirements in ISO/IEC 17025. The quality policy and quality objectives for the OTSC laboratory are included in subsection 4.2.2. The documents listed above are accessible to all personnel.

**4.2.2 Management System Quality Policies**

**Mission**

The Office of the Texas State Chemist (OTSC) works to protect Texas consumers and to help maintain an equitable marketplace for feed and fertilizer manufacturers.

The mission of Agricultural Analytical Services (AAS) is to provide high quality, timely analyses of feed and fertilizer samples to the Feed and Fertilizer Control Service (FFCS) for the regulation of industry, the protection of consumer rights and the safeguarding of human and animal health in the State of Texas.

*In pursuit of our mission we intend to:*

* be nationally recognized by our peers (state feed and fertilizer regulatory agencies) as producing the most reliable analytical results.
* expand local and state awareness of AAS and increase recognition of our services in protecting public health and fair commerce.
* provide a professionally and personally satisfying workplace for its employee family.

The Office of the Texas State Chemist (OTSC) fulfills its mission of serving agribusiness in Texas and the world by working to ensure food safety, protect the environment and enhance agricultural competitiveness. The Office accomplishes this mission through its regulatory compliance program, surveillance and monitoring of the Texas feed and grain supply, and preparedness planning in concert with other state agencies.

The Agricultural Analytical Services (AAS) enables OTSC to accomplish this mission by providing high quality, timely analyses of feed and fertilizer samples to the Feed and Fertilizer Control Service and by ensuring that all data generated and processed will be scientifically valid, of known precision and accuracy, of acceptable completeness and, where appropriate, legally defensible.

The management within our organization is responsible for the quality and integrity of all data generated by OTSC. The management, collectively, assures this quality through adherence to our Quality Management System.

**Commitments to Quality Issued by State Chemist and Director, OTSC**

**4.2.2 a. Good Professional Practice and Quality of Analysis**

The OTSC Laboratory Quality Management System is implemented by the State Chemist and Director to ensure that our clients are provided timely, high quality and professional scientific services which meet their expectations; and to ensure that the Laboratory meets standards of service required by its clients and maintains and improves upon its standards of quality.

The policy statement is achieved by the commitment of management and personnel to apply good professional practices that ensure the quality of testing services and the laboratory is compliant with ISO/IEC 17025. This effort is aided by the distribution of a Quality System Manual which is kept current under the direction and authority of the Quality Assurance Manager. All personnel are trained in the application of quality related procedures.

**4.2.2 b. Standard of Service**

The laboratory’s standard of service for the analytical testing program is defined by ISO/IEC 17025 requirements, OTSC regulatory needs, and the following:

* Established and maintained documented procedures for laboratory operation based upon consensus methods for testing. Methods are specified or cited in compendiums or by the customer. In some cases, testing and procedures as established by the instrument or test kit manufacturer are used.
* Sample handling and management procedures to maintain integrity of both the samples and the documentation to support the analytical data.
* Maintenance of records in such manner that facilitates retrieving them later. Archival retention periods are stated in the laboratory’s document control and management procedure.
* Employment of qualified and trained personnel to perform the tasks to support the laboratory objectives. Performance demonstrations by personnel conducting laboratory methods are conducted and documented.
* Routine maintenance of quality control data to support testing results by demonstrating that analytical processes are maintained in statistical control. Accuracy and precision control charts are used to monitor performance.
* Maintenance of an instrument calibration program that provides traceability to International System of Units (SI) units. This is accomplished with the use of national, international, or industry accepted standards of measurement.
* OTSC laboratory personnel follow the policies included in this manual, the processes described in their local operating procedures, and the processes described in laboratory methods referenced in this manual.
* Changes to management system documents are made according to the laboratory document control procedure and involve periodic revisions of this manual as part of the annual management review of the management system.
* An internal audit process is used to evaluate the effectiveness of the management system established for laboratory operations. It is the policy of the OTSC laboratory to participate in inter-laboratory proficiency programs. The sections in this manual describe elements and reference procedures that outline the management system established to accomplish the mission of the laboratory.
* Analytical results and the communication of information generated by the laboratory are conducted under the direction of the State Chemist and Director of the Office of the Texas State Chemist.

**4.2.2 c. Management System Objectives**

* The primary objective of the management system established by the OTSC laboratory is to assure the accuracy and precision of laboratory results so that they will be reliable, interpretable, repeatable, and defensible. Data quality objectives are described in the terms of:

Accuracy

Precision

Detection and quantitation limits

Timeliness

Comparability

* The second objective is to establish and maintain national and international recognition through compatibility with the requirements of relevant standards.
* Third, strive to meet or exceed the customer’s needs and expectations for precision, accuracy, sensitivity, and specificity.
* Fourth, maintain the OTSC laboratory’s reputation for quality by fostering continuous process improvement and problem prevention. OTSC is committed to the continuous improvement of the Laboratory Manual as we strive to maintain and foster excellence in our daily laboratory operations.

These objectives are taken into account as part of the reviews performed by management.

**4.2.2 d. Management System Awareness and Implementation**

The management system documents and test methods are included in the laboratory’s training program. The implementation of the quality policies is evidenced by the manner in which work activities are conducted. Implementation of the management system procedures is evidenced by the generation of required records. The audit and management review activities are the mechanisms that are used to monitor the implementation effort of the laboratory management system.

**4.2.2 e. Commitment to ISO/IEC 17025**

The policies for operation of the laboratory management system are established to address the requirements of ISO/IEC 17025. This commitment is evident by the approval signature of the State Chemist and Director, OTSC for this quality manual.

**4.2.3** Evidence of management’s commitment to the management system and its continual improvement in effectiveness is demonstrated by but not limited to participation of managers in the management reviews, performance of internal audits, proficiency testing, and the analysis of quality control samples.

**4.2.4** Effective communication from management occurs through the use of but not limited to memos, newsletters, electronic presentations, emails, or verbally to laboratory personnel regarding the importance of meeting FFCS, customer, statutory, and regulatory requirements.

**4.2.5 Procedures and Outline of the Management System**

Management system procedures supporting quality policies are cited within each section of this manual. The outline of the management system is included in Subsection 4.2.1.

**4.2.6 Roles and Responsibilities**

General roles and responsibilities for OTSC laboratory positions are summarized as follows:

●Quality Assurance Manager

 Ensures that the management system is established, implemented, and maintained in conformance with the requirements of ISO/IEC 17025

 Advocates and coordinates quality improvements to the management system

 Ensures that analytical results satisfy customer requirements

● Laboratory Operations Manager

 Oversees technical functions

 Ensures compliance with the requirements of ISO/IEC 17025

 Ensures management system procedures, applicable standards, specifications, and regulations are followed

 Ensures that qualified, skilled, and trained personnel and other resources are available

 Ensures that analytical results satisfy customer requirements

●Analysts, Research Scientists, and laboratory support staff

Ensure the quality of their work

 Operate in conformance with the requirements of the management system

●Research Scientists

Develop and validate new methods

Conduct research involving feed and food safety

Provide input and perform technical functions

**4.2.7** The management system policies and procedures as defined in this manual maintain the integrity of the management system when a change in the structure of OTSC or management, or changes in policies or procedures are made.

**4.3 Document Control**

**4.3.1 General**

The document control and management procedure, described in SOP M0034, “Document Control and Management,” describes the process for controlling quality documents that form part of the management system. The quality documents include those required for the generation of laboratory data. These documents include those published by the laboratory and those published externally. Documents of external origin include regulations, standards, test methods, instructions, and manuals.

**4.3.2 Document Approval and Issue**

**4.3.2.1** Documents issued to personnel in the laboratory as part of the management system are reviewed and approved for use prior to issue in accordance with the laboratory’s document control and management procedure. The laboratory’s master list identifies the current revision status and distribution of documents. Through the use of the master list, quality documents are posted to personnel to preclude the use of obsolete documents.

**4.3.2.2 Procedure Content**

The laboratory’s master list and document control and record management system provides for the following:

a. Authorized management system documents and external documents are at locations where operations essential to the effective functioning of the laboratory are performed.

b. Documents are reviewed according to a schedule and revised to ensure continuing suitability and conformance with the management system and ISO/IEC 17025 requirements.

c. Invalid or obsolete documents are promptly removed from all points of issue or use and marked uncontrolled or obsolete to assure against unintended use.

d. Obsolete documents retained for either legal or knowledge preservation purposes are marked as archived or obsolete.

**4.3.2.3 Document Identification**

A document control header as described in the laboratory’s document control and management procedure uniquely identifies management system documents generated by the laboratory. Such identification includes the date of revision, identification number, and inclusive pagination. The issuing authority is indicated by the name of the approving official in the document history section of each document.

**4.3.3 Document Changes**

**4.3.3.1** Changes to documents are reviewed and approved in accordance with the laboratory’s document control and management procedure. Unless designated otherwise, this procedure is followed by the same personnel as in the original review or approval. The use of reference documents and information is required upon which to base the review and approval.

**4.3.3.2** The altered or new text is identified either in the document, on a cover page, or in the attachments.

**4.3.3.3** The laboratory’s document control and management procedure addresses the handling of document amendments by hand (pending re-issue). All hand edits must be initialed and dated by the State Chemist/Director and Quality Manager.

**4.3.3.4** **Computerized Systems**

The laboratory’s document control and management procedure addresses the control of electronic management system documents. Access to laboratory computer documents will be controlled by limiting access to the laboratory computer drive to authorized staff.

**4.4 Review of Requests, Tenders, and Contracts**

**4.4.1 Review**

The Director of the OTSC reviews and approves requests, tenders and contracts. The procedure is defined in SOP F0004, “Checklist for Special Projects Analytical Services”.

The work agreements specify and define the methods to be used, resources required, and the turnaround requirements.

Differences between the tender and contract is resolved before laboratory analysis is begun.

**4.4.2 Records of Review**

The OTSC laboratory maintains records of workplan reviews, change requests, and changes. Records are also maintained of discussions regarding ad hoc assignments.

**4.4.3 Subcontracting Laboratories**

The policies regarding the review of requests, tenders, and contracts also apply to the use of subcontracting laboratories.

**4.4.4 Contract Deviations**

Deviations from the contracted work will be reviewed by the Quality Assurance Manager. The Quality Assurance Manager will then interact with the Director and customer to determine if the requested changes are acceptable. Records of contract changes are maintained.

**4.4.5 Contract Amendments**

If a contract needs to be amended after work has commenced the review process found in Section 4.4.1 is followed.

**4.5 Subcontracting of Tests**

**4.5.1** The OTSC laboratory does not subcontract routine analyses. Based on resource needs and workload fluctuations or unforeseen reasons, the OTSC laboratory may subcontract some analyses to competent laboratories. The laboratory may assist the FFCS in locating a competent laboratory to perform a non-routine analysis. See SOP F0002 “Guidelines for Qualifying Laboratories for Use in Appeals” and “F0005 “Subcontracting of Laboratory Tests.”.

**4.5.2** When using a subcontracting laboratory written notification will be made. When possible, written approval by the customer will be obtained prior to the analysis of samples.

**4.5.3** The OTSC laboratory is responsible for the contracting laboratory’s work unless the contracting laboratory is specified by the customer.

**4.5.4** The OTSC laboratory maintains a record of subcontractors that have met F0002.

**4.6 Purchasing Services and Supplies**

**4.6.1 Policy and Procedures**

The laboratory or designated purchasing agents use Texas A&M AgriLife Research and related State of Texas procedures for the procurement of materials, supplies, and services. The OTSC Feed and Fertilizer Control Service has work instructions describing the processing of requisitions. Laboratory procedures describe the process for the selection, purchase, reception, and storage of equipment, services and supplies, including reagents and laboratory consumable materials, used in the performance of the tests. See SOP F0006 “Procedure for Purchasing of Services and Supplies” and S0004 “Guidelines for Receiving Shipments Delivered to the Office of the Texas State Chemist”

**4.6.2 Inspection and Verification**

The laboratory’s purchasing and receiving procedures describes how purchased equipment, supplies, services, reagents, and consumable materials that critically affect the quality of tests are inspected or verified prior to use or concurrently with use. Inspection or verification criteria are used to establish conformance with requests made by the customer, included in standard specifications, or defined in the methods.

**4.6.3 Purchasing Documents**

Purchasing documents for items affecting the quality of laboratory results describe the services or supplies ordered. These purchasing documents are reviewed and approved for technical content prior to submission.

**4.6.4 Records of Suppliers**

Records of supplier evaluations and a list of approved suppliers are maintained by purchasers of laboratory equipment, services, and supplies.

**4.7 Service to Customer**

**4.7.1** The laboratory affords the requesting customer cooperation to clarify the customer’s request within the framework of the contract review process described in Section 4.4 Review of Requests, Tenders, and Contracts. The opportunity for the customer to witness laboratory activity (audit) is given upon request, providing the laboratory is able to maintain confidentiality to other customers.

**4.7.2** The laboratory seeks customer feedback on their services and general performance. Records of the comments, both positive and negative, are maintained and are taken into account for identifying management system improvements during reviews performed by management. See Section 4.12 “Preventative Action” and Section 4.15 “Management Review”.

**4.8 Complaints**

The laboratory has a complaint procedure; see SOP M0051 “Complaint Resolution Procedure” and F0003 “Handling of Portion and Referee Sample Requests”. Records of all complaints received are maintained according to the procedure.

**4.9 Control of nonconforming work**

**4.9.1 Procedure**

The OTSC laboratory has a control of non-conforming work procedure, M0035 “Control of Non-conforming Work”, which is implemented when any aspect of their testing work or the results of this work does not conform to requirements of the management system, testing methods, or the requirements of the customer. The procedure addresses:

a. responsibilities and authorities for the management of identified non-conforming work and taking actions such as halting of work, the withholding of test reports;

b. application of criteria to evaluate the significance of non-conforming work;

c. remedial action taken, together with any decision about the acceptability of the non-conforming work;

d. notification of the customer and recall of work, if necessary; and

e. responsibility for authorizing the resumption of work.

**4.9.2 Follow-Up**

If the non-conforming work could recur, or other significant problems are identified, or there is doubt about the compliance of the laboratory’s operations with its own policies and procedures, the corrective action procedures in Section 4.11, Corrective Action are promptly followed.

**4.10 Improvement**

The OTSC laboratory continually improves the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventative actions, and management review, see Section 4.15 “Management Review”.

**4.11 Corrective Action**

**4.11.1 General**

The OTSC laboratory has a corrective action procedure, M0037 “Corrective Action Procedure” that designates the authorities for implementing corrective action when one of the following is identified:

Non-conforming work, QC failure

Proficiency testing problems

Departures from the policies and procedures in the management system, and

 Departures from required technical operations.

**4.11.2 Cause Analysis**

The procedure for corrective action includes investigating and determining the root cause of the non-conformance.

**4.11.3 Selection and Implementation of Corrective Actions**

Potential corrective actions are identified. The action(s) most likely to eliminate the problem and to prevent recurrence is selected.

The corrective action chosen addresses the magnitude of the non-conformance and the risk attributed to the non-conformance.

Corrective actions are documented, and any changes resulting from the corrective action investigation are implemented.

**4.11.4 Monitoring Corrective Actions**

The corrective action procedure addresses the monitoring for the effectiveness of corrective actions performed.

**4.11.5 Additional Audits**

Where the identification of non-conformances or departures casts doubts on the laboratory’s conformance with management system policies and procedures or conformance with ISO/IEC 17025, the areas of activity affected by the non-conformance are audited as soon as possible in accordance with Section 4.14 Internal Audits.

**4.12 Preventative Action**

**4.12.1 General**

Needed improvements and potential sources of non-conformance are identified according to the process described in the laboratory’s preventative action procedure, M0036 “Improvement and Preventative Action Procedure”, and are part of the management review process. Preventative action plans are developed, implemented, and monitored to address the identified opportunities for improvement.

**4.12.2 Procedure**

The procedure includes the initiation of action. The management review process monitors the effectiveness of such actions in providing improvement to the management system. See preventative action procedure and management review procedure, including reference to forms.

**4.13 Control of Records**

**4.13.1 General**

**4.13.1.1 Procedure**

The OTSC laboratory has a control of records procedure, M0038 “Control of Records Procedure” for identifying, collecting, indexing, accessing, filing, storing, maintaining, and disposing of quality and technical records. Quality records include those from internal audits, management reviews, corrective actions, and preventative actions.

**4.13.1.2 Legibility, Storage, and Retention**

Records are to be legible. Laboratory reports are archived upon final review. A record retention schedule is included in the laboratory’s procedure.

**4.13.1.3 Security and Confidentially**

Access is controlled to both the OTSC office and laboratory. Guests are escorted at all times. Only authorized personnel are allowed in the laboratory and record management center. Records are stored in secured areas. Records are confidential and released in accordance with the Freedom of Information (FOI) process.

**4.13.1.4 Electronic Records**

The OTSC laboratory has a procedure describing the back-up and protection of electronic records. The procedure describes the safeguards in place to prevent unauthorized access to electronic records.

**4.13.2 Technical Records**

**4.13.2.1 Retained Records, Audit Trail, and Identification**

Laboratory reports, depending on the type of analysis, include the original observations, derived data, calculations, standard preparation, instrument printouts, and results. The reports, staff records, equipment calibration, and verification reports are retained in accordance with the laboratory’s control of records procedure.

The records contain sufficient information to establish an audit trail.

The records of each analysis contain sufficient information in order to repeat the analysis under conditions as close as possible to the original. This information includes factors that affect uncertainty and any environmental conditions that affect the analysis.

The laboratory analytical summary sheet includes the identity of the personnel responsible for the performance of each analysis and for the review of the results.

**4.13.2.2 Recording and Identification**

Observations, data, and calculations are recorded at the time they are made and are identifiable to the activity performed. Set numbers, method numbers, and titles are used to provide traceability of records to activities.

**4.13.2.3 Corrections**

When errors occur in records, each mistake is lined out, not erased, not made illegible, nor deleted. The correct value is entered, initialed, and dated. See SOP M0021 “General Guidelines for Documentation in the Agricultural Analytical Services Laboratory”. In the case of records stored electronically, equivalent measures are taken to avoid loss or change of original data.

**4.14 Internal Audits**

**4.14.1 General**

Internal audits are conducted as needed (minimum of annually). See SOP M0025 “Laboratory Quality Audit Checklist”. The internal audits are conducted to verify that operations continue to conform to the requirements of the management system and ISO/IEC 17025.

The internal audit program addresses all elements of the management system, including written documents and analytical activities. The OTSC Quality Assurance Manager is responsible for the coordination of the annual internal audits in addition to any additional audits requested by management.

Trained and qualified personnel are responsible for conducting internal audits. Audits are performed by personnel other than those who performed the work being audited.

**4.14.2 Corrective Actions**

When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory’s analytical results, corrective action is undertaken according to the laboratory’s corrective action procedure.

The customer is notified if investigations show that non-conformances related to audit results also have affected work performed for the customer. This notification is documented.

**4.14.3 Audit Records**

The area of activity audited, the audit findings, and corrective actions that arise from them are recorded according the laboratory’s audit procedure.

**4.14.4 Follow-up Audit Activities**

Follow-up audit activities are conducted to verify and record implementation and effectiveness of the corrective action taken. This follow-up is included as part of the management review process.

**4.15 Management Review**

**4.15.1 General**

The laboratory’s management review procedure, M0039 “Management review Procedure”, includes the schedule for conducting management reviews. This review is conducted by the laboratory’s executive management to ensure continuing fitness for use and effectiveness of the management system and to introduce needed changes or improvements.

The management review addresses the elements of the management system and includes but is not limited to the following elements:

 Suitability of policies and procedures (section 4.2)

 Reports from managerial and supervisory personnel (section 4.1)

 Outcome of recent internal audits (section 4.14)

 Corrective and preventive actions (section 4.11, 4.12)

 Assessments by external bodies (section 4.14)

 Results of inter-laboratory comparisons and proficiency test (section 5.9)

 Changes in the volume and type of work (section 4.4)

 Customer feedback (section 4.7)

 Complaints (section 4.8)

Recommendations for improvement (4.10)

Other factors, quality control activities, resources and staff training (section 4.1 and 5.2)

**4.15.2 Findings and Actions**

The findings and the actions that arise from the review are recorded according to the laboratory’s management review procedure. Each action includes a target date for resolution.

**5.0 Technical Requirements**

**5.1 General**

The sections following below address the factors affecting the correctness and reliability of the analyses performed by a laboratory. These factors include contributions from:

Personnel (section 5.2)

Accommodation and environmental conditions (section 5.3)

Test and calibration methods and method selection and validation (section 5.4)

Equipment selection and calibration (section 4.6 and 5.5)

Measurement uncertainty and traceability (section 5.4 and 5.6)

Sampling and sub-sampling (5.7)

Handling of test and calibration items (section 5.8)

The procedures listed in each section address these factors.

**5.1.2 Contribution to Total Uncertainty of Measurement**

These factors are considered in determining total measurement uncertainty and in developing uncertainty budgets. Additionally, these factors are considered by the laboratory when developing analytical procedures, in the training and qualification of personnel, and in the selection of the equipment utilized.

**5.2 Personnel**

**5.2.1 Personnel Competence**

Laboratory management ensures that laboratory personnel have the knowledge, skills, and abilities to perform their duties. Competence is based on education, experience, demonstrated skills, and training. Staff records contain the documentation of personnel education, experience, skills, and training for the position held.

Analysts undergo a training program in accordance with the laboratory’s training procedure, P0001 “Method for the Qualification of Analysts”. For in-house training a qualified analyst serves as the trainer. After the trainee performs procedures and specified criteria have been successfully met, the trainee is considered competent and is allowed to analyze customer samples.

**5.2.2 Goals for Education, Training and Skills**

The individual and management are jointly responsible for the setting, the pursuit, and achievement of educational goals for professional advancement. The annual performance evaluation process can be used by the individual to discuss career advancement and training possibilities. By using this process, individuals have the opportunity to identify areas of study and request training oriented towards the attainment of their goals.

In-house training is conducted according to the laboratory’s training procedure (SOP P0001 Method for the Qualification of Chemists). Present and anticipated tasks of the laboratory are addressed in the planning of special training. Examples of such sources of training include: FDA – ORA, TAMU Human Resources, TAMU Health and Safety, numerous instrument manufacturers, and other organizations such as FERN courses.

Skills of personnel are based upon demonstration of competence. This demonstration is to be completed successfully before analysts generate data independently. The effectiveness of personnel training is documented in, but not limited to, management reviews, internal audits, proficiency testing, and performance evaluations.

**5.2.3 Employees and Contracted Personnel**

The laboratory utilizes the skills and talent of full time employees and occasionally other employees of TAMU or Texas A&M AgriLife Research. Supervision, training, and competence are documented for all technical and key support personnel.

**5.2.4 Job Descriptions**

The laboratory maintains active job descriptions for managerial, technical, and key support personnel involved in tests. See section 4.1.5 f.

**5.2.5 Management Authorization**

The OTSC Director authorizes identified personnel to:

 Perform testing and calibration

 Issue analytical test reports

 Give opinions and interpretations

 Operate particular laboratory instruments

Records of the demonstration of competence, education, training, and authorizations are maintained by the laboratory and/or in OTSC personnel records.

**5.3 Accommodation and Environmental** **Conditions**

**5.3.1 Facilities and Environmental Conditions**

The laboratory environmental conditions facilitate the correct performance of analytical testing. Test methods used by the laboratory include instructions addressing applicable environmental conditions (energy sources, lighting, dust, humidity, temperature, and biological sterility). The laboratory monitors critical environmental conditions to ensure that results and the quality of the measurement are not adversely affected or invalidated.

**5.3.2 Monitoring**

Environmental conditions that may require monitoring include, but are not limited to:

 Room temperature and humidity

 Air flow rates for chemical fume hoods

 Bio-safety hoods and laminar flow hoods

 Microbiological contamination on bench surfaces and hoods in microbiology laboratories

 Metal contamination on benches and hoods in laboratories performing metal analysis

**5.3.3 Cross-contamination**

Separate areas are maintained for incompatible activities. Measures taken to prevent cross-contamination include but are not limited to:

 Chemistry laboratories are separated from microbiology laboratories

 Sample receiving and storage are conducted in designated areas

 Microbiological media preparation and sterilization are separated from work areas

 Separate storage for standards and reference materials and cultures

**5.3.4 Access**

Laboratories are limited access areas. Access is controlled by issuance of keycards to authorized employees and by escorting all visitors (non-employees).

**5.3.5 Housekeeping**

Laboratory areas are maintained clean and orderly to prevent contamination of samples and to facilitate the efficiency of laboratory operations. Facility and environmental conditions specifies minimum housekeeping measures. The laboratory’s chemical hygiene plan includes measures to properly dispose of hazardous waste (see S0001 “Safety Manual”).

**5.4 Test Methods and Method Validation**

**5.4.1 General**

The appropriate methods the laboratory uses are determined by the analyte to be determined and the matrix of the samples.

The estimation of the uncertainty of measurement is addressed in Section 5.4.6.

The laboratory instructions for the use and operation of equipment called for by the laboratory methods is either a laboratory procedure or equipment manual. Procedures for the handling of samples are found in Section 5.8. Deviations from test methods are documented, technically justified, and authorized.

**5.4.2 Selection of Methods**

When the customer does not specify the method to be used, a standard method is preferred for use. Standard methods are those published by AOAC, FDA, EPA, USDA or other international, regional, or national standards-writing bodies. If a standard method is not found the laboratory may use either a non-standard method or modify a method for use with the concurrence of the customer. The non-standard or modified method is validated according to Section 5.4.5 Validation of Methods.

The laboratory informs the customer when the method proposed by the customer is considered to be inappropriate for the intended purpose (see Section 4.4 Review of Requests, Tenders and Contracts).

**5.4.3 Laboratory Developed Methods**

When the laboratory develops methods for its own use, the laboratory has a procedure for its introduction (see SOP M0033 “Validation of New Methods of Analysis” and Section 5.4.5 Validation of Methods). During the development of methods effective communication is maintained between the Chemist, Quality Manager, and Director.

**5.4.4 Non-standard Methods**

Non-standard methods are those methods not taken from authoritative, validated sources. The method’s performance capabilities have not undergone evaluation by a collaborative study.

Non-standard methods are selected for use when a customer request cannot be addressed with the use of a standard method. Such methods are subject to agreement with the customer (Section 4.4.5) and are validated (Section 5.4.5).

**5.4.5 Validation of Methods**

**5.4.5.1 Definition**

Validation is the confirmation by examination and the provision of objective evidence that the particular specifications for an intended use are fulfilled.

**5.4.5.2 Methods Requiring Validation**

The laboratory validates standard methods, non-standard methods, laboratory-developed methods, and modified standard methods including use outside the intended scope and applications. Validation is conducted to confirm that the methods are fit for the intended use. The performance is verified for all methods before being used to generate reportable data. The results of the validation, the procedures used, and a statement regarding the fitness of the method for its intended use are recorded.

**5.4.5.3 Process**

The validation process (see SOP M0033) addresses the needs of the given application. The attributes and data quality objectives include but are not limited to:

 Accuracy

 Precision

 Detection limit

 Limit of quantitation

 Linearity

If all the data quality objectives are met as indicated by the data collected, the method is considered as validated.

**5.4.6 Estimation of Uncertainty of Measurement**

**5.4.6.1 Procedure for Calibration Activities**

The OTSC laboratory does not perform calibration activities.

**5.4.6.2 Procedure for Testing Activities**

An attempt is made to identify all the components of uncertainty and make a reasonable estimation of the measurement of uncertainty. This estimation is based on knowledge, experience, and validation data of the performance of the method. If needed as part of the laboratory data, the uncertainty estimation is reported. The form of reporting shall not give an inaccurate impression of the uncertainty. The procedure used to estimate uncertainty for routine analysis is found in M0047 “Calculating measurement uncertainty”.

**5.4.6.3 Uncertainty Components**

When estimating the uncertainty of measurement, all important components are recorded in the uncertainty records for each analytical procedure or test. The data used to estimate the uncertainty of measurement are obtained from internal quality control samples.

**5.4.7 Control of Data**

**5.4.7.1 Data Transfers**

Calculations and data transfers are reviewed before the data is reported. All changes are identified and verified where they occur. See Section 5.9 “Assuring the Quality of Test Results” and SOP M0021 “General Guidelines for Documentation in the AAS Laboratory”.

**5.4.7.2 Computer Use**

When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage, or retrieval of test data, the laboratory follows the process in the laboratory’s data protection procedure.

**5.4.7.2.a.** If computer software is developed by the user, its development is documented in detail and validated.

**5.4.7.2.b.** The laboratory’s data protection procedure addresses the protection of the data to include, but not limited to, data integrity, data confidentiality during entry, collection, storage, transmission and processing.

**5.5 Equipment**

**5.5.1 Laboratory Equipment**

The laboratory has sample preparation, measurement, and test equipment for the correct performance of the tests. The laboratory also has ancillary equipment for processing samples and for processing data.

The laboratory purchases the equipment used by the laboratory, M0032 “instrument Selection and purchase”. Maintenance contracts are established as needed. The laboratory maintains an equipment inventory of all laboratory equipment used to perform regulatory testing.

**5.5.2 Equipment Capability**

Equipment and its software used for testing are to achieve the accuracy expected and comply with specifications of the testing concerned. Laboratory equipment that has a significant effect on the results has a calibration schedule. See M0029 “Protocol for Equipment Maintenance and General Guidelines for Calibration Procedures”, M0004 “Protocol for the use of laboratory balances”, M0012 “Quality control quality assurance document for use with pipets and dispensers”. The equipment performance is verified and verification records are maintained. Equipment is to meet the laboratory’s testing parameters and conform to standard specifications before being placed into service.

**5.5.3 Authorized Operation**

Personnel are authorized to operate equipment according to Section 5.2 Personnel Training Procedure. Authorization is based on work assignment, training, experience, and demonstrated proficiency. Equipment manuals and maintenance procedures are available to laboratory personnel.

**5.5.4 Equipment Identification**

Each significant item of equipment used for testing has an AAS (Agricultural Analytical Services) and/or TAMAR (Texas A&M Agrilife Research) identification number that is unique.

**5.5.5 Equipment Records**

Records are maintained on each item of equipment and its software significant to the tests performed according to the procedure SOP M0029 ”Equipment Maintenance and General Guidelines for Calibration Procedures”.

The records include at least the following items:

 Identity of the item of equipment and its software

 Manufacturer’s name, type identification, serial number or unique ID

 Performance checks that equipment conforms to acceptance criteria

 Location of equipment (if appropriate)

 Manufacturer’s instructions or reference to location

 Results, dates of reports of calibrations, adjustments, acceptance criteria, and the due date of next calibration

 Maintenance plan and maintenance carried out to date

 Any damage, malfunction, modification or repair to the equipment

**5.5.6 Management of Equipment**

The laboratory has a procedure in section 5.5.2 for the safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and to prevent contamination or deterioration.

**5.5.7.1 Out of Service**

Equipment that has been subjected to mishandling, gives suspect results or has been shown to be defective or outside of specified limits, is taken out of service. It is isolated and clearly marked as being out of service to prevent its use until it has been repaired and shown by calibration or test to perform correctly.

**5.5.7.2 Retesting and Calibration**

Laboratory personnel examine the effect of quality control analyses that indicate a defect or departure from specified limits on previous tests. See Section 4.9 Control of Non-conforming work.

**5.5.8 Calibration Status**

Equipment under the control of the laboratory and requiring calibration is labeled to indicate the calibration status, including the last date of calibration and the next calibration due date. Alternatively, equipment calibration status may be identified in an associated record to indicate the status of calibration.

**5.5.9 Equipment leaving the laboratory**

If for any reason equipment leaves the direct control of the laboratory, the function and calibration status of the equipment is checked upon return and shown to be satisfactory before the equipment is returned to service.

**5.5.10 Calibration Confirmation**

When needed to maintain confidence, intermediate calibration confirmation checks are performed according to SOPs M0004, M0012, or M0029.

**5.5.11 Correction Factors**

Where calibrations give rise to a set of correction factors, these factors are communicated to users.

**5.5.12 Safeguards**

Test and calibration equipment, including both hardware and software, are safeguarded from adjustments that would invalidate the test or calibration results. Safeguards are provided using access control to the laboratory.

**5.6 Measurement Traceability**

**5.6.1 General**

The laboratory equipment having a significant effect on the accuracy of the test is calibrated before being placed into service, as scheduled and following repairs. Procedures for equipment calibration are provided in section 5.5.

**5.6.2 Specific requirements**

**5.6.2.1 Calibration**

**5.6.2.1.1 Measurement Traceability**

The OTSC laboratory performs no calibration services. However, since all measurements made by the laboratory must be traceable to the International System of Units, contracting metrologists providing services to the OTSC laboratory are to provide evidence of measurement traceability of its own measurement standards and measuring instrument to the SI. Contracting metrologists providing services to OTSC are to provide documentation demonstrating measurement capability and competence to perform the calibration services requested by OTSC.

Calibration certificates issued by contracting metrologists are to include the measurement results, including the measurement uncertainty and/or a statement of conformance with an identified metrological specification.

**5.6.2.1.2 Non traceability of reference standards to SI units and Interlaboratory comparisons**

Calibrations that cannot provide strict measurement traceability to SI units are conducted such that the calibration results can provide confidence in the measurements made in the course of the analyses. This is accomplished by use of certified reference materials, use of specified methods or consensus standards, and/or participation in a program of interlaboratory comparisons.

The OTSC laboratory participates in the following proficiency testing programs:

Association of American Feed Control Officials (AAFCO)

Association of American Plant Food Control Officials (AAPFCO) Magruder

Association of American Oil Chemists (AOCS) mycotoxin and microscopy

American Association of Cereal Chemists (AACC) microbiological

**5.6.2.2 Testing**

**5.6.2.2.1 Testing and Calibration Activities**

The requirements of section 5.6.2.1 Calibration are included in the laboratory’s calibration program for equipment that has a significant contribution from its calibration to the total measurement uncertainty. Contributions are considered significant if they are greater than a fifth of the largest contributor.

Equipment that does not contribute appreciably to the total uncertainty of the test result is exempt from the activities described in Section 5.6.2.1 Calibration. The measurement of uncertainty is determined and recorded.

**5.6.2.2.2 Non-traceability to SI Units**

Where measurement traceability for testing and calibration activities to SI units is not possible, the policies in Section 5.6.2.1 Calibration are followed.

**5.6.3 Reference Standards and Reference Materials**

**5.6.3.1 Reference Standards**

The laboratory has a program for calibration its reference standards (weights) M0029. Calibration is performed by an accredited body that provides traceability. The reference standards are used for calibration only.

**5.6.3.2 Reference Materials**

A reference material is a homogeneous and well characterized substance used for standardization of equipment used in the testing process. Reference materials or calibration standards are traceable to national (NIST) or competent suppliers of certified reference materials (CRMs) where possible.

The measurement integrity of internal reference materials generated by the laboratory is evaluated against either standard reference materials or certified reference materials from and independent source when it is technically and economically possible.

**5.6.3.3 Intermediate Checks of Standards and Reference Materials**

Confirmation of reference standards and materials included in the calibration program is conducted according to a schedule addressed in M0029. The confirmation is conducted to maintain confidence in the calibration status of reference standards and reference materials.

**5.6.3.4 Transport and Storage**

The procedures found in M0010 “Proper Use and Labeling of Chemicals and Expiration Dates” and M0021 “General Guidelines for Documentation in the Agricultural Analytical Services Laboratory” address the labeling, safe handling, transport, storage, and use of reference standards and reference materials. These activities are established in order to prevent contamination, deterioration, and to protect the integrity of reference standards and reference materials.

**5.7 Sampling Operations**

**5.7.1 Procedure**

The OTSC laboratory does not routinely perform sampling in the sense of collecting a representative sample from a product lot to represent the whole. Most samples are collected by the Feed and Fertilizer Control Service investigator staff. Instructions for sample collection are found in the Investigator’s Manual. Furthermore, some samples are supplied by other customers. Occasionally, laboratory personnel are consulted about sampling parameters such as sample type or size or guidance for a particular sampling or analytical need. The OTSC laboratory, however, exerts no direct control over such sampling.

Sampling conducted by the OTSC laboratory involves for the most part those analyses that call for a portion or aliquot of the total sample received by the laboratory to be analyzed. Generally this calls for grinding, mixing, or preparing samples to assure homogeneity before portions are taken for analysis. These procedures can be found in SOPs M0001 “Protocol for the Preparation of Samples” and M0017 “Method for the Proper Handling of Feed and Fertilizer Samples”.

**5.8 Handling of Samples**

**5.8.1 Protection of Samples**

Laboratory procedures for Sample Management, describe the receipt, processing, and disposal of samples (see SOP M0001 “Protocol for the Preparation of Samples”). This procedure addresses the laboratory activities conducted to protect sample integrity.

**5.8.2 Identification of Samples**

The laboratory has a system for uniquely identifying samples. The OTSC (sample) number is used to track its progress from the time the sample is collected in the field until the analysis is completed and the sample is disposed. The sample number is also used to provide traceability between the sample and the data. The system is described in M0001 “Protocol for the Preparation of Samples”.

**5.8.3 Departures, Additions, or Exclusions**

Upon receipt of sample, abnormalities or departures from normal or specified conditions are recorded according to M0001 “Protocol for the Preparation of Samples”.

**5.8.4 Protection of Samples During Processing and Storage**

The procedure in M0001 “Protocol for the Preparation of Samples” provides details for the protection of sample test items from deterioration during storage and processing. The laboratory has arrangements for storage and security that protect the condition and integrity of samples.

When samples are held under environmental conditions specified in the test method, those conditions are maintained, monitored, and recorded. Monitoring records are maintained according to established procedures.

**5.9 Assuring the Quality of Test Results**

**5.9.1 Procedures**

The laboratory has quality control procedures to validate the results of analytical test results. The monitoring data is recorded in such a way that trends may be detected (control charts). Monitoring activities are planned and evaluated. Monitoring techniques may include, but are not limited to, the following:

Scheduled use of certified reference materials

Routine use of internally generated control samples, see M0044 “Statistical Quality Control Using Excel”

Scheduled participation in inter-laboratory proficiency testing programs, see M0056 “Handling of Proficiency Samples”

Replicate tests

Correlation of results for different characteristics of an item

The laboratory follows Proficiency Testing Requirements as defined by the accrediting body.

**5.9.2 Evaluation**

The laboratory has defined the criteria for quality control data and performs analysis by such means as control charting. When data is found to be outside the established criteria, action is taken in accordance with the laboratory’s control of non-conforming work procedure.

**5.10 Reporting the Results**

**5.10.1 General**

Test reporting is addressed in the procedures found in M0021 “General Guidelines for Documentation in the Agricultural Analytical Services Laboratory” and in M0041 “Reporting Laboratory Data”.

Results are reported on analytical worksheets and in the Laboratory Information Management System (Nautilus). Results are reported in the format requested by the customer.

**5.10.2 Reporting Results**

Data entered into the laboratory analytical worksheets and into Nautilus includes all the information specified in SOP M0021 “General Guidelines for Documentation in the Agricultural Analytical Services Laboratory”. Some associated Quality Control Data is recorded in laboratory notebooks and logbooks. See M0041 “Reporting Laboratory Data” for information reported to our internal customer, FFCS.

**5.10.3 Test Reports**

**5.10.3.1 Specific Requirements**

When necessary for interpreting the results, the following information may be included in the comments section of the worksheet and in the notes section of the Nautilus system:

 Deviations from, additions to, or exclusions from the test method and information on test conditions, such as environmental conditions

 A statement of conformance or non-conformance with specifications

 A statement of the estimated uncertainty of measurement (when customer requests it)

 Opinions and interpretations

 Additional information that may be requested by methods or customers.

**5.10.3.2 Sampling Results**

Sampling information (date, location, technique) is entered into the OTSC Feed and Fertilizer Control Service computer data base by the field investigator.

**5.10.4 Calibration Certificates**

The OTSC laboratory does not conduct calibration activities and therefore does not issue calibration certificates.

**5.10.5 Opinions and Interpretations**

## Opinions and interpretations of results are not routinely expressed in the lab results worksheet. However, if given they are to be recorded in the Notes section of the Nautilus database and in the comments section of the analytical worksheet. (See M0021General Guidelines for Documentation in the Agricultural Analytical Services Laboratory).

**5.10.6 Testing Results Obtained from Subcontractors**

In some cases, subcontractors are used to produce test data. When subcontractors are used, the laboratories are selected according to SOP F0002 “Guidelines for Qualifying Laboratories for Use in Appeals” or as requested by the customer, FFCS. Results are sent directly from the subcontracting lab to the FFCS. Documentation of subcontracting activity is stored in the FFCS database under Portion Requests/Outside.

**5.10.7 Electronic Transmission of Results**

In the case of transmission of test results by telephone, facsimile, or other electronic means, such transmission is conducted under conditions that meet the criteria of section 5.4.7 Control of Data.

**5.10.8 Format of Reports and Worksheets**

The format for laboratory reports and worksheets are designed to accommodate the type of test conducted to minimize the probability of misunderstanding or misuse. The content of the worksheet is specified in M0021 “General Guidelines for Documentation in the Agricultural Analytical Services Laboratory”.

**5.10.9 Amendments to a Report**

Material amendments to a report are made in the form of a supplement to the original. If a completely new report is required, the new document references the original document.

# Revision History

Original Version – Nov. 15, 2007 – The Quality Manual consisted of two volumes, Volume I Policies and Volume II Procedures, The Laboratory Manual is expanded to include laboratory quality objectives for ISO 17025 accreditation. Volume I contains the OTSC Laboratory Manual of Quality Policies. Volume II contains the ISO 17025 OTSC Laboratory Procedures in two sections. Section 1 contains Management Requirement Procedures and Section 2 contains Technical Requirement Procedures. This version was derived and updated from the Quality Management Plan of Jan. 13, 2006, which was preceded by the original June 13, 1990 “Quality Control/Quality Assurance Procedures for Use in the Laboratories of the Office of the Texas State Chemist”.

Revision 1 – March 23, 2013 - Combined the two volumes into the Laboratory Manual. This version of the Laboratory Manual was edited to reflect changes in personnel and organizational responsibilities with minor substantive edits.

Revision 2 – October 7, 2013 – Deputies for key personnel were added to page 2. The lab’s relationship to FFCS was explained, page 11.

Revision 3 – Oct.26, 2015 - Edits made to section 4.3.3.3 to require hand edits to be initialed/dated by State Chemist/Director and Quality Manager.

Revision 4 – June, 2016 – Removed duplicative wording. Procedures that were referenced in Revision 3 Volume II Procedures section are now referenced in appropriate policy sections. Updated responsibilities for additional lab personnel.