## Sections in This Document

## 1. Introduction

This Laboratory Manual of Quality Policies has been prepared to meet the requirements for the laboratories' accreditation to the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC 17025:2017). This document applies to the medical product and specialty laboratories within the Office of Analytical Regulatory Laboratories (OARL) and the Office of Specialty Laboratories and Enforcement Support (OSLES) in the Office of Chief Scientist (OCS) and the human and animal food labs in the Office of Regulatory Testing and Surveillance (ORTS) in the Human Food Program (HFP).

## 2. Controlled Distribution of the Quality Manual

The Quality Managers for the laboratories under the Office of Chief Scientist and the Human Foods Program are jointly responsible for maintaining this Manual of Quality Policies.

## 3. Quality Policy Statement

The laboratories are committed to providing testing that meets both the needs of the customers and the requirements of ISO/IEC 17025:2017 and to continually improving the effectiveness of the management system. Test results are reported within stated limits of accuracy, precision, and detection as described in the methods used for analysis.

### 3.1. Management System Objectives

A. The primary objective of the management system established by the laboratories 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 terms of:

1. accuracy,
2. precision,
3. detection and quantitation limits,
4. timeliness, and
5. comparability.

B. The second objective is to establish and maintain national and international recognition through compatibility with the requirements of relevant standards.

C. The third objective is to strive to meet or exceed the customer's needs and expectations.

D. The fourth objective is to maintain the laboratories' reputation for quality by fostering continuous process improvement and problem prevention.

E. These objectives are considered as part of the reviews performed by management.

### 3.2. Management System Awareness and Implementation

The management system documents, and test methods are included as training elements in the laboratories' training program. This ensures that staff are familiar with quality documentation and implement the quality policies and procedures in their work.

## 4. General Requirements

### 4.1. Impartiality

A. To avoid conflicts of interest, pressures, and influences, FDA employees are familiar with and observe the Standards of Ethical Conduct. These principles of ethics can be found at FDA Division of Ethics and Integrity.

B. Laboratory management is committed to sustaining impartiality of all personnel by enforcing existing FDA policies and requirements on ethics that were implemented to ensure impartiality in the agency's work.

C. The FDA provides several means to ensure impartiality of its employees, such as the HHS 520 Request for Approval of Outside Activity and OGE 450 Confidential Financial Disclosure Report Filer forms, which are filled out annually and reviewed by the FDA Division of Ethics and Integrity to identify

potential risks in relationships, ownership, finances, contracts, etc. that may impact personnel's neutrality regarding FDA related activities. In addition, a monthly list of significantly regulated organizations (SROs) is distributed for review in keeping with 18 USC § 208 prohibiting personal and substantial participation in matters that have direct and predictable effect on their financial interests.

D. The Office of Government Ethics (OGE) also requires one hour of ethics training annually. Training is provided on ethics rules, regulations, and integrity to help employees avoid placing themselves in a conflict-of-interest situation.

E. Risks to impartiality are continuously reviewed and eliminated or minimized to ensure there is no compromise to the objectivity of staff engaged in laboratories' activities. Employees are familiar with and observe the Standards of Ethical Conduct. Executive Order 12674, issued in 1989 and modified in 1990 by Executive Order 12731, states fourteen general principles that broadly define the obligations of public service. Two core concepts are embodied in these principles: (a) Employees shall not use public office for private gain, (b) and employees shall act impartially and not give preferential treatment to any private organization or individual.

F. Risks to impartiality may be identified during required routine disclosures by employees, management reviews, or during audits. When the laboratories' employees or processes pose a risk to impartiality, an assessment is made of the nature of the risk and appropriate corrective actions are taken by the laboratories and/or the designated agency authority.

### 4.2. Confidentiality

A. All FDA staff certify their agreement to abide with 5 USC § 552a(1) the Privacy Act and 21 USC § 331 The Trade Secret Act when completing Computer Security Awareness training. Contract employees are required to sign FDA FORM 3398 Commitment to Protect Non-Public Information Employee Agreement upon entry to duty. This form certifies their agreement to abide with 21 U.S.C. 331(j), 21 U.S.C 360j(c), and 18 U.S.C 1905. Confidentiality requirements are included in purchasing agreements, as needed, with vendors performing work in areas where laboratory work is performed.

B. The laboratories do not release confidential information to external parties.

C. Reports of information and data are transmitted and filed in accordance with official policies, directives, and notices of the department and the agency. Most reports are only transmitted internally within the agency, except as required by law or regulation. Information is released only to the customer or designated representative.

D. FDA facilities are controlled-access buildings to further ensure protection of data. Names and purpose of all non-FDA visitors are provided to security prior to planned visits. Additional department policies are in place for visitors from other countries. Visitors are continuously escorted by FDA representatives and allowed only in areas approved by mandated security protocols in place to ensure no customer or federal information is compromised. Additionally, employees sign commitments to properly keep and use confidential information obtained or witnessed during their duties.

## 5. Structural Requirements

### 5.1. Laboratory as Legal Entity

The Food and Drug Administration (FDA) is a government agency under the Department of Health and Human Services (DHHS). The agency is required to follow the federal regulations in 21 CFR, 29 CFR, 40 CFR, 49 CFR, the FD&C Act and PHS Act.) The laboratories are legally responsible for all activities within their operations.

### 5.2. Management Responsible for Laboratory

The Deputy Commissioner for Human Foods and the Chief Scientist are responsible for establishing their respective organization's commitment to the management system, implementing it, and delegating responsibility for its accomplishment.

The HFP Office of Regulatory Testing and Surveillance (ORTS), the OCS Office of Analytical Regulatory Laboratories (OARL), and the OCS Office of Specialty Laboratories and Enforcement Support (OSLES) are responsible for issuing policy and procedures for their respective laboratories and monitoring their implementation.

The laboratories' management, analysts, and quality managers are responsible for ensuring that analytical activities meet the requirements of the agency, its customers, and regulations in 21 Code of Federal Regulations (CFR), 29 CFR, Part 1910.1450, 40 CFR, Parts 260-264, 49 CFR, Parts 171-173 and the Food, Drug and Cosmetic (FD&C) Act. In addition, each person involved in the generation of data is part of the management system.

### 5.3. Scope of Accredited Laboratory Activities

The laboratories' activities encompass all processes from the review of vendors for external products and services to sample, equipment, supply, and data handling and reporting within the laboratories. The laboratories have documented training, proficiency, method validation and verification programs in place. To ensure consistency in these processes, controlled approved documents are maintained to provide guidance and records are retained to recreate processes, if needed. These activities also provide the basis to evaluate risks and improvements where gaps are identified through nonconformances, complaints, and annual management review of the inputs and outputs of operations.

### 5.4. Laboratory Requirements

A. The laboratories are operated per the following requirements:

1. FDA policies and procedures,
2. ISO/IEC 17025:2017,
3. Customer contracts (workplan),
4. Compliance programs and assignments,
5. Federal and State laws and regulations, and
6. Accreditation registrar requirements.

B. The laboratories operate permanent facilities across the United States and Puerto Rico at the locations identified in the Staff Manual Guides (SMG), 1232A.41 HFP Office of Regulatory Testing and Surveillance, 1119A.8 OCS Office of Analytical Regulatory Laboratories, and 1119A.9 OCS Office of Specialty Laboratories and Enforcement Support.

### 5.5. Laboratory Organizational Structure and Procedures

A. The laboratories are a part of the HFP Office of Regulatory Testing and Surveillance; OCS Office of Analytical Regulatory Laboratories; and OCS Office of Specialty Laboratories and Enforcement Support identified in the SMG series listed in §5.4.B above. The organization and the relationship among the laboratories staff are reflected in each laboratories' organizational chart. These charts provide relationships among management, technical operations, and support personnel.

B. The laboratories have a managerial staff with the authority to discharge their duties as reflected in the prepared job descriptions by the laboratories. This authority includes the implementation, maintenance, and improvement of the management system. Management authorities are defined in government classification standards found on the U.S. Office of Personnel Management website.

C. Job responsibilities for the laboratories' employees are documented in the management system procedures and operating instructions. Position descriptions are maintained by the Office of Talent Solutions (OTS).

D. The laboratories' management system is outlined in the following documents:

1. Laboratory Manual of Quality Policies,
2. Written procedures,
3. Work Instructions,
4. References, and
5. Forms and records.

E. This management system is established to address the requirements in ISO/IEC 17025:2017. Each entity establishes and maintains documents per their organizational procedures for document control. The quality policies and quality objectives for the laboratories are included in Section 3 of this document. The documents listed above are accessible to all personnel and are included in the laboratories' training program.

### 5.6. Personnel Responsibilities and Authority

The laboratories' personnel are aware of their roles and contributions in the management system and of its objectives through regularly scheduled training provided by the quality staff. The laboratories' personnel irrespective of other responsibilities have the authority and resources to carry out their duties.

A. General roles and responsibilities for the laboratories' personnel are summarized as follows:

1. Quality System Manager
    a. Ensures that the management system is established, implemented, and maintained in conformance with the requirements of ISO/IEC 17025:2017.
    b. Advocates and coordinates quality improvements to the management system.
2. Responsible Managers (technical management)
    a. Oversee technical functions.
    b. Ensure compliance with the requirements of ISO/IEC 17025:2017.
    c. Ensure management system procedures, applicable standards, specifications, and regulations are followed.

d. Ensure that qualified, skilled, and trained personnel and other resources are available.

e. Ensure that products and services satisfy customer requirements.

3. Analysts and support staff

a. Ensure the quality of their work.

b. Operate in conformance with the requirements of the management system.

B. All the laboratories' employees have the authority and are encouraged to identify and report deviations from the management system or procedures for laboratory activities.

C. All the laboratories' employees contribute toward initiation of actions to minimize such deviations or provide input toward improvement to the system. These actions are monitored and reviewed by laboratory management.

D. The laboratories' Quality System Managers (QSM) are responsible for monitoring the laboratories' management system and reporting its performance and any need for improvement to laboratory management.

E. The Laboratories' Management is responsible for the technical operations of the laboratories. Resources for training, laboratory methods, measurement traceability, and purchasing are described in other sections of this manual and in relevant FDA procedures and policies.

F. Qualified laboratory personnel are assigned to serve in the absence of key managerial personnel, such as Laboratory Director, Quality System Manager, and Supervisors, to maintain unbroken continuation of operations. In addition, the laboratories have an active and executable contingency plan for the Continuity of Operations (COOP) in place with effectiveness drills enacted at least once each year.

## 5.7. Communication and Integrity of the Management System

A. Effective communication from management occurs through, but is not limited to, memos, newsletters, electronic presentations, emails, or verbally to the laboratories' personnel regarding the effectiveness of the management system and the importance of meeting customer, statutory, and regulatory requirements.

B. The management system processes and procedures as defined in this manual maintain the integrity of the management system when changes such as a change in the structure of the organization or management, or procedural changes are made.

# 6. Resource Requirements

## 6.1. General

Personnel, facilities, equipment, systems, and support services necessary for the management and performance of the laboratories' activities are evaluated and put in place to ensure defensible data and conformity to the requirements of ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories.

The sections following below address the factors affecting the correctness and reliability of the tests performed by the laboratories.

Procedures addressing these factors are maintained by the laboratories' organization.

## 6.2. Personnel

### 6.2.1. Laboratory Personnel

All laboratories' personnel that could influence the laboratories activities act impartially, are competent, and perform their work according to the laboratories' management system. These positions include, but are not limited to analysts, supervisors and managers, laboratory support staff, sample evidence specialists, and administrative staff.

The laboratories' follow applicable local, state, and/or federal-specific requirements for hiring specific laboratory personnel.

### 6.2.2. Competence Requirements

A. Competence is based on education, experience, demonstrated skills, and training. Staff records contain the documentation of personnel education, qualification, experience, technical knowledge, skills, and training for the position held.

B. Skills of personnel are based upon demonstration of competence. Competency requirements for each function influencing the results of the laboratories activities are documented in the laboratories' training documents. This demonstration is to be completed successfully before the laboratories' personnel generate data independently. The effectiveness of personnel training is documented in, but not limited to management reviews, internal audits, external assessments, proficiency testing, and performance evaluations.

### 6.2.3. Personnel Competence

A. The laboratories' management ensures that the laboratories' personnel have the competence to perform their duties and to evaluate the significance of deviations.
B. Trainees undergo a training program in accordance with the laboratories' training documents and organizational training standards. Trainees perform procedures when training and competency has been demonstrated. The documented demonstration of competence is an exercise that the trainee performs independent of supervision. The trainee is considered competent after the specified criteria have been successfully met.

6.2.4. Communication of Duties, Responsibilities and Authorities

A. Job duties, responsibilities and authorities for the laboratories' employees are documented in the management system procedures and operating instructions.
B. Position descriptions are maintained by the Office of Talent Solutions (OTS). The laboratories maintain active job descriptions for managerial, technical, and key support personnel involved in laboratories activities. Job descriptions are established based on current duties and technologies utilized.
C. The laboratories' employees involved in the laboratories' activities have access to consensus standards, instrument manufacturers' manuals, and laboratory procedures for reference.
D. Effective communication from management occurs through, but is not limited to, memos, newsletters, electronic presentations, emails, or verbally to laboratory personnel regarding the effectiveness of the management system.

6.2.5. Personnel Procedures

A. The procedures for determining competence requirements are defined in organizational and laboratory documents.
B. The Food and Drug Administration's Office of Talent Solutions (OTS) establishes the hiring procedures for the agency.
C. 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 can identify areas of study and request training oriented towards the attainment of their

goals. Procedures for employee career development are described in SMG 3120.1, Staff Development and Training.

D. Training needs are identified in accordance with the analyst's discipline (e.g., Chemist, Microbiologist) and organizational standards. In-house training is conducted per the laboratories' training procedure. Present and anticipated tasks of the laboratories are addressed in the planning of special training modules.

E. The management system documents, and test methods are included as training elements in the laboratories' training program and are addressed in the laboratories' training procedures. This ensures that staff are familiar with quality documentation and implement the quality policies and procedures in their work.

F. The laboratories utilize the skills and talent of both full-time employees and contract personnel. The requirements of the management system are administered equally to both categories. No differentiation is made between the two categories of workers. Supervision, training, and competence are documented for all technical and key support personnel.

G. Supervisors are designated, and trainees do not perform laboratory work until competent as per the laboratories' training program.

H. Personnel are authorized to perform specific laboratory activities according to Section 6.2.6 of this document and other laboratory documents.

I. Personnel competency is monitored through onsite reviews, reporting and worksheet write-ups, demonstration through documentation of the required instrument maintenance and function checks, results obtained on proficiency test samples, number of samples analyzed satisfactorily, and results from analysis of QC samples within established criteria.

6.2.6. Personnel Authorization

A. The Laboratories' Management authorizes personnel to perform specific laboratory activities, including but not limited to:

1. Development, modification, verification, and validation of methods.
2. Analysis of results, including statements of conformity or opinions and interpretations.
3. Report, review, and authorization of results.

B. Records of authorizations, demonstration of competence, education, training, and experience are maintained by the laboratories and dated. Training files are maintained and include these records.

## 6.3. Facilities and Environmental Conditions

6.3.1. Suitability of Facilities and Environmental Conditions

The laboratories' environmental conditions facilitate the correct performance of analytical testing. Examples of environmental influences are energy sources, lighting, biological sterility, dust, humidity, and temperature. The laboratories monitor critical environmental conditions to ensure that results and the quality of the measurement are not adversely affected or invalidated.

6.3.2. Documentation of Requirements for Facilities and Environmental Conditions

Test methods and environmental monitoring procedures used by the laboratories include instructions addressing applicable environmental conditions.

6.3.3. Monitoring, Controlling and Recording Environmental Conditions

A. Environmental conditions requiring monitoring include, but are not limited to:

1. room temperature and humidity,
2. air flow rates for chemical fume hoods,
3. biosafety hoods and laminar flow hoods,
4. metal contamination on benches and hoods in laboratories performing metal analysis,
5. microbiological contamination on bench surfaces and hoods in microbiology laboratories, and air sampling for microbiological contamination in microbiology areas.

B. Where environmental controls are needed, the environmental conditions are recorded.

C. Testing activities are stopped when the environmental conditions invalidate the test results or adversely affect quality control. Monitoring activities are conducted as part of the laboratories test or calibration methods.

D. Laboratories use aseptic technique when conducting microbiological testing.

6.3.4. Measures to Control Facilities

The following measures to control facilities are implemented, monitored, and periodically reviewed:

A. Access and use of areas affecting the laboratories activities.

The laboratories are limited access areas. Access and use are controlled by, but are not limited to:

1. issuance of keycards for entrance,
2. escorting visitors,
3. issuance of identification badges, and
4. the use of security guards.

B. Housekeeping

Laboratories' areas are maintained clean and orderly to prevent contamination of samples and to facilitate the efficiency of the laboratories' operations. Organizational and the laboratories' procedures specify minimum housekeeping measures. The laboratories' Chemical Hygiene Plan and Hazardous Waste Management Plan include measures taken to ensure good housekeeping in the laboratories.

C. Cross-contamination

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

1. chemistry laboratories are separated from microbiology laboratories,
2. sample receiving, and storage are conducted in designated areas,
3. separate storage for standards and reference materials and cultures, and
4. microbiology media preparation and sterilization are separated from work areas.

6.3.5. Work Performed Outside the Laboratory's Permanent Control

In the event staff perform laboratory activities at sites outside of the laboratories' control, facility and environmental requirements are met.

## 6.4. Equipment

6.4.1. Access to Laboratory Equipment

A. The laboratories have sample preparation, measurement, and test equipment for the correct performance of the tests and calibrations. The laboratories also have ancillary equipment for processing samples and for processing data. Also see Section 6.5 Metrological Traceability.

B. The laboratories or organizations purchase the equipment used by the laboratories. Maintenance contracts are established as needed. In those cases where the laboratories lease equipment they have direct control concerning use. Leased equipment is managed in the same manner as purchased equipment according to the management system requirements.

C. The laboratories maintain an equipment inventory of all analytical laboratory equipment used to perform regulatory testing.

6.4.2. Equipment Outside the Laboratory's Permanent Control

If for any reason equipment leaves the direct control of the laboratories, they ensure the equipment requirements are met before using the equipment.

6.4.3. Procedure for Handling, Transport, Storage, Use and Planned Maintenance of Equipment

The laboratories have procedures for the safe handling, transport, storage, use and planned maintenance of equipment to ensure proper functioning and to prevent contamination or deterioration.

6.4.4. Verification of Equipment Prior to Being Placed or Returned into Service

A. The equipment performance is verified, and verification records are maintained. Equipment meets the laboratories' testing parameters and conforms to standard specifications before being placed or returned into service.

B. Procedures for equipment verification are provided in organizational and laboratory documents.

6.4.5. Equipment Accuracy/Uncertainty

Equipment and its software used for testing achieve the accuracy expected, measurement uncertainty required, and comply with specifications of the testing concerned.

The uncertainty contributions are addressed in organizational and laboratory documents.

6.4.6. Equipment Calibration

Measuring equipment is calibrated when the measurement accuracy or uncertainty affect the reported results and/or calibration of the equipment is required to establish metrological traceability of the reported result.

Procedures for equipment calibration are provided in organizational and laboratory documents.

6.4.7. Calibration Program

The equipment calibration program is defined in organizational and laboratory documents. These procedures are reviewed and revised according to organizational and laboratory document control procedures.

6.4.8. Calibration Status

Equipment under the control of the laboratories and requiring calibration, or having a defined period of validity, is labeled, or coded to indicate the calibration status or period of validity. Alternatively, equipment calibration status may be identified in an associated record to indicate the status of calibration.

6.4.9. Out of Service

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

The laboratories’ personnel examine the effect of the defect or departure from specified limits on previous tests according to Section 7.10 Non-conforming Work.

6.4.10. Calibration Confirmation

Intermediate calibration confirmation checks are performed to maintain confidence in the calibration status of the equipment. These checks are conducted according to the procedure in Section 7.7 Ensuring the Quality of Test Results.

Metrological confirmation for reference standards and reference materials included in the calibration program is conducted according to a schedule addressed in the organizational and laboratory procedures. The

confirmation is conducted to maintain confidence in the calibration status of reference standards and reference materials.

6.4.11. Correction Factors

Where calibrations give rise to a set of correction factors, these factors are updated and implemented to meet specified requirements.

6.4.12. 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 laboratories.

6.4.13. Equipment Records

Records are maintained of each item of equipment and its software that can influence the laboratories activities according to organizational and laboratory procedures.

The records include at least the following items, where applicable:

A. identity of equipment, including its software and firmware version.

B. manufacturer's name, type identification, and serial number or other unique identification.

C. evidence of verification that equipment conforms with specified requirements.

D. current location of the equipment.

E. calibration dates, results and copies of reports and certificates of calibrations, adjustments, acceptance criteria, and the due date of next calibration or the calibration interval.

F. documentation of reference materials, results, acceptance criteria, relevant dates, and the period of validity.

G. maintenance plan and maintenance carried out to date, where relevant to the performance of the equipment; and

H. details of any damage, malfunction, modification, or repair to the equipment.

## 6.5. Metrological Traceability

6.5.1. Establishing and maintaining metrological traceability

The program for calibration of equipment demands that calibrations and measurements made by the laboratories are traceable to the International System of Units.

Calibration laboratories providing services to laboratories are to provide evidence of measurement traceability of the lab's own measurement standards and measuring instruments to the SI. This is done by means of an unbroken chain of calibration or comparisons linking them to primary standards of the SI units of measurement. Such primary standards are those used by national measurement standards.

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

6.5.2. Ensuring measurement results are traceable.

A. Calibration laboratories providing services to laboratories are to provide documentation demonstrating measurement capability and competence to perform the calibration services requested by the laboratories.

B. A reference material is a homogenous and well characterized substance used for standardization of equipment used in the testing process. Reference materials are traceable to national or international standard reference materials (SRMs), such as National Institute of Standards and Technology (NIST), or certified reference materials (CRMs) from competent suppliers of reference materials.

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

D. The measurement traceability to SI units may be achieved by measurements related to national measurement standards. National measurement standards may be used as primary standards that are primary realizations of the SI units or agreed representations of SI units. National measurement standards based on fundamental physical constants, or standards calibrated by another national metrological institute may be used as primary standards.

6.5.3. Non-traceability of reference standards to SI units

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. Traceability alternatives to SI units are described in organizational and laboratory procedures.

## 6.6. Externally Provided Products and Services

6.6.1. Suitability of Externally Provided Products and Services

The laboratories ensure that only suitable externally provided products and services that affect laboratory activities are used when they are intended for incorporation into laboratory activities and/or used to support the operations of the laboratories.

The laboratories do not subcontract routine analyses to external laboratories.

Based on workload fluctuations and resource needs, laboratories may request samples be assigned to other FDA laboratories within the scope of this document for analysis. Samples are administratively transferred after arrangements are made to ensure that the receiving laboratory has the capacity and capability to complete it in a timely manner.

Samples are shipped per Department of Transportation (DOT), United States Post Office (USPS), and carrier regulations. Sample handling procedures describe procedures documenting administratively transferred samples (ATS).

Collaborative activities conducted with external laboratories, such as universities, are research in nature and do not involve the routine analysis of FDA samples.

6.6.2. Notification of Customer

CMS (Compliance Management System) or FACTS (Field Accomplishment and Compliance Tracking System), which is accessible to the customer, serves as a notice of the transfer.

6.6.3. Laboratory Responsibility

The laboratory to which the sample has been transferred assumes responsibility to the collector for the work.

6.6.4. Purchasing services and supplies

A. Organizational and laboratory procedures provide policies and instructions for procurement of supplies, materials, equipment, and services that affect the quality of tests. They document the procedures for purchase, reception, and storage of supplies, materials, and equipment relevant to tests.

B. The laboratories or designated purchasing agents use Federal Acquisition Regulations (FAR) and related procedures for the procurement of materials, supplies and services that critically affect the quality of the tests or calibrations. These 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 and calibrations.

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

D. Records of supplier evaluations are maintained by purchasers of equipment, services, and supplies.

E. A laboratories' purchasing procedure describes how purchased equipment, supplies, services, reagents, and consumable materials that critically affect the quality of tests or calibrations are inspected or verified prior to 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.

F. Records of unsatisfactory materials and supplies and their disposition are maintained. These records establish trends in vendor performance and ensure that continuing quality material is accepted. A vendor is considered unacceptable and is not used when the quality of product or service does not meet expectations or specifications.

6.6.5. Communicating requirements to external providers

Critical specifications and requirements are clearly described on the purchasing requests and are communicated to external providers by the Purchasing Agent. These criteria include:

A. The products and services to be provided.

B. The acceptance criteria; and

C. Competence, including any required qualification of personnel.

The laboratories do not subcontract routine analyses within their scope of accreditation.

6.6.6. Related Procedures/References

A. Government Accounting Office (GAO) Policy and Procedures Manual

B. SMG 2610 Procurement and Supply Management

C. Federal Acquisition Requirements

D. Office of Management and Budget (OMB), General Service Administration (GSA), HHS, Federal Property Management Regulations (FPMR), FDA manuals, specific issuances

E. Public Law (PL) 95-507

## 7. Process Requirements

### 7.1. Review of Requests, Tenders, and Contracts

7.1.1. Procedure

HFP/OCS laboratory program work planners develop and issue the Annual Fiscal Year (FY) Workplan for its laboratories. The workplan is a cooperative effort among all relevant stakeholder entities. The workplan is based on several factors such as the budget, the number of analysts and number of resources, the Agency's performance goals, the compliance program accomplishment goals, the inventory of regulated industry maintained by the field units, and FDA-targeted products. Distribution of assignments is by Program Assignment Code (PAC) and full time equivalent (FTE) hours within the different program areas. The compliance programs specify or cite the methods for analyses. The laboratories' stakeholders review the annual workplan to ensure that each laboratory has the capability and resources to provide the requested services. Any differences between the workplan and the laboratory capability are resolved in accordance with organizational and laboratory procedures.

In addition to the workplan, assignments may be issued to the laboratories by an FDA headquarters unit or a Center. Assignments specify or cite the methods for analyses.

Requests not covered by compliance programs or assignments are reviewed prior to receipt of samples by the laboratory's management when possible.

The results of this process are discussed and documented as part of the laboratory's annual management review.

Laboratory methods are selected based on compliance and surveillance programs. When the customer does not specify the method to be used, a standard method is preferred for use. 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 7.2.2 Validation of Methods.

7.1.2. Method Requested is Inappropriate or Out of Date

The laboratory informs the customer when the method proposed by the customer is considered to be the incorrect choice or the incorrect revision for the intended purpose. This is done as part of contract review addressed in Section 7.1.1.

7.1.3. Statements of Conformity

When the customer requests a statement of conformity to a specification or standard for the test, the specification or standard and the decision rule are clearly defined in the compliance programs or standard. Otherwise, the laboratory communicates the decision rule selected to the customer and obtains their agreement. See Section 7.8.6, Reporting Statements of Conformity.

7.1.4. Differences and Deviations

The laboratories and stakeholder entities offices review the annual workplan to ensure that each laboratory has the capability and resources to provide the requested services. Any differences between the workplan and the laboratory capability are resolved prior to commencing work and in accordance with applicable policies and procedures, or through consultation with Agency management.

7.1.5. Communicating with the customer

Requests for deviations from work assignments or compliance programs are processed by the laboratory's organization. The office interacts with the customer to determine whether the requested changes are acceptable and do not impact the integrity of the laboratory or the validity of the results. Records of contract changes are maintained.

7.1.6. Amendments to Contracts

If a contract needs to be amended after work has commenced, the same contract review process is repeated, and any amendments are communicated to all affected personnel named in the contract.

7.1.7. Customer Service

The laboratory affords the requesting customer cooperation to clarify the customer's request within the framework of the contract review process described in section 7.1.1. The laboratory maintains communications regarding deviations from contract work. Communications regarding compliance programs, workplan and assignments are conducted through the laboratory's organization.

The opportunity for the customer to witness laboratory activity is given upon request, providing the laboratory can maintain confidentiality to other customers during such cases.

7.1.8. Records of Review

Laboratories maintain records of workplan reviews, changes, and change requests. Records are also maintained of discussions regarding ad hoc assignments.

## 7.2. Selection, Verification and Validation of Methods

7.2.1. Selection and Verification of Methods

Specific requirements for the Verification and Validation of methods process for laboratories are outlined in organizational and laboratory documents.

A. The scope of test technologies and associated methods routinely used are identified in the laboratories' accreditation program documentation.

B. The Evaluation of the Measurement of Uncertainty is addressed in Section 7.6. Section 7.7, Ensuring the Validity of Results, of this manual describes the quality control processes, including the application of statistical techniques, for supporting test and calibration data.

C. The laboratories' methods and supporting documents are controlled according to Section 8.3, Control of Management System Documents, and are readily available.

D. The laboratories' methods are selected to meet the customer's need as addressed in Section 7.1, Review of Requests, Tenders and Contracts. The laboratories ensure that they use the latest valid version of analytical methods unless not appropriate or possible to do so.

E. Standard methods are those published by international, regional, or national standards-writing bodies; by reputable technical organizations; in legal references; and FDA published methods. FDA “official” methods are those in compendia specified in the FD&C Act and prescribed in the CFR and methods in applications and petitions that have official status are included. These methods include those in the United States Pharmacopeia, National Formulary, Homeopathic Pharmacopeia of the United States, Official Methods of Analysis of AOAC INTERNATIONAL or any supplement of any of them, American Public Health Association (APHA) Compendium of Methods for the Microbiological Examination of Foods, FDA compliance programs, the Pesticide Analytical Manual (PAM), the Food Additives Analytical Manual, the Food Chemicals Codex, FDA Bacteriological Analytical Manual (BAM), FDA Macro analytical Procedures Manual (MPM), and Laboratory Information Bulletins (LIBs) that are included in compliance programs and special assignments. Standard methods are preferred for use and are verified for use in the laboratories. A standard method may be supplemented with additional details in the form of a laboratory procedure to ensure consistent application. Those methods specified by the manufacturer of the equipment are considered as standard methods. Standard methods are verified according to organizational and laboratory procedures.

F. When the customer does not specify the method to be used, a standard method is preferred for use. 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 7.2.2, Validation of Methods.

G. The laboratories inform the customer when the method proposed by the customer is an incorrect choice or the incorrect revision for the intended purpose. This is done as part of contract review addressed in Section 7.1, Review of Requests, Tenders and Contracts.

H. Standard methods are verified according to organizational and laboratory procedures.

I. Records of verifications are retained by the laboratories. If methods are revised by the issuing body, verifications are repeated to the extent necessary.

J. Non-standard methods are those methods not taken from authoritative, validated sources. A nonstandard method has not undergone validation, such as a collaborative study or process to evaluate the method’s performance capabilities.

K. 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 and a clear specification of the customer's work requests, including the purpose of the test, is made. This process is described for contract amendments in Section 7.1.6, Amendments to Contracts, with laboratory management concurrence. Non-standard methods are validated according to Section 7.2.2, Validation of Methods.

L. Organizational and laboratory procedures provide the planned activities, identification of competent personnel, and resources for laboratory developed methods. Method development plans are reviewed periodically to confirm the customer's requirements are still being met. Any modifications to the development plan shall be approved and authorized. Laboratory developed methods adopted by the laboratory are used if they are validated according to Section 7.2.2, Validation of Methods.

M. Deviations from test methods are documented, technically justified, authorized, and where circumstances call for it, accepted by the customer according to organizational and laboratory procedures for reporting data.

7.2.2. Validation of Methods

A. The laboratories validate non-standard methods, laboratory developed methods, and modified standard methods including use outside the intended scope or otherwise modified. Validation is conducted to confirm that the methods are fit for the intended use, relevant to the customers' needs, and consistent with specified requirements. The validation is as extensive as is necessary to meet the needs of the given application or field of application.

B. When changes are made to a validated method, the influence of such changes shall be determined and where they are found to affect the original validation, a new method validation shall be performed.

C. The validation process addresses the needs of the given application or field of application. The laboratories' analysts record the results obtained according to organizational and laboratory procedures. The validation results include a statement as to whether the method is fit for the intended use. The needs of the customer define the intended use of the method. The attributes and data quality objectives include but are not limited to:

1. accuracy,

2. precision,
3. specificity,
4. detection limit,
5. limit of quantitation,
6. linearity,
7. range, and
8. ruggedness or robustness.

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

E. The following records are maintained for each validation:

1. the validation procedure used.
2. specification of the requirements
3. determination of the performance characteristics of the method.
4. results obtained.
5. a statement on the validity of the method, detailing its fitness for the intended use.

### 7.3. Sampling

A. Laboratories do not routinely perform sampling in the sense of collecting a representative sample from a product lot to represent the whole.

B. Sample Collection Conducted by the Customer: Most test samples are obtained and sent to the laboratory by Office of Inspections and Investigations (OII) staff or another formalized source. Instructions for sample collection, including methods and sampling plans, by such personnel are provided in the Investigations Operations Manual (IOM) Chapter 4.

C. Sample Collection Conducted by the Lab: In cases where the laboratory collects or purchases samples, they are required to comply with established sampling procedures for those programs (e.g. IOM).

D. Occasionally, laboratory personnel are consulted about sampling parameters such as sample type or size or guidance for a sampling or analytical need. The laboratories, however, exert no direct control over such sampling and do not have responsibility for sampling.

E. Sampling data (i.e., date and time of sampling, description, environmental conditions, collector identification, etc.) required as part of testing is included in

the Collection Report accompanying the request in FACTS or ALIS. When the request in entered, a unique identifier is assigned to the sample.

F. Sampling conducted by laboratories 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 mixing or preparing of samples to assure homogeneity before portions are taken for analysis. Sample preparation and subsampling protocols are found in the analytical methods, compliance programs, and assignments.

### 7.4. Handling of Test or Calibration Items

A. Organizational and laboratory procedures describe the receipt, processing, protection, storage, retention, and disposal of samples. These procedures also provide the details for handling and protecting test items from deterioration, loss or damage during storage and processing. The laboratories have arrangements for storage and security that protect the condition and integrity of samples. Sample security arrangements apply both in the laboratories and in the custodial areas.

B. The sample number is used to track and uniquely identify samples and their 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 numbering system also provides traceability during transfer of samples within a single laboratory and between multiple laboratories in the case of administratively transferred samples. The identification system is described in organizational and laboratory procedures.

C. When samples received do not meet established acceptance criteria, for example, contract/program specifications, analysis requested, abnormalities or departures from normal or specified conditions, and chain of custody criteria, these deviations are recorded according to organizational and laboratory procedures. The customer is consulted prior to commencement of analysis for further instructions. Communication with the customer is recorded in accordance with SOP-000285 Sample Feedback Report Process.

D. Sample abnormalities or departures are also noted on the analytical worksheet.

E. When samples and calibration items have specific environmental conditions, those conditions are maintained, monitored and recorded. Monitoring records are collected according to established procedures. These activities are conducted according to the policies stated in Section 6.3, Facilities and Environmental Conditions.

## 7.5. Technical Records

A. Technical records for all activities that contribute to data reporting, depending on the type of analysis, include the original observations, derived data, calculations, standard preparation, instrument printouts, and results. These records contain the date each activity is completed and the identity of all persons who perform each activity throughout the process, including those who review the data and results.

B. Observations, data, and calculations are recorded at the time they are made and are identifiable to the activity performed.

C. The records of each test contain sufficient information to repeat the test under conditions as close as possible to the original. This information includes environmental conditions that affect the test and factors that affect the measurement results and its associated measurement uncertainty.

D. Staff records, equipment calibration, and verification reports are retained in accordance with the laboratories' control of records procedures. These records contain sufficient information to establish an audit trail. The requirements for an audit trail in the laboratories' records are outlined in organizational and laboratory procedures.

E. The laboratories' results are reported electronically in FACTS and/or the Automated Laboratory Information System (ALIS) interface and uploaded into the Compliance Management Services (CMS) portal.

F. Laboratories ensure changes to technical records can be tracked to the previous version or to original observations. Both the original and amended data and files are retained, including the date the record was changed, an indication of what was changed and the person responsible for the alteration.

## 7.6. Evaluation of Measurement Uncertainty

### 7.6.1. Uncertainty Components

When estimating the uncertainty of measurement, all important uncertainty components are recorded in the uncertainty records for each determination and test technology as addressed in the organizational and laboratory procedures.

### 7.6.2. Procedure for Calibration Activities

The laboratories do not perform calibration activities. At such time that calibration activities are performed, the laboratories are to address the requirements of ISO/IEC 17025:2017.

### 7.6.3. Procedure for Testing Activities

The laboratories use organizational or laboratory procedures to estimate the uncertainty of measurement for testing activities.

The application of details in cases where the nature of the test method may preclude rigorous metrologically and statistically valid calculation of uncertainty of measurement is addressed in these procedures.

An attempt is made to identify all the components of uncertainty and make a reasonable estimation of the measurement uncertainty. This estimation is based on knowledge, experience, and validation data of the performance of the method and on the measurement scope. If needed as a part of the laboratory data, the uncertainty estimation is reported according to measurement uncertainty procedures.

## 7.7. Ensuring the Validity of Results

7.7.1. Quality Control Procedures

A. The laboratories have quality control procedures to validate the results of tests.

B. The monitoring data is recorded in such a way that trends may be detected, for example, statistical process control charts (SPCs). Monitoring activities are planned and evaluated according to organizational and laboratory procedures. Monitoring techniques may include, but are not limited to, the following:

1. Scheduled use of certified reference materials or quality control materials.
2. Use of alternative instrumentation that has been calibrated to provide traceable results.
3. Functional check(s) of measuring and testing equipment.
4. Use of check or working standards with control charts.
5. Intermediate checks on measuring equipment.
6. Replicate tests using the same or different methods.
7. Retesting of reference materials and retained customer samples.
8. Correlation of results from tests conducted for different characteristics of a sample.
9. Review of reported results.
10. Scheduled participation in interlaboratory comparison or proficiency-testing and calibration programs.
11. Testing of blind samples.

C. Laboratories participate in proficiency testing programs and/or interlaboratory comparisons other than proficiency testing, where available and appropriate.

D. The laboratories have defined the criteria for quality control data and perform analysis by such means as control charting. When data are found to be outside the established criteria, action is taken in accordance with organizational and laboratory control of nonconforming work procedures.

## 7.8. Reporting Results

### 7.8.1. General Requirements

A. Test reporting is addressed in organizational and laboratory procedures. These procedures give the details for reporting data using consistent reporting formats for laboratory worksheets. Results are reported on analytical worksheets and FACTS or via ALIS.

B. Laboratory results are reviewed and authorized for release by supervisors or designees. Reports are reviewed for accuracy, clarity, and objectivity. Laboratory management expresses its opinion and interpretation of the compliance or non-compliance of the results through the laboratory classification assigned to each sample. This laboratory classification is recorded in FACTS or via ALIS and may be recorded on the FDA form FD-465 as well. The laboratory classifications are defined in organizational procedures.

C. Laboratory reports, depending on the type of analysis, include the original observations, derived data, calculations, standard preparation, instrument printouts, and results. These reports are retained until closed in FACTS or ALIS and final review is performed. An electronic test report is maintained in CMS. Staff records, equipment calibration, and verification reports are retained in accordance with the laboratory's control of records procedure.

D. The records contain sufficient information to establish an audit trail.

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

F. The collection report in FACTS or ALIS identifies the personnel responsible for sampling. The FDA form FDA-431a or ALIS continuation report (ACR) include the identity of the personnel responsible for performance of each test and for checking the results.

G. Test reporting is addressed in organizational procedures. These procedures give the details for reporting data using consistent reporting formats for laboratory worksheets.

7.8.2. Common Requirements for Reports (test, calibration, or sampling)

7.8.2.1. Format

The format for laboratory worksheets is designed to accommodate the type of test conducted to minimize the possibility of misunderstanding or misuse. The worksheet format is described in organizational procedures.

Subcontracting laboratories are not utilized by the laboratories; therefore, there is no such data found for incorporation in the analysis report to the customer.

7.8.2.2. Data Provided by Customer

Analysts describe the sample as received, including any information provided by the customer, on the sample worksheet in the description of sample block (Block 7). Unless noted in the sample worksheet, results apply to the sample as received.

7.8.3. Specific Requirements for Test Reports

A. The following information is included in test reports for the interpretation of the test results:

1. Information on test conditions, such as environmental conditions.
2. Where relevant, a statement of conformance or non-conformance with specifications.
3. The measurement uncertainty presented in the same unit as the measurand, or in a term relative to the measurand when:
   a. It is relevant to the validity of the test results.
   b. A customer requires it, or;
   c. The measurement uncertainty affects conformity to a specification limit.
4. Opinions and interpretations as detailed in Section 7.8.8; and,
5. Additional information that may be requested by methods, customers, or groups of customers.

7.8.4. Specific Requirements for Calibration Certificates

Laboratories conduct in-house calibration activities on measuring and test equipment only and, therefore, do not issue calibration certificates. In-house calibrations are documented by a report, or sticker, or other suitable method.

7.8.5. Reporting Sampling – specific requirements

In addition to the instructions listed in Sections 7.8.1 General Requirements and 7.8.3 Specific Requirements, sampling information and conditions are posted to the laboratory for review on the FACTS sample collection record which is also available via ALIS.

7.8.6. Reporting Statements of Conformity

A. Statements of conformity reported on worksheets clearly identify:

1. The results the statement applies to.
2. Which specifications or standards were met, or not met.

7.8.7. Decision Rules

Statements of conformity to a specification or standard require the use of a decision rule to consider the uncertainty associated with method. Most decision rules used by laboratories are documented in the compliance programs or standard methods. When the decision rule is not provided, the laboratories will use simple acceptance, where the acceptance level equals the tolerance level or customer requirements. Uncertainty measurements are available upon request.

7.8.8. Reporting Opinions and Interpretations

The laboratories management expresses its opinion and interpretation of the compliance or non-compliance of the results through the laboratory classification assigned to each sample. This laboratory classification is recorded in FACTS or via ALIS and may be recorded on the FDA form FD-465 as well. The laboratory classifications are defined in the FDA Data Codes Manual.

Records are maintained of conversations expressing opinions and interpretations about a sample with the customer.

7.8.9. Amendments to Reports

Material amendments to analytical findings after issue are made only in the form of an additional document. They are flagged "Additional Analyses" in accordance with organizational procedures. Amendments are to meet the same reporting criteria. Any changed information is clearly identified and where appropriate, the reason for the change is included in the report.

## 7.9. Complaints

A. The laboratories have a complaint process describing the handling of complaints received from any party. In addition to the resolution of these complaints, improvement in the area of concern is addressed and implemented in most cases.

B. The process for handling complaints is documented in organizational and laboratory procedures and these are available to any interested party upon request. The laboratory receiving the complaint confirms whether the complaint relates to laboratory activities that it is responsible for and, if so, then addresses it.

C. The process for handling complaints includes the following:

1. Description of the process for receiving, validating, investigating the complaint, and deciding appropriate actions to respond to it.
2. Tracking and recording complaints, including actions taken to resolve them.
3. Ensuring appropriate action is taken.

D. The laboratory receiving the complaint will gather all information required to investigate, validate, address, and review the complaint and its outcome.

E. When possible, the laboratory will acknowledge receipt of the complaint, provide progress reports with the outcome of resolution, and formal notice of completion to the complainant.

F. Communications to the complainant is addressed in organizational and laboratory procedures.

## 7.10. Nonconforming Work

A. The laboratories have control of non-conforming work procedures that are implemented when any aspect of their activities, or the results of this work, does not conform to requirements of the management system, testing methods, or the requests of the customer. These procedures address the following elements:

1. Responsibilities and authorities for the management of identified non-conforming work to include taking actions such as the halting of work

and/or the withholding of test reports based upon risk levels established by the laboratory.

2. Actions are based upon the risk levels established by the laboratory.
3. An evaluation of the significance of non-conforming work including an impact analysis on previous results and, if necessary, recall of work with notification to the customer.
4. Remedial action taken, together with any decision about the acceptability of the non-conforming work.
    a. The customer is notified if investigations show that non-conformances have affected work performed for or data reported to the customer. This notification is documented.
5. Responsibility for authorizing the resumption of work.

B. Records of nonconforming work and actions taken are maintained in the quality information management system.

C. If the non-conforming work could recur, or there are other significant problems identified, the corrective action procedures in Section 8.7, Corrective Action are promptly followed.

### 7.11. Control of Data and Information Management

A. Laboratories have access to the data and information needed to perform laboratory activities through various electronic records management systems (i.e., FACTS, ALIS, LIMS, CMS, Quality Management Information System) and paper records maintained according to organizational and laboratory procedures.

B. Information management system applications used for the acquisition, processing, recording, reporting, storage, or retrieval of data are validated prior to introduction by the FDA's Office of Information Management and Technology.

C. If computer software is developed by the user, its development is authorized, documented in detail and algorithms are validated prior to implementation.

D. Changes to laboratory software configuration or modifications to commercial off-the-shelf software are also authorized, documented, and validated prior to use.

E. Laboratories have processes for the protection of data to include, but not limited to data integrity, data confidentiality during entry, collection, storage, transmission, and processing. The processes also ensure safeguards are in place to prevent unauthorized access to or amendment of records.

F. Information management system failures are recorded, and appropriate immediate and corrective actions are taken.

G. Laboratory information systems managed and maintained off-site meet all applicable requirements of ISO 17025:2017.

H. Instructions, manuals, and reference data relevant to the laboratory information systems are readily available to personnel through the document control process (see Section 8.3).

I. Calculations and data transfers are reviewed before the data is reported. All changes are identified and verified where they occur. This process is detailed in the procedure for laboratory quality control identified in Section 7.7, Ensuring the Validity of Results.

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## 8. Management System Requirements

### 8.1. Options

8.1.1. General

The laboratories have established, documented, implemented, and maintained a management system capable of supporting and demonstrating the consistent achievement of the requirements of ISO/IEC 17025:2017 to assure the quality of laboratory results. In addition to meeting the requirements outlined in Sections 4 - 7 of this document, the Standard requires the laboratories to implement a management system in accordance one of the two following options:

8.1.2. Option A

The Laboratories follow the requirements for option A, outlined in Sections 8.2 to 8.9.

8.1.3. Option B

Option B of ISO/IEC 17025:2017 addresses minimal requirements for laboratories with a separate management system either certified to or at least structured to the requirements of ISO 9001. The laboratories do not fall within this category.

### 8.2. Management System Documentation (Option A)

8.2.1. Management System Policy

A. Mission

The laboratories are committed to providing testing that meets both the needs of the customers and the requirements of ISO/IEC 17025:2017 and to continually improve the effectiveness of the management system. Testing results are reported within stated limits of accuracy, precision, and detection limits as described in the methods used for analysis.

8.2.2. Commitments to Quality

A. Good Professional Practice and the Quality of Testing

The laboratories are committed to the Standards of Ethical Conduct which define the obligations of public service issued under Executive Order 12674. Testing is conducted per the policies stated in Section 2. The laboratory management and personnel are committed to performing quality activities to assure integrity, accuracy, precision, reliability, and timeliness of the data.

8.2.3. Standard of Service

A. The laboratory's standard of service for the testing program is defined by the ISO/IEC 17025:2017 requirements, FDA regulatory needs included as part of the laboratory methods, and the following:

1. Established and maintained documented procedures for laboratory operation based upon consensus methods for testing. Methods are specified or cited in the compliance program and compendiums, or by the customer. In some cases, testing and procedures as established by the instrument manufacturer are used.
2. Sample handling and management procedures to maintain integrity of both the samples and the documentation to support the analytical data.
3. Maintenance of records in such manner that facilitates retrieving them later. Records are maintained in the analyst worksheet packet or web application by sample number. Records may be archived on- or off-site depending on the home division of the collector or in a web application. Archival retention periods are stated in the laboratories' record management procedures and are in accordance with the agency's established record retention schedule.
4. Employment of qualified and trained personnel to perform the tasks to support the laboratory objectives. Competency demonstrations by technical personnel conducting laboratory methods are conducted and documented.

5. Routine maintenance of quality control data to support testing results by demonstrating that measurement processes are maintained in statistical control. Accuracy and precision control charts are used to monitor performance.
6. Maintenance of an instrument calibration program that provides measurement traceability to International System of Units (SI) units. This is accomplished with the use of national, international, or industry accepted standards of measurement.

B. Laboratory personnel follow the policies included in this manual, the processes described in their laboratory operating procedures, and the processes described in laboratory methods referenced in this manual.

C. The sections in this manual describe elements and refer to procedures that outline the management system established to accomplish the mission of the laboratory.

D. The management system process and procedures as defined in this manual maintain the integrity of the management system for consistent operations when changes such as a change in the structure of the organization or management, or a change in a procedure are made.

E. Primary consideration in all policies, procedures, and objectives is given toward retaining personnel competence and impartiality.

F. The policies for operation of the laboratory management system are established to address the requirements of ISO/IEC 17025:2017. The laboratories are committed to laboratory accreditation to the requirements of ISO/IEC 17025:2017.

G. The implementation of the quality policies is evidenced by the way 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 of the laboratory management system.

H. 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.

I. Management system procedures supporting quality policies are independently implemented and maintained by the laboratory organizations. Where needed, each laboratory shall have procedures

to implement the quality policies. These procedures are included in the document control system. All documentation, processes, systems, and records related to the fulfillment of the requirements of ISO/IEC 17025:2017 shall be included in, referenced from, or linked to the management system.

J. All laboratory employees involved in laboratory activities have access to approved and controlled consensus standards, instrument manufacturers' manuals, and procedures for reference, ensuring consistent application and validity of activities that contribute toward results reported.

### 8.3. Control of Management System Documents (Option A)

A. Changes to management system documents are made per organizational and laboratory document control procedures and include periodic review and revision of this manual.

1. The document control and management procedures describe the process for controlling quality documents that form part of the laboratory 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.
2. Control of electronic management system documents and data is addressed in Section 7.11.

B. Document control requirements:

1. Documents issued to personnel in the laboratory as part of the management system are reviewed for adequacy and approved by authorized personnel prior to issue in accordance with document control and management procedures.
2. Documents are reviewed per an established schedule and revised as necessary to ensure continuing suitability and conformance with the management system and ISO/IEC 17025:2017 requirements. These reviews should include an assessment of reference documents and pertinent background information.
3. Altered or new text is identified either in the document, document change history section, on a cover page, change-tracked archival file, or in attachments. Changes can be described in general terms since the details can be demonstrated in the archived document. Document revision is recorded on each document and tracked within the document management control system.

4. Authorized management system documents and external documents are available at locations where operations essential to the effective functioning of the laboratory are performed. Distribution and locale of these documents is controlled.
5. A document control header as described in the organizational document control and management procedures uniquely identifies management system documents generated by the laboratories. Such identification includes the revision status, identification number and inclusive pagination.
6. The unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose.

## 8.4. Control of Records

A. Laboratories maintain records according to organizational and laboratory procedures to sustain objective evidence showing fulfilment of the requirements of the quality system. These records are required to be legible and readily identifiable for retrieval.

B. Retention time, archival, and disposal of laboratory records are in accordance with SMG 3291.1 Records Management Policy and existing FDA organizational record retention schedules.

C. Quality records are maintained in the quality information management system or recorded within each laboratory's individual records file plan.

D. Internal access to records is controlled through various methods, such as, but not inclusive of, password protected storage, both electronic and physical, provided to authorized personnel to maintain confidentiality. Access from entities outside FDA is governed by statutes within the Freedom of Information Act (FOIA) July 4,1966; President Obama's Freedom of Information Act Memorandum, dated January 21, 2009; and Attorney General Holder's Freedom of Information Act Guidelines, March 19, 2009.

E. Additional requirements regarding technical records are addressed in Section 7.5 and control of electronic records is covered in Section 7.11 of this manual.

## 8.5. Actions to Address Risks and Opportunities

A. Top management in the laboratories meet regularly to assess risks and opportunities associated with the laboratories' activities to:

1. Assure the management system achieves its intended results.
2. Enhance opportunities to achieve the purpose and objectives of the laboratories.
3. Prevent, or reduce negative impacts and potential failures in laboratories' activities.

4. Achieve improvement.
5. Examples of areas evaluated consist of the following, although the list is not all inclusive:
    a. Turnaround times for data reporting
    b. Training and competency
    c. Structure to ensure impartiality of personnel
    d. Equipment issues
    e. Program requirements
    f. Facilities/Environment
    g. Effectiveness of corrective and preventive actions
    h. Outcomes of internal audits
    i. Complaints
    j. Processes to ensure confidentiality

B. Plans, final evaluation, actions and implementation of actions, improvement, and assurance of intended actions are outlined in Section 8.9, Management Reviews.

C. Actions taken to address risks and opportunities are proportional to the potential impact on the validity of the laboratories' results.

## 8.6. Improvement

A. The effectiveness of the laboratories' management system is improved by using the following activities: internal audits; management reviews; analysis of quality control data; corrective actions; improvements; the quality policy; and the quality objectives.

B. The laboratories seek customer feedback on their services and general performance. Records of the comments, both positive and negative, are maintained and are considered for identifying management system improvements during reviews performed by laboratories' management.

## 8.7. Corrective Actions

A. Laboratories designate the authorities for implementing corrective action when one of the following is identified:

1. non-conforming work,
2. departures from the policies and activities outlined within the management system, and

3. departures from required technical operations.

B. When a non-conformance is identified, the corrective action chosen addresses the magnitude of the non-conformance and the risk attributed to the non-conformance.

1. Immediate action is implemented to correct a nonconformity and address the consequences.
2. An evaluation is performed to determine the cause(s), a history of similar issue(s), potential for recurrence, and the need for action to eliminate the problem to prevent recurrence.
3. Corrective actions are determined and implemented based upon this evaluation.
4. A review of the effectiveness of corrective actions is performed.
5. If necessary, updates for risks and opportunities are determined during planning.
6. Essential changes discovered during the corrective action investigation are implemented within the management system, where necessary.

C. Corrective actions are appropriate to the effects of the nonconformities encountered.

D. Corrective actions are recorded, to include the nature of the nonconformities, cause(s) and subsequent actions taken, including the results of any corrective action.

## 8.8. Internal Audits

### 8.8.1. General

Conduct internal audits according to a schedule included in the laboratories' audit procedures. Conduct internal audits of activities to verify that operations continue to conform to the requirements of the management system and ISO/IEC 17025:2017.

An internal audit process is used to evaluate the effectiveness of the management system established for laboratory operations.

Note: The laboratory information management system is audited at least once per accreditation cycle.

### 8.8.2. Audit Program

A. The internal audit program is defined in organizational and laboratory procedures. The program takes into consideration the risks and the

importance of the laboratory activities concerned, changes affecting the laboratory, and the results of previous audits.

B. The QSM defines the audit criteria and scope for each audit in an audit plan.

C. Results of the audits are reported to laboratory management.

D. When audit findings cast doubt on the effectiveness of operations or the correctness or validity of the laboratories' test or calibration results, the laboratories implement appropriate correction and corrective actions in a timely manner according to organizational and laboratory procedures.

E. The area of activity audited, the audit findings, and corrective action that arise from them are recorded according to the laboratories and organizational audit procedures.

### 8.9. Management Reviews

A management review is conducted by each laboratory's executive management at least once each fiscal year FY; however, it can be conducted more often according to planned intervals determined by each laboratory.

This review is conducted to ensure continuing suitability, adequacy, and effectiveness based upon information related to the inputs and outputs of laboratory activities and operations and stated policies and objectives.

Reviews of nonconforming work, personnel, and customer feedback are performed during management review to identify trends.

## 9. Document History

| Revision # | Status* (D, I, R) | Date | Author Name and Title | Approving Official Name and Title |
|---|---|---|---|---|
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| 03 | R | 08/13/2019 | LMEB | LMEB |
| 04 | R | 01/22/2021 | LMEB | LMEB |
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| 07 | R | REFER TO QMIS | OCS QUALITY STAFF<br>HFP/ORTS QUALITY STAFF | SELEN STROMGREN, OCS/OSLA DIRECTOR<br>YUGUANG WANG, HFP/OQAM/QSM DIRECTOR |
| | | | | |

* - D: Draft, I: Initial, R: Revision

## 10. Change History

| Revision # | Change |
|---|---|
| 2.0 | 1.0– deleted “2005”<br>4.13, 4.14, & 4.15 e. – changed Sections 1300.1-1316.4 to Volume I, Section 1300<br>4.15 a. – deleted OPM manual reference and added OPM website<br>4.2.2 b. – added web application and added to last sentence on 3rd bullet<br>4.3.2.3 – revised 1st paragraph<br>4.13.1.2 – revised<br>4.13.2.1 – added “and/or LIMS”<br>5,8.3, 5.10.1., 5.10.2., & 5.10.5 – added reference to LIMS |
| 03 | All section numbering and content updated to reflect changeover from ISO/IEC 17025:2005 revision requirements to 2017 version requirements |

| Revision # | Change |
|---|---|
| 04 | 5.6.5 and 5.6.6 – Added numbering to these two paragraphs and in 5.6.5, replaced "FDA Division of Ethics and Integrity" with the more generic "FDA procedures and policies"<br>7.8.2.2 – clarified that results in worksheets apply to the sample as received<br>7.8.6.1 – clarified the Decision Rule requirement with steps to take when a decision rule is not provided.<br>7.8.6.2 – Deleted Bullet C.<br>8.8.1 – Added AOAC requirement for internal audit of lab information management system.<br>8.9 – Added AOAC requirement for review of nonconforming work and other items during management review |
| 05 | Obsolete references have been removed. All remaining references were updated to ensure adequate searches by user and links within document were verified or updated as needed. Additions or Changes are highlighted within document. Reformatted. |
| 06 | Document updated for reorganization of ORS into HFP and OCS.<br>Document name changed. |
| 07 | 6.2 Personnel, 6.2.1 Laboratory Personnel added the following "The laboratories' follow applicable local, state and/or federal-specific requirements for hiring specific laboratory personnel."<br>6.3.3 Monitoring, controlling and recording environmental conditions added the following "C. Laboratories use aseptic technique when conducting microbiological testing." |
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## 11. Attachments

None