ORA
Quality Manual

JANUARY 2007

Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs

Quality Management System

Foreword

The *ORA Quality Manual* contains the required policy elements to structure the Office of Regulatory Affairs (ORA) Quality Management System (QMS). The anticipated audience for this manual includes those in the public, regulated industry, counterpart agencies, and FDA who wish to understand the ORA QMS. Use of this manual presumes some understanding of quality system principles and standards.

> Quality system implementation has three goals: first, to provide product and services that are fit-for-use; second, to satisfy the customer; and third, to provide a mechanism for continual improvement of the organization, its products, services, and the QMS system. To meet these goals, an organization sets up formal business practices—a quality system—for which the organization's managers are accountable. These business practices define managers' responsibilities for organizational structure, processes, procedures, and resources. The result is a management system, aligned with the organization's strategic direction, that controls the processes that create the product or service and assures that proper planning, monitoring and improvement takes place.

Training is an essential element of QMS implementation. For ORA, training is necessary prior to achieving accountability for the policies and procedures described in this Manual. For others, general information about quality systems may be found on the Internet at

- American Society for Quality, "Learn About Quality" (www.asq.org); and
- International Organization for Standardization, "ISO 9000" (www.iso.org).

Initial Release Note

The ORA QMS is not fully implemented. Accordingly, some implementing procedures are in draft stage. Under the "supporting information" headings, these are marked as 'draft.' As implementation progresses and procedures are finalized, the supporting information references will be updated.

Distribution within the FDA: FDA employees may access the current ('controlled') version of *the ORA Quality Manual* through the "QMS master list" on the FDA Intranet.

Public distribution: The public may obtain a copy of the *ORA Quality Manual* through the FDA Internet (www.fda.gov/ora) or by making a written Freedom of Information request (www.fda.gov, see "Freedom of Information").

Comments: ORA welcomes comments as to how this publication may be improved. Please send your comments to the Director, Office of Enforcement, HFC-200, ATTN: QMS Program Manager, U.S. Food & Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

THIS COPY OF THE *ORA QUALITY MANUAL*
[ ] IS CONTROLLED TO BE CURRENT
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Table of Contents

Appendices

Document history					
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1. Introduction

1.1 Purpose of this manual

The Office of Regulatory Affairs (ORA), a component of Food and Drug Administration (FDA), manages work quality through the Quality Management System (QMS). Work quality is critical to the services that ORA provides to its customers and stakeholders. ORA defines quality by the extent to which a product or service satisfies the customer's stated or implied needs. For over two decades ORA has had quality plans for field activities that affect regulated industries. Now, with the sponsorship of the Associate Commissioner for Regulatory Affairs, ORA is incorporating long-standing field quality control and assurance plans into a quality system for ORA field and headquarters.

The ORA Quality Manual meets the requirements of FDA Staff Manual Guide (SMG) 2020, Quality System Framework for Internal Activities. The Quality Manual provides the scope and structure of the ORA QMS—the policies, objectives, authority, accountability, and plans needed to ensure quality in work processes, products, and services. To build quality into the organization, ORA plans, implements, documents, and assesses work activities for continual improvement. ORA's goals are to ensure work products, services and decisions are fit for their intended use, and that resources and processes are aligned with ORA's strategic directions.

A quality system is an integral part of a dynamic, growing organization. The ORA QMS uses the tools outlined in this Manual—the quality policy and objectives, process and product measurement, data analysis, feedback, audit results, corrective and preventive action, and management review—to facilitate continual improvement.

For your information: §1.4 contains definitions and §2.1 contains scope of application.

The following descriptions borrow extensively from "A Tour of the FDA" on the FDA Internet site [1].

1.2 The Food and Drug Administration

(a) **Overview** – FDA is a federal, science-based, law enforcement agency mandated to protect public health and safety. Founded in 1906, FDA is one of the nation's oldest public health agencies. The 1997 FDA Modernization Act reaffirmed FDA's public health protection mission: [2, 3]

- to promote public health by promptly and efficiently reviewing clinical

[1] EduNeering, Inc. "About the Food and Drug Administration; Short Course: A Tour of the FDA." *U.S. Food and Drug Administration*. 20 Jul. 2006 http://www.fda.gov/opacom/hpview.html.
[2] U.S. Government. Federal Food Drug and Cosmetic Act. "§903(b) Mission." *U.S. Food and Drug Administration.* 20 Jul. 2006 http://www.fda.gov/opacom/laws/fdcact/fdcact9.htm;
[3] "FDA's Mission Statement." *U.S. Food and Drug Administration.* 20 Jul. 2006 http://www.fda.gov/opacom/morechoices/mission.html

research and taking appropriate action on the marketing of regulated products in a timely manner;

- to protect public health by ensuring foods are safe, wholesome, sanitary, and properly labeled; human and veterinary drugs are safe and effective; there is reasonable assurance of the safety and effectiveness of devices intended for human use; cosmetics are safe and properly labeled; and public health and safety are protected from electronic product radiation;
- to participate with representatives of other countries to reduce the burden of regulation, coordinate regulatory requirements, and achieve appropriate equivalent arrangements; and
- as determined by the Secretary of Health and Human Services, to carry out the tasks above by consulting with experts in science, medicine, and public health, and by cooperating with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products.

FDA accomplishes its mission by establishing and enforcing standards and other regulatory requirements authorized or mandated by the Federal Food, Drug and Cosmetic Act and other public health laws[4].

Products regulated by FDA include all foods except for domesticated meat and poultry[5]; prescription and non-prescription drugs; blood products, vaccines, and tissues for transplantation; medical devices and radiological products, including cellular telephones; animal drugs and feed; and cosmetics.

(b) **Organization** – FDA is part of the executive branch of the U.S. government, under the Department of Health and Human Services. FDA is headed by the Commissioner of Food and Drugs, who is appointed by the President of the United States, confirmed by the U.S. Senate, and serves at the President's discretion. The Office of the Commissioner oversees all agency components and is responsible for the efficient and effective implementation of FDA's mission.

The Office of the Commissioner is made up of several components. Among these are

- Office of Chief Counsel – in collaboration with the Department of Justice, responsible for pursuing litigation of enforcement actions initiated by ORA and the FDA centers;
- Office of Policy and Planning – responsible for managing the agency's policies and evaluation activities;
- Office of External Relations – responsible for primary contacts with the news media;
- Office of International Activities and Strategic Initiatives – responsible for special health issues, consumer affairs, and international programs;

[4] "Laws Enforced by FDA and Related Statutes." *U.S. Food and Drug Administration.* 20 Jul. 2006 http://www.fda.gov/opacom/laws/

[5] FDA regulates all food products except the meat, poultry, and egg products regulated by USDA under the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act.

- Office of Crisis Management – responsible for coordinating emergency and crisis-response activities involving FDA-regulated products; and
- Office of Legislation – responsible for oversight of drafting congressional testimony, responding to congressional inquiries, and assisting in public health legislation.

ORA is FDA's lead component for compliance issues and field activities. ORA is headed by the Associate Commissioner for Regulatory Affairs, who reports directly to the Commissioner (see *FDA organizational chart* in appendix). ORA achieves effective and risk-based compliance of regulated products through quality, science-based work that maximizes consumer protection.

FDA has five specialized program centers responsible for ensuring the safety and, in some cases, the effectiveness, of the products in their program areas. The program centers also regulate the manufacture, labeling, and advertising of many of those products. Each center reports directly to the Office of the Commissioner:

- Center for Biologics Evaluation and Research (CBER) – blood and blood products, vaccines, allergenics, and biological therapeutics;
- Center for Devices and Radiological Health (CDRH) – medical devices and radiation-emitting products;
- Center for Drug Evaluation and Research (CDER) – human drug products;
- Center for Food Safety and Applied Nutrition (CFSAN) – human foods (both imported and domestic) and cosmetics; and
- Center for Veterinary Medicine (CVM) – food additives, drugs, feeds, and devices used for food animals and pet or companion animals.

An additional center, the National Center for Toxicological Research (NCTR), conducts research aimed at understanding critical biological events in the expression of toxicity and at developing methods for assessment of human exposure, susceptibility, and risk.

1.3 The Office of Regulatory Affairs

(a) **Mission**

ORA protects consumers and enhances public health by maximizing compliance of FDA regulated products and minimizing risk associated with those products.

ORA minimizes risk primarily by reducing consumer exposure to unsafe and/or ineffective products through prevention, detection, and interception of products that do not comply with applicable legal requirements. ORA is responsible for the effective implementation of the activities required to assure that regulated establishments comply with laws and regulations enforced by FDA, including

- managing and operating field activities using risk based principles;
- inspecting regulated firms;
- assessing products imported into the U.S.;

- directing and conducting criminal investigative activities;
- analyzing regulated products;
- developing evidence and initiating regulatory action;
- developing and maintaining cooperative relationships with state, local, and other federal public health authorities and regulators;
- providing advice and assistance to FDA components on program development and execution; emerging problems; regulations; and compliance policy matters;
- coordinating and collaborating with program centers to meet identified needs in providing input and implementing policies, programs, and procedures that maximize compliance and minimize risk; and
- providing information to industry to facilitate voluntary compliance.

(b) **Organization** – ORA consists of headquarters offices located in Rockville, MD, and field offices located throughout the U.S. (see *ORA organizational charts* in appendix showing chain of command).

- ORA headquarters units oversee, coordinate, and facilitate ORA programs and the operations of the field. ORA headquarters employees are organized into four offices, each headed by an Office Director:
  - Office of Criminal Investigations,
  - Office of Enforcement,
  - Office of Regional Operations, and
  - Office of Resource Management.

  Within each office there are staffs and divisions that report to the Office Director.

- ORA field units support consumer protection by ensuring industry compliance with laws and regulations that FDA is charged with enforcing. ORA field employees are organized into five regions, each headed by a Regional Food and Drug Director (RFDD). Within each region there are district offices, regional laboratories, and regional staff that report to the RFDD. The field units within ORA perform the majority of FDA's regulatory inspections, investigations, and analyses as well as other regulatory work that support ORA's mission.

(c) **Scope of work** – ORA's work includes oversight of domestic and foreign regulated products in both pre-market and post-market venues for all FDA program areas: foods, human and animal drugs, blood products, vaccines, tissues, medical devices and radiological products, animal feed, and cosmetics. ORA works cooperatively with states, other federal agencies, and foreign governments. ORA may outsource work to counterpart federal and state agencies or other third-parties.

(d) **Personnel** – ORA field and headquarters employees include

- Investigators and Inspectors;
- Criminal Investigators;
- Analysts;

- Compliance Officers;
- Outreach staff for industry, consumers, and state and local governments;
- Administrative support staff; and
- Managers and Supervisors.

1.4 Definitions and abbreviations

(a) FDA has internal definitions for several quality-related terms; see SMG 2020[6].

(b) The following definitions are used in the *ORA Quality Manual:*

(1) **Contract** – ORA uses this term to refer to the use of state and local counterpart agency resources to perform regulatory work on behalf of ORA; this could be called 'subcontracting' in a commercial context. ORA does *not* use the term 'contract' to mean a commitment to supply a product to the customer, but uses 'work plan' and 'assignment' to identify commitments.

(2) **Customer / Stakeholder** – Stakeholders include all those parties with an interest in FDA work products or service. Customers are a subset of stakeholders and receive the work product or service and may appropriately determine the needs and requirements associated with that work product or service. According to FDA SMG 2020

- 'CUSTOMER' is an internal or external recipient of a product or service anywhere along the product's life-cycle[7].

  Examples: FDA's program centers are customers when the field prepares a warning letter recommendation that requires center concurrence; district compliance officers are the customers when investigators write their inspection reports; consumers are the customers when a district logs their complaint about a regulated product.

- 'STAKEHOLDER' is an owner or interested party regarding the delivery of a product or service.

  Examples: regulated industry is a stakeholder when ORA issues compliance policies.

(3) **Document / Directives** – FDA and ORA use the terms

- 'DOCUMENT' to refer to work products and records, and
- 'DIRECTIVES' to refer to policies, procedures, instructions, and forms

(4) **Managers** – ORA uses these terms to distinguish between levels of management:

- 'MANAGER' – those in management positions that typically supervise one or more supervisors, but also branch directors in districts and regional laboratories, and headquarters division directors.
- 'SENIOR MANAGER' – a subset of managers; those in Senior Executive Service positions in ORA responsible for strategic direction: Associate Commissioner and Deputies, Office Directors, and RFDDs.
- 'BOARD OF DIRECTORS' – a group of senior managers selected by the

[6] "FDA Quality System Framework for Internal Activities." *U.S. Food and Drug Administration.* 20 Jul. 2006, specifically Section 6 and Attachment A http://www.fda.gov/smg/vol3/2000/2020.html

[7] "Defining the Customer in a Regulatory Agency." *U.S. Food and Drug Administration.* 20 Jul. 2006 http://www.fda.gov/cder/gmp/gmp2004/defining_customer.pdf

Associate Commissioner to oversee the QMS.

- 'ORA MANAGEMENT REPRESENTATIVE' – Board chair; a senior manager with authority to manage the QMS and to report to the Associate Commissioner and customers on quality system issues.
- 'QUALITY SYSTEM MANAGER' – trained staff member assigned responsibilities for implementing and maintaining a unit's quality system.
- 'QMS PROGRAM MANAGER' – a quality system manager assigned responsibilities for implementing and maintaining the ORA-wide QMS.

(5) **Supporting information** – Within the *Quality Manual*, ORA uses this term to designate other directives used to implement the policy being discussed. If marked 'Draft,' the directive is planned but not yet available.

(6) **Unit** – Within the *Quality Manual*, ORA uses this term to indicate a region or headquarters office in its entirety; a district office, regional laboratory, or a headquarters division in its entirety; and the immediate offices of the Associate Commissioner, RFDD, or headquarters Office Director (see *ORA organizational charts* in appendix).

(7) **Work** – ORA defines this term to encompass the products and services ORA provides to internal and external customers.

Examples – analytical analysis and worksheet; investigation and report; policy drafting and publication; planning spreadsheets and reports; training course preparation and presentation.

(c) The following abbreviations are used throughout the *Quality Manual*:

- FDA – Food and Drug Administration
- FMD – Field Management Directive
- ORA – Office of Regulatory Affairs
- QMS – Quality Management System
- RFDD – Regional Food and Drug Director
- SMG – Staff Manual Guide

2. Quality Management System

2.1 Scope

Once an organization decides to develop a quality system, the first question to answer is: to what will the quality system apply?

(a) ORA maintains an effective, documented quality system to ensure quality is built into ORA work products and services[8]. The ORA QMS applies to ORA activities that significantly affect the quality of ORA work processes and the resulting work products.

(b) The ORA QMS

(1) applies to all ORA headquarters and field units, with the exception of the Office of Criminal Investigations;
(2) applies to all facilities—permanent, mobile, or temporary—where ORA work activities take place;
(3) defines the responsibility and authority for ORA activities which significantly affect work product quality;
(4) includes policies, procedures, quality requirements, forms, references, and records of work activities;
(5) incorporates review mechanisms for ensuring ORA work, including work performed by a state counterpart or other party, is done according to current policy, procedures, and quality requirements; and
(6) documents plans for the quality of specific work processes.

(c) ORA has limited control over central–or shared–services provided by the FDA in some personnel, administrative, and information technology areas.

2.2 Applicable requirements

In designing and implementing a quality system, an organization determines the regulatory requirements for their work processes and products and adopts quality system requirements from voluntary standards such as ISO 9001.

(a) As a component of a federal agency, ORA is subject to statutes, regulations, and orders which affect the QMS. Federal and FDA-wide policies and procedures supersede ORA policies and procedures:

(1) government-wide management and administrative requirements are supported by FDA SMGs, e.g., the Federal Manager Financial Integrity Act sets quality control and assurance requirements and is interpreted for FDA by SMG 2350.1 *Procedures for the Implementation of the Federal Managers' Financial Integrity Act (FMFIA)*;
(2) statutes and regulations that direct FDA activities may set requirements for QMS procedures, e.g., the Good Guidance Practice regulation (21 CFR 10.115) affects directive control requirements; and
(3) FDA has instituted agency-wide requirements for quality systems.

[8] For brevity, 'work products and services' are hereafter referred to as 'work products.'

(b) ORA is not seeking registration to any third-party standard although ORA laboratories have achieved and maintain third-party accreditations. Elements of the ORA QMS are adapted from international standards for quality systems and for laboratory competence:

(1) ISO 9001, formally known as ANSI/ISO/ASQ Q9001-2000: Quality Management Systems: Requirements;
(2) ANSI/ISO/IEC 17025-2005: General requirements for the competence of testing and calibration laboratories; and
(3) American Society of Crime Laboratory Directors' Crime Laboratory Accreditation Program.

(c) Continual improvement of the ORA QMS may be based on additional quality system and work standards, e.g.,

(1) ANSI/ISO/ASQ Q9004-2000 - Quality Management Systems: Guidelines for Performance Improvements;
(2) ANSI/ISO/ASQ Q10015:2001: Quality Management - Guidelines for Training;
(3) ANSI/ASQ Z1.13-1999: Quality Systems Guide for Research;
(4) PIC/S Quality System Requirements for Pharmaceutical Inspectorates;
(5) ANSI/ISO/ASQ QE19011-2004: Guidelines for quality and/or environmental management systems auditing; and
(6) ANSI/ISO/ASQ E14001-2004: Environmental management systems - Requirements with guidance for use.

Supporting information

- FDA Intranet: FDA Staff Manual Guides
- "Laws Enforced by the FDA and Related Statutes" http://www.fda.gov/opacom/laws/
- FDA SMG 2020, *FDA Quality System Framework for Internal Activities* http://www.fda.gov/smg/vol3/2000/2020.html
- DRAFT - QMS.1, *Cross-references to ORA Quality Manual*

2.3 Documentation

Organizations use directives and evidentiary records to establish and maintain a quality system and to support effective and efficient work processes. Customer, stakeholder, and regulatory needs drive the type and degree of system and work documentation.

(a) The ORA QMS is defined by

Type	Description
1. Quality Manual	The *Quality Manual* contains quality policies for FDA's ORA field and headquarters components.
2. National directives	Nationally mandated directives, which are used FDA-wide or ORA-wide, include • Quality system procedures, instructions and forms; and • Work directives.
3. Local directives	Local directives include quality system and work procedures and instructions for a specific unit. Generally referred to as standard operating procedures, they may be responsive to national directives.
4. Records	Includes work and quality records and many ORA in-process and final documents.

(b) For controlling work processes, ORA maintains manuals of work directives and internal standard operating procedures. These documents are a mixture of procedural and instructional information and are controlled within the QMS.

(c) ORA maintains strategic plans and work plans which specify and implement quality objectives. These documents are controlled within the QMS.

2.3.1 Quality manual

A quality manual is the central resource for understanding an organization's quality system. Certain content is required and changes must be controlled. This entire ORA.1.1 document is the "ORA Quality Manual."

(a) The QMS Board of Directors ensures the *ORA Quality Manual* contains
- (1) the scope of the ORA QMS including details of any exclusions (see *Scope)*;
- (2) a description of the elements of the quality system and their integration (see further chapters of this *Manual*); and
- (3) references to national procedural documents implementing the quality policies (see *'supporting information'* notes throughout the *Manual*).

(b) The *ORA Quality Manual* is a controlled directive approved by the Associate Commissioner for Regulatory Affairs and maintained by the ORA QMS program manager.

2.3.2 Directive control

Work quality depends on access to accurate and timely direction, requiring organizational control of directives, i.e., defined approval authority and availability of the proper revision in its entirety.

(a) ORA senior managers ensure all policies, procedures, routine work instructions, forms, and standards used by ORA employees are properly approved, current, and available when needed.

(b) ORA senior managers ensure ORA units establish and maintain documented procedures to control internally generated directives, and externally supplied directives[9] as applicable, which contain policies, procedures or instructions for
- (1) ORA-wide work and quality system activities, and
- (2) local work and quality system activities.

Supporting information
- Draft - ORA-QMS.1, *Directive Control System*

[9] Examples: The *Investigations Operations Manual* is an internal directive; the *Official Methods of Analysis of AOAC International* is an external directive.

2.3.3
Record control

An organization's records provide evidence of conformance to process and product requirements and of the effective management of the quality system. Records need to be accurate, complete, and controlled.

(a) ORA senior managers ensure records are identified, protected and retrievable whether in electronic or paper form.

(b) ORA senior managers ensure ORA units establish and maintain documented procedures for

(1) work records/work products such as collection reports, analytical worksheets, establishment inspection reports (see *Reporting results*);
(2) data records/work process records such as investigational notes, quality control/quality assurance records, and data from equipment (see *Operations/Integrity*);
(3) employee qualification records related to quality such as training records, position descriptions (see *Competency*); and
(4) QMS records such as reports regarding nonconformities, audits, corrective and preventive actions, and management review (see *Measurement chapter*).

(c) As established in the relevant work-related or QMS procedures, ORA managers ensure records contain sufficient information to establish audit trails for the activity as needed to ensure quality.

(d) QMS records may be requested by auditors or other parties to evaluate the effectiveness of the quality system. Quality system managers ensure records are supplied as consistent with information disclosure requirements (see *Confidentiality*).

Supporting information

- Draft - ORA-QMS.4, *Records Management System*
- FDA SMG, 3291 series, "Records Management"
- FDA Record Schedule
- ORA Information Security procedures
- *ORA Laboratory Manual* Volume I, ORA-LAB.QM, §4.12

3. Management Responsibility

3.1 Management commitment

In implementing a quality system, the first responsibility of an organization's management to demonstrate their support. Management's leadership and participation is necessary for a quality system to be effectively implemented and sustained.

(a) ORA senior managers are committed to the development, implementation, maintenance, and improvement of a quality system that meets ORA customer needs as well as regulatory and statutory requirements. They make their commitment evident by

(1) establishing and documenting the ORA quality policy, strategic plans, work objectives, and quality objectives;
(2) participating in QMS management reviews and in follow-up actions; and
(3) ensuring the availability of resources for conducting work and QMS processes.

(b) ORA managers demonstrate their commitment by

(1) establishing quality plans for work activities;
(2) communicating the importance of a customer orientation when fulfilling quality requirements);
(3) participating in reviews of their unit's quality system and in follow-up actions; and
(4) assuring communication, understanding, and implementation throughout ORA units.

Supporting information

- ORA.1 *ORA Quality Policy*
- ORA.1.1 *ORA Quality Manual* (this manual)

3.2 Customer focus

An organization accomplishes its mission by meeting the customers' needs. Once committed to building a quality system, management's next responsibility to ensure the organization has a customer orientation. The organization's success rests on identifying the current and future needs of its customers (and other interested parties), and achieving satisfaction in meeting those needs.

(a) ORA senior managers ensure customers are identified along with the particular needs associated with each work product and service. The customer needs are translated into defined work requirements associated with specific work products. Included in the work requirements are additional conditions that may not have been specified by the customer but are needed for the product's intended use, to meet regulations, or to meet organizational needs.

(b) ORA managers and supervisors ensure the defined work requirements are communicated, understood, and met through

(1) work planning processes (see *Work plans*);
(2) regular and productive communication with FDA customers and stakeholders;

(3) monitoring customer satisfaction and complaints (see *Customer*); and
(4) continual improvement to maximize alignment between customer needs and defined work requirements (see *Continual improvement*).

(c) ORA managers ensure customers and stakeholders are provided information about work processes and products, work plans and amendments, and customer feedback and complaints as consistent with information disclosure rules (See *Confidentiality*). Customers and stakeholders may be provided access to ORA facilities as consistent with security rules (see *Facilities*).

Supporting information

- FMD 30, *ORA Advisory Committee System* http://www.fda.gov/ora/inspect_ref/fmd/fmd30.html
- "FDA Customer Service Standards" http://www.fda.gov/comments/standard.html
- "Defining the Customer in a Regulatory Agency" http://www.fda.gov/cder/gmp/gmp2004/defining_customer.pdf

3.3 Quality policy

Understanding the customers' needs leads to a formal declaration of the organization's intentions and direction related to quality. An organization publishes its intent in a 'quality policy' statement that is consistent with overall business policies. The quality policy may be a separate statement or combined with an organization's mission or values statements.

(a) The QMS Board of Directors ensures the quality policy
(1) is appropriate for the needs and requirements of ORA and FDA;
(2) includes a commitment to meet the QMS requirements and a commitment for continual improvement
(3) provides a framework to establish and review quality objectives;
(4) is communicated, understood, and implemented throughout ORA; and
(5) is regularly reviewed for continuing suitability.

(b) The ORA quality policy is a controlled directive approved by the Associate Commissioner for Regulatory Affairs.

(c) ORA managers may develop other statements regarding service, professional practice, and strategic, quality or work objectives; such statements are aligned with the ORA Quality Policy and objectives; controlled; and approved by appropriate authorities defined in quality or work procedures.

Supporting information

- ORA.1, *Quality Policy*

3.4 Strategic and quality planning

Having established a customer focus and determined their approach to quality, management's next responsibility is to move the organization forward to mission and vision success. Organizations chart their direction through strategic goals and develop objectives to achieve those goals. Quality system objectives are aligned with the strategic direction so that the right work is being done the right way. Planning therefore is a formal rather than ad-hoc activity, done systematically to support strategic goals. Objectives related to work quality are developed in terms of completeness, timeliness, consistency, conformance with documented procedures, and in support of customer needs.

(a) ORA senior managers ensure strategic plans and objectives are developed and aligned with the vision, mission, and quality policy of ORA. Strategic planning includes

(1) using risk-based priorities that are developed with ORA stakeholders;
(2) maximizing ORA's ability to protect public health with the resources available; and
(3) ensuring planning output is reflected in plans and directives for ORA's work and the QMS.

(b) For relevant functions and levels within the organization, ORA managers ensure quality objectives and quality plans are established for ORA processes and products. They ensure the quality objectives are consistent with strategic plans and the quality policy; measurable; and current.

(c) When carrying out planning activities, ORA managers ensure the following are considered:

(1) the QMS processes and procedures required;
(2) work processes, procedures, and methods needed;
(3) resources needed;
(4) measurement activities; and
(5) continual improvement in fulfilling customer needs as reflected in the work requirements for work products.

Supporting information

- Draft - ORA Strategic Plan

3.5 Responsibility and authority

To carry out the strategic plan and to meet established objectives, an organization's managers and staff need to know their responsibilities and authorities. An organization works more effectively when everyone knows who is responsible for decision-making. Organizations generally have standard ways to define authorities but may make modifications by delegation and roles specification.

(a) ORA uses several means to define and manage responsibility and authority:

(1) Organizational responsibilities of ORA components and the authorities to change responsibilities are defined within the FDA SMGs, Volume I "Organizations and Functions."
(2) Authorities are defined in government personnel classification standards and reflected in individual position descriptions (see *Competency*).
(3) Chains of command, specific work process roles, and interrelationships are defined within readily accessible organizational charts, and

procedural documentation.

(4) Authority and responsibility, but not accountability, may be delegated; delegations are recorded.

(5) Actors for key management positions are assigned when needed to keep decision-making authorities clear. Acting assignments are communicated to necessary employees; and units maintain lists of approved signatories as defined in procedures.

(b) Responsibilities and authorities in ORA are generally proportionate to the organizational hierarchy and specific roles. Roles may overlap, i.e., a senior manger is also the manager of the immediate office, the supervisor of staff therein, and an employee with assigned work.

(1) ORA senior managers define and manage both work systems and the quality system—thus they act both within the systems and on the systems. Within their spans of control they ensure work and quality systems are designed, capable, and implemented.

(i) The Associate Commissioner is ORA's top management official.

(ii) The QMS Board of Directors is accountable to the Associate Commissioner for the design, implementation, and improvement of a functioning ORA QMS.

(iii) The Board chair is the ORA management representative. The management representative, working with other senior managers, is responsible for ensuring the QMS is implemented and maintained; for reporting to the Associate Commissioner on the performance of the QMS and need for improvements; and for ensuring awareness of quality requirements throughout the organization.

(2) ORA managers direct and use the work and quality systems to accomplish organizational goals—acting within the systems. According to their authority, they may work on the systems by customizing procedures and instructions so that ORA maintains flexibility relevant to local circumstances.

(i) Managers are accountable within the chain of command for work accomplishments commensurate with their assigned authority. Unit directors are accountable to customers and stakeholders for the quality of the work produced by their unit.

(ii) Mangers, including committee chairs, ensure procedures are established and used to monitor adherence to work and quality system directives.

(iii) Managers may delegate authority and responsibility but retain accountability; any delegations are recorded.

(iv) A unit-wide manager (director, deputy director, executive officer or equivalent) carries out 'management representative' duties for the unit. These duties, similar to the ORA-level responsibilities above, may not be permanently delegated to staff or subordinate managers.

(3) ORA supervisors ensure planned work is accomplished and quality system is used—they do their work generally within the established systems. They are accountable for ensuring staff are knowledgeable of work and quality system procedures and tools. Supervisors are accountable for performing many quality control and assurance functions.

(4) ORA employees generally act within the work and quality systems.
   (i) Employees are accountable to their supervisors for the quality of their work and have the authority—and the responsibility—to initiate action to prevent the occurrence of product nonconformities and to identify and report any quality problems.
   (ii) Staff members are encouraged to recommend process and product improvements.
   (iii) Staff may be assigned quality-related duties such as peer review, record management, or equipment maintenance.
   (iv) Staff selected for quality system manager duties assist managers in establishing and maintaining the quality system either at the ORA-wide level (program manager) or the unit level. Quality system managers are accountable to the respective management representative (see *ORA organizational charts* in appendix).

Supporting information

- FDA SMG 1005.1, *Policy and Procedures Regarding Organizational Changes*
- FDA SMG series
  - 1120, "Office of Regulatory Affairs-Headquarters"
  - 1300, "Office of Regulatory Affairs-Field"
  - 1400 "Delegations of Authority"
- FDA SMG 1415.5, *Authority to Approve Organization Structure and Functional Statements*.
- *ORA Quality Manual* appendices
- Draft - FMD, *QMS Board of Directors Charter*
- Draft - FMD, *Quality System Managers Roles and Responsibilities*

3.6 Internal communication

As the plans are implemented and the quality system is functioning, an organization needs to make sure information is flowing so that the responsible parties may make the best decisions. To involve mangers and staff in quality improvement and attainment of the quality objectives, an organization needs effective communication.

(a) ORA managers ensure procedures are maintained for internal communication regarding the QMS and its effectiveness, communicating both 'vertically' between organizational levels and 'horizontally' between functional areas.

(b) ORA communication tools may include:
   (1) periodic management reports and conference calls;
   (2) periodic headquarters' divisions/field branches director calls;
   (3) change requests and transmittals regarding changes to directives;
   (4) periodic senior management meetings and QMS reports; and
   (5) ORA Intranet web site for QMS.

(c) Coordination with non-ORA stakeholders is also essential for achieving quality objectives (see *Customer focus*).

Supporting information

- ORA unit suggestion procedures
- FMD 56, *Weekly Management Review* http://www.fda.gov/ora/inspect_ref/fmd/fmd56.htm
- Draft - ORA-QMS.1, *Directive Control System*

3.7 Management review

Systems need a feedback loop to be stable and to allow change to happen in a controlled manner. As part of the commitment to a quality system, an organization's senior managers regularly review the quality system to be certain that it is working effectively and to take action for its improvements by providing feedback to the planning and other quality processes of the organization.

(a) At planned intervals, the QMS Board of Directors ensures the ORA QMS is reviewed according to documented procedures to ensure continuing suitability, adequacy and effectiveness of the QMS. Unit management representatives ensure similar reviews are performed.

(b) The Board ensures that their review of the QMS results in action plans to improve

(1) the QMS and related quality processes,
(2) work processes and products, and
(3) resource allocations.

(c) The ORA quality system managers ensure the results of management review meetings are recorded and subsequent actions monitored.

Supporting information

- Draft – ORA-QMS.5, *Management Review Requirements*
- Draft – QMS.2, *QMS Board Management Review*

4. Resource Management

4.1 Resource provision

An organization's managers are responsible for providing and prioritizing resources to accomplish work and quality system activities.

(a) ORA receives resources from FDA through fiscal and staff budgeting processes. Within that constraint, ORA managers ensure the necessary resources for work and quality system activities are determined, including the resources needed to

(1) assess customer needs,
(2) design and implement systems and processes,
(3) monitor the systems through assessments
(4) improve system processes, and
(5) evaluate improvements for effectiveness.

(b) If resources are inadequate to maintain quality or to perform expected work, ORA managers use established internal communication channels as well as corrective or preventive action procedures to document resource issues and to elevate them to the accountable management level. In the event that adequate resources are not available to fully fund activities, ORA managers may not be able to ensure certain aspects of QMS are fully implemented or work fully accomplished. In such cases, when resource shortfalls are elevated to the accountable management level, senior managers will establish priorities for allocating resources based on ORA's strategic priorities.

4.2 Personnel assignment

When assigning employees, permanent or temporary, to do work, an organization's managers match the needs of the work to the competence and authorities of the employees.

(a) ORA managers and supervisors ensure responsibilities and activities—work or QMS—are assigned based on competency as shown by applicable education, training, skills and experience, and, as needed, assigned authorities.

(b) ORA managers ensure employees, including trainees, are supervised by supervisors, or senior investigators and analysts, familiar with work and quality procedures and purpose of activity.

(c) ORA managers ensure employees may initiate action to prevent the occurrence of work nonconformities and to identify and report any quality problems.

4.3 Competency and training

An organization's employees need to know what their job is, what they are authorized to do, and how their job relates to the organization.

(a) ORA managers and supervisors ensure

(1) employees are aware of the significance of the employee's own activities in relation to the FDA and ORA missions, the particular work

product, and quality objectives;

(2) employees' specific position descriptions are maintained and available; and

(3) if required to perform specific work, employees' authorizations are recorded.

(b) When competency is not provided by education and experience, ORA managers and supervisors ensure training is provided according to documented procedures.

Supporting information

- OPM Qualifications Standards
- FDA Benchmark Position Descriptions
- Draft - ORA-QMS.6, *Training and Competency Requirements*
- ORA Div. of Human Resource Development procedures and functional area training programs
- FMD 101, *ORA System and Criteria for Selection of Employees for Training* http://www.fda.gov/ora/inspect_ref/fmd/fmd101.htm

4.4 Ethics

To best serve customers, stakeholders, and employees, an organization's managers and staff need to be free of undue internal and external pressures that may adversely affect the quality of their work. Ethics standards promote and strengthen confidence in the integrity of the organization.

ORA managers and supervisors ensure federal, departmental, and FDA ethical standards are understood and followed by employees.

Supporting information

- "FDA Ethics Program" http://www.fda.gov/opacom/ethics
- FDA SMG 1318 series, "Conflict of Interest"
- Form HHS 520, *Request for Approval for Outside Activity*
- Form OGE 450, *Confidential Financial Disclosure Report*

4.5 Confidentiality

To serve their customers, an organization protects information from inappropriate release or misuse while maintaining appropriate transparency in their operations.

ORA managers and supervisors ensure information disclosure liabilities, responsibilities, and procedures are understood and followed by employees.

Supporting information

- FDA SMG 2280.10, *Protection of Non-Public Information (NPI)*;
- FDA SMG 2830.3, *Sharing Non-Public Information with Foreign Government Officials*
- FDA/OM Division of Freedom of Information's Intranet page

4.6 Facilities and work environment

An organization's facilities support the work processes needed in achieving the required work quality and cause no adverse effects. To achieve product quality—and to maintain employees' health and safety—an organization considers the human and physical factors of the work environment.

(a) ORA senior managers ensure facility and workspace needs are defined, provided, and maintained to ensure the work products conform to quality requirements.

(b) ORA managers ensure technical requirements for facilities are recorded and monitored.

(c) ORA managers ensure health, safety, and ambient working conditions of both FDA facilities and other work locations are considered for impact on employees and work quality.

Supporting information

- FDA Environmental Health and Safety System
- ORA/ORM/DMO ORA-wide procedures on safety and facilities
- ORA/ORO/DFS procedures for animal care
- *ORA Lab Manual*, Volume II, Section 2, ORA-LAB.5.3 *Facilities and Environmental Conditions*
- ORA Laboratory chemical hygiene and hazardous waste disposal plans
- FDA SMG 2130 series, "Safety and Occupational Health Programs"
- Individual ORA units' safety and health procedures

4.7 Equipment

Organizations maintain appropriate equipment inventories and controls for equipment used for testing or measuring.

(a) ORA managers ensure investigational and analytical units are equipped with sampling, measuring, and test equipment required for the correct performance of tests and/or calibrations.

(b) If an ORA unit uses equipment outside its permanent control, supervisors or staff ensure the equipment meets ORA's requirements (see *Control of Equipment*).

Supporting information

- FMD 81, *Field Laboratory Equipment Requests* http://www.fda.gov/ora/inspect_ref/fmd/fmd81.htm
- *ORA Laboratory Manual*
- FDA Equipment Inventory & Property Management procedures

4.8 Purchase of supplies and services

An organization's work products are dependent on the quality of the goods and services purchased by the organization to create the products. To meet work quality requirements, managers control purchases of equipment, materials, or services that impact the quality of work produced by the organization.

(a) For purchases that will affect the quality of ORA work, ORA managers ensure agency procurement processes are used to assure that purchased supplies and services conform to ORA requirements.

(b) ORA managers and supervisors ensure

(1) requisitions contain necessary specifications;

(2) within ORA control, vendors are selected for ability to satisfy requirements (selection includes using established evaluations criteria, and maintaining records of vendor evaluations and follow-up action); and

(3) received goods are examined to verify the specifications and the verification is recorded.

Supporting information

- FDA i-Procurement System

4.9 Support services

Organizations provide support services to assist employees in meeting quality requirements and increase work efficiencies. In ORA, many traditional support services are supplied by FDA Office of Management's "shared services" organization.

(a) ORA senior managers ensure employees have access to support, technology, and administrative services needed to follow work and QMS processes.

(b) ORA managers and supervisors ensure agency-provided support services receive accurate specifications of ORA needs as well as complete and timely feedback.

Supporting information

- FDA Employee Resource and Information Center
- FDA SMG series 3400 "Information Resources Management"
- FDA Information Technology procedures

5. Work Processes, Controls, and Execution

5.1 Planning work processes

An organization functions as a system of integrated processes, with a process defined as activities that transform inputs into desired outputs. The output of one process may be the input of another; changes in one process affect other processes and available resources. An organization controls existing processes and the design of new processes and products to ensure the customer's requirements are being met. In ORA, any single work product may be the result of a series of activities, e.g., a seizure enforcement action may result from an assignment, investigation, sample collection, sample analysis, and/or compliance evaluation. Alternatively, any single process may be involved in multiple work products, e.g., a sample analysis may result in recalls, warning letters, new compliance programs, denial of industry applications, etc.

(a) ORA senior managers ensure work processes are planned and developed consistent with the needs of the QMS and documented. Changes in plans are appropriately controlled.

(b) In planning, ORA managers ensure necessary process criteria have been determined. Criteria considered are the quality objectives for the product based on known requirements, directives, resources including facilities, process verification and validation activities, and product acceptance measures.

(c) ORA senior managers ensure the design and development of new work processes and products are planned and controlled in order to assess the impact on related work and the ability to meet customer requirements. ORA's role and authority with respect to the new process or product determines whether ORA has approval or review responsibilities.

Example: new legislation in the area of food transportation, or new regulations for dietary supplement GMPs, might result in new compliance programs that may affect existing work processes, products, and the ability to meet customer requirements. ORA's review of the center's compliance program is controlled to address unintended consequences or competing priorities.

Supporting information

- Draft – ORA-QMS.7, *Work Planning Requirements*
- ORA/ORM/DPEM procedures for work planning
- Supporting documentation is available in individual ORA units with processes clearance and approval authorities including ORA committees.
- *ORA Laboratory Manual* ORA-LAB.2.6: *Assuring the Quality of Test Results*
- Draft - ORA-QMS.8, *Design and Development Requirements*

5.2 Work plans and assignments

Once the work processes are planned, an organization controls work agreements with their customers to ensure they can meet the customer requirements. Agreements are formally reviewed and any concerns discussed with the customer. In ORA, work agreements are arrangements with other FDA components or internal unit decisions.

(a) ORA managers and supervisors accept work and assignments through a series of planning activities, including the following: headquarters unit managers and/or designated committee chairs

(1) collaborate with the FDA Centers and other components to develop work specifications, including through Compliance Programs and

Compliance Policy Guides;
(2) develop an annual Work Plan with the FDA centers and the field, and
(3) review certain work assignments from the centers and issue them to field units; and
(4) Field unit managers and supervisors accept plans and specific assignments from headquarters or the centers; and initiate plans and assignments as authorized.

(b) ORA unit managers and ORA committee chairs ensure procedures and communication channels for work planning and the review, issuance, and acceptance of certain assignments are established. The unit director or chair ensures procedures needed to communicate information between FDA components are used, and records kept, concerning
(1) assignment status and outcomes,
(2) changes/amendments made to plans or assignments,
(3) competing priorities between centers or between planned and unplanned work,
(4) complaints and actions relating to nonconformities, and
(5) feedback relating to ORA performance.

Supporting information
- Draft – ORA-QMS.7, *Work Planning Requirements*
- ORA/ORM/DPEM procedures for work planning
- FMD 17, ORA Field Assignments - *Guidelines for Issuance by Headquarters Offices* http://www.fda.gov/ora/inspect_ref/fmd/fmd17.htm
- Individual ORA unit procedures on assignment creation and review

5.3 Contracting work

If an organization contracts with another party to do work on the organization's behalf, the organization remains accountable for the quality of the work delivered to the customer. To meet work quality requirements, the organization controls contracts and evaluates the contractor's performance.

(a) ORA managers ensure agency contracting processes and ORA documented procedures are used as appropriate to assure that contractor-produced work conforms to ORA requirements for the work process and work product.

(b) Unless the contractor is mandated, ORA managers place contracts with a competent contractor in order to achieve equivalent level of quality control as if ORA performed the work. A competent contractor is one that, for example, complies with a comparable quality system for the work in question.

(c) ORA managers and supervisors ensure:
(1) contracts are reviewed and approved based on adequate specification of work and quality requirements,
(2) arrangements are planned for verification of work quality, and
(3) verification is implemented and records of the contractor's performance are maintained.

(d) When work is contracted rather than performed by ORA, ORA managers ensure the customer is advised in writing and, when appropriate, gain the

approval of the customer; ORA work reports clearly identify any contributions from contracts (see *Reporting).*

(e) ORA managers are accountable to their FDA customer for the contractor's work. The customer may share accountability if arrangement or oversight responsibilities are shared.

Supporting information
- Draft - ORA/ORO/DFSR Procedures for Contracts to States

5.4 Control of equipment and materials

An organization generally uses some equipment or materials in their work processes. If these items impact product quality, then they are controlled appropriately.

(a) ORA managers and supervisors ensure equipment and materials needed to meet work and method requirements are identified and selected.

(b) ORA supervisors ensure staff are provided with methods of handling, preservation, and storage to protect equipment and materials from damage or deterioration and to maintain their integrity.

(c) ORA supervisors ensure equipment and materials are uniquely identified as needed to meet traceability requirements.

(d) If equipment or materials are found to be improperly functioning, ORA supervisors ensure the validity of the work previously performed with the equipment or materials is assessed, and appropriate actions are taken if fitness for use is compromised.

(e) ORA supervisors ensure staff use procedures for control of equipment used for measurement, sampling and analysis, and for control of reference materials and standards.

Supporting information
- Draft – ORA-QMS.9, *Equipment and materials control requirements*

5.5 Operations

An organization plans and controls its work processes in order to add value, create effective products, and improve efficiencies. In actually doing *the work, the organization gathers data to evaluate how well work products meet customer requirements (i.e., are fit for their intended use) and to continually improve in meeting customer requirements.*

ORA managers, supervisors, and staff use defined procedures for performing work, for assuring work is reproducible, and for maintaining information integrity.

5.5.1 Work and method controls

An organization performs and controls the work processes according to plan.

(a) ORA managers and supervisors ensure work activities are performed according to established procedures and methods. These procedures and methods are readily available (see *Directive control*) and

(1) define work product requirements;
(2) specify procedural steps to a degree necessary for proper performance

by competent personnel;
(3) describe equipment used for processing, measuring, or monitoring; and
(4) instruct how product is delivered to the customer.

(b) ORA laboratory supervisors ensure staff use documented procedures to select analysis methods.

(c) ORA supervisors ensure defined procedures are used to perform quality control activities and to report non-conformances in accepted work processes.

Supporting information
- *FDA Compliance Program Guidance Manual*
- *FDA Investigations Operations Manual*
- *FDA Regulatory Procedures Manual*
- *FDA Compliance Policy Guides*
- *ORA Field Management Directives*
- *ORA Laboratory Manual*
- *ORA Laboratory Manual*, Volume II, Section 2, ORA-LAB.5.4.5.

5.5.2 Verification and validation of work processes

An organization may have multiple groups performing a process. The organization needs to know the group is capable of getting the desired result. Under some circumstances, if standard procedures cannot be followed, the organization must control the impact of the change on product quality. Verification under conditions of use is demonstrated by meeting criteria established for the process or work product, as well as a demonstration of accuracy and precision or other parameters for the type of work performed.

(a) ORA managers ensure their unit is capable of following a standard procedure to an acceptable level of performance. Approaches to verifying capability may vary by the type of work (e.g. laboratory activities versus inspection or compliance) but include quality controls.

(b) When a work process or product does not meet standard practice, or is significantly modified due to unusual circumstances, then ORA managers and supervisors ensure the impact of the non-conformity is evaluated in regards to meeting customer needs.

(c) In situations where the work product cannot be verified by monitoring and measurement, ORA managers ensure the work process is validated by a combination of training and process controls.

Supporting information
- *ORA Laboratory Manual*, Volume II, Section 2, ORA-LAB.5.4.5 *Methods, Method Verification and Validation*.

5.5.3 Integrity, traceability and identification

As an organization performs work, it tracks who does what, where, when, and how—or, as sometimes stated, manpower, methods, machinery, methods, and environment. As a regulatory agency, ORA has a particular interest in maintaining the integrity of ORA work information and products.

(a) ORA managers and supervisors ensure ORA and FDA procedures are used to maintain the integrity of
(1) information provided by regulated industry, consumers, and other FDA employees;
(2) physical or documentary samples collected for regulatory testing or examination; and

(3) ORA-created data and work products.

(b) As appropriate, ORA supervisors ensure work products and components are clearly identified and clearly note the interim and final status to prevent misuse.

(c) As appropriate for traceability, ORA supervisors ensure relevant information is recorded regarding the personnel, materials, equipment, chronology, methods and environment associated with a work activity.

(d) To the extent integrity is compromised or uncertain, ORA supervisors ensure relevant information is recorded and the customer is informed of the issues relating to fitness-for-use and regulatory compliance.

Supporting information

- *FDA Compliance Program Guidance Manual*
- *FDA Investigations Operations Manual*
- *FDA Regulatory Procedures Manual*
- *ORA Field Management Directives*
- *ORA Laboratory Manual*

5.6 Reporting results

An organization's work products may take the form of informational reports rather than physical "widgets.'. The organization may establish standardized formats, content guidelines, delivery methods, and storage conditions to effectively and efficiently meet the customer's requirements.

(a) ORA senior managers ensure requirements for reports are set so that
(1) work results may be reported accurately, clearly, unambiguously, and objectively, and in accordance with any specific directives;
(2) reports account for all information requested by the customer and necessary for the interpretation of results;
(3) approved non-conformance to procedures are identified in the report; and
(4) reports that express opinions and interpretations will also contain the basis upon which the opinions and interpretations have been made.

(b) As needed, designated headquarters managers control report formats to
(1) accommodate different types of results,
(2) minimize the possibility of misunderstanding or misuse,
(3) provide unique identification as needed for traceability, and
(4) ensure identification of responsible individual(s).

(c) ORA managers and supervisors ensure
(1) information needed for traceability or evaluation not included in a report is readily available in the performing unit (e.g., log books, notes, quality control records), and
(2) reports that are stored other than with the performing unit are readily retrievable (e.g., analytical worksheets held by the sampling district).

(d) To maintain the integrity and accountability for reports, ORA managers and supervisors ensure
(1) non-ORA information used in reports is clearly identified;
(2) this section's requirements are met when transmission of reports is

made by telephone, facsimile or other electronic or electromagnetic means; and

(3) material amendments to an issued report are made as an additional report, or data transfer:
   (i) amendments meet this section's requirements; and
   (ii) when it is necessary to issue a complete new report, the report is uniquely identified and contains a reference to the original that it replaces and includes the reasons for replacement.

Supporting information

- *FDA Compliance Program Guidance Manual*
- *FDA Investigations Operations Manual*
- *FDA Regulatory Procedures Manual*
- *ORA Field Management Directives*
- *ORA Laboratory Manual*

6. Quality Measurement, Acceptance, and Improvement

6.1 Measurement planning and implementation

An organization uses measurement and monitoring activities to ensure processes and products conform to requirements and the quality system conforms to plans.

Using appropriate methodologies or statistical techniques, ORA managers define, plan and implement procedures

- to measure, monitor and analyze work processes and products, and functioning of the QMS (e.g., to measure effectiveness in meeting customer requirements); and
- to identify system improvement opportunities (e.g., revising work product requirements to better reflect customer needs).

6.1.1 Customer satisfaction and complaints

To serve its customers and stakeholders, an organization monitors information and data on satisfaction and dissatisfaction regarding requirements being met.

(a) ORA managers ensure methods and metrics for obtaining customer feedback are defined and the nature and frequency of the information obtained are reviewed. ORA unit managers or committee chairs determine the data gathering activities with appropriate input from customers.

(b) ORA managers ensure complaints by customers or other parties external to ORA are resolved. ORA senior managers ensure ORA units establish and maintain documented handling and resolution procedures for complaints relating to the ORA products and services (as distinct from consumer and industry complaints about regulated products).

Supporting information

- Draft - ORA-QMS.3, *Customer Feedback*

6.1.2 Process/product measures and monitoring

An organization designs the controls it needs to observe the process and to examine the product—capturing nonconformance to the process procedures and product requirements. An organization's controls vary according to the work: tests such as size and amount, or reviews such as examination by a supervisor.

(a) Based on prior planning (see *Planning work processes*), ORA managers ensure suitable methods are applied to the monitoring and the measurement of

(1) work processes necessary to meet customer requirements and to demonstrate the process's continuing ability to satisfy its intended purpose; and
(2) work products to verify that requirements for the product are met.

(b) ORA senior managers ensure ORA units

(1) use uniform metrics when available,
(2) record evidence of conformance with required measurements and monitoring,
(3) record who is responsible for release of work product, and

(4) do not proceed with the work process or with the release of work products until all specified activities have been satisfactorily completed and the related decisions are authorized and recorded.

(c) When measuring and monitoring methods indicate that processes and product plans have not been achieved, ORA managers ensure non-conformities are controlled according to established procedures.

Supporting information
- Draft - ORA-QMS.10, *Work quality factors, use and analysis*

6.2 Nonconformity control

When an organization finds that work products do not conform to procedures or to customer requirements, then nonconforming work is identified so it cannot be inadvertently used. Nonconforming work is then reviewed and an appropriate disposition chosen.

(a) ORA senior managers ensure ORA units establish and maintain documented procedures to record nonconformities and control non-conforming work.

(b) ORA managers and supervisors ensure nonconforming work is controlled so

(1) if possible, remedial corrections are made and the work is reexamined for conformance; and
(2) when corrections cannot be made, a determination is made as to whether the work product still meets the customer needs (i.e., is fit for use):
    (i) if the work is fit for use, then the non-conformance is clearly identified for the next user/customer; or
    (ii) if the work is not fit for use, then work is stopped.

Supporting information
- Draft - ORA-QMS.11, *Nonconformity Reporting*

6.3 Data analysis

In addition to working with identified nonconformities, an organization proactively analyzes applicable data to determine the effectiveness of the QMS and to identify where improvements can be made. Trending data are collected from measuring and monitoring activities and other relevant sources.

(a) ORA managers and supervisors ensure data are analyzed to provide information on

(1) characteristics and trends of processes and products including compliance status of regulated firms, investigatory and laboratory data used for compliance decisions, and laboratory data regarding equipment, facilities, and proficiency testing;
(2) work product conformance to customer requirements;
(3) supplier/contractor performance; and
(4) customer satisfaction and dissatisfaction.

Supporting information
- Draft - ORA-QMS.10, *Work Quality Factors, Use, and Analysis*

6.4 Risk assessment

Risk assessment is a tool used by an organization to set priorities. Risks are viewed in context of their impact on customer satisfaction and the organization's mission and strategic objectives.

(a) When determining priorities for action in work or the QMS, ORA managers and supervisors ensure the risks associated with action or inaction are assessed (e.g., in determining the appropriate response to non-conformance with work product requirements); and in prioritizing QMS implementation (see *Priority work processes* in appendix), with input from appropriate parties, including customers and/or other stakeholders.

(b) To assess risk, ORA managers consider issue definition and context; risks and benefits; options for addressing the risks and rationale for choice of action; evaluation of the results after action is taken; and new information that may require additional risk assessment.

Supporting information

- Draft - ORA-QMS.10, *Work Quality Factors, Use, and Analysis*

6.5 Audits

An organization undergoes audits and/or assessments to determine if their quality system conforms to plan and is effectively implemented and maintained: audits measure *the quality system. Actions taken based on audit results can enhance strengths and reduce weaknesses in an organization.*

(a) In ORA, audits may be internal to a unit, ORA-wide, or solicited from or imposed by an external party. ORA senior managers ensure audits are planned and conducted according to documented procedures.

(b) ORA senior managers ensure

(1) designated ORA headquarters units establish and maintain documented procedures for facilitating audits from sources external to ORA;

(2) the ORA QMS program manager establishes and maintains a national audit program, procedures, and schedule for conducting audits of ORA units covered by the QMS; and

(3) ORA units establish and maintain documented procedures to conduct internal audits of their unit.

Supporting information

- Draft - ORA-QMS. 12, *Audit System*
- Draft - ORA-QMS.12.1, *Audits - Program for ORA*
- Draft - ORA-QMS.12.2, *Audits - Internal Audit Requirements*
- FDA SMG 2830.2, *Internal Guidance for Site Audits of Agency Components Relative to International Agreements or Other Circumstances*
- Draft - FMD *Foreign Assessment Audits of ORA Components*
- Draft - ORA/ORO/DFS Accreditation audit procedures

6.6 Corrective action

When quality-related problems and issues are identified, the organization resolves them and prevents them from recurring. Problems may be identified through data analysis, nonconformity reports, audit and proficiency reports, management review meetings, complaints, customer satisfaction queries, or internal feedback. Corrective action includes evaluation of the significance of the problem and the impact on operating costs, error costs, product fitness, and customer satisfaction.

(a) ORA senior managers ensure ORA units establish and maintain documented procedures to investigate the root causes of nonconformities and complaints, to implement effective corrective action to prevent recurrence, and to prepare summaries for management review.

(b) ORA managers ensure corrective action is taken in reaction to identification of a significant risk to quality from a nonconformance or departure from established procedure.

Supporting information

- Draft - ORA-QMS.13, *Corrective Action System*

6.7 Preventive action

Quality is most efficiently achieved by preventing problems from occurring rather than detecting problems. Prevention is based on quality and process planning, process control, training, and other aspects of the quality system. Results of data analysis, changes in organization, or changes in the operating environment may suggest potential problems. The need for preventive actions is based upon the significance and impact of the potential problem.

(a) ORA senior managers ensure ORA units establish and maintain documented procedures to identify the root causes of potential quality problems, to select the necessary deterrents so that the problem does not occur, and to prepare summaries for management review.

(b) ORA managers ensure preventive action procedures are used proactively when significant risk of possible problems is identified.

Supporting information

- Draft - ORA-QMS.14, *Preventive Action System*

6.8 Continual improvement

A quality system is an integral part of a dynamic, growing organization. ORA managers continually improve the quality system. Improvements may be reactive or proactive.

(a) The ORA QMS uses the tools outlined in this *Quality Manual*—the quality policy and objectives, process and product measurement, data analysis, feedback, audit results, corrective and preventive action, and management review—to facilitate continual improvement. Continual improvement encompasses both incremental improvements within the existing processes and major changes in process redesign.

(b) ORA senior managers ensure that the integrity of the QMS is maintained when changes are made to the work and quality systems.

A.1. FDA organizational chart

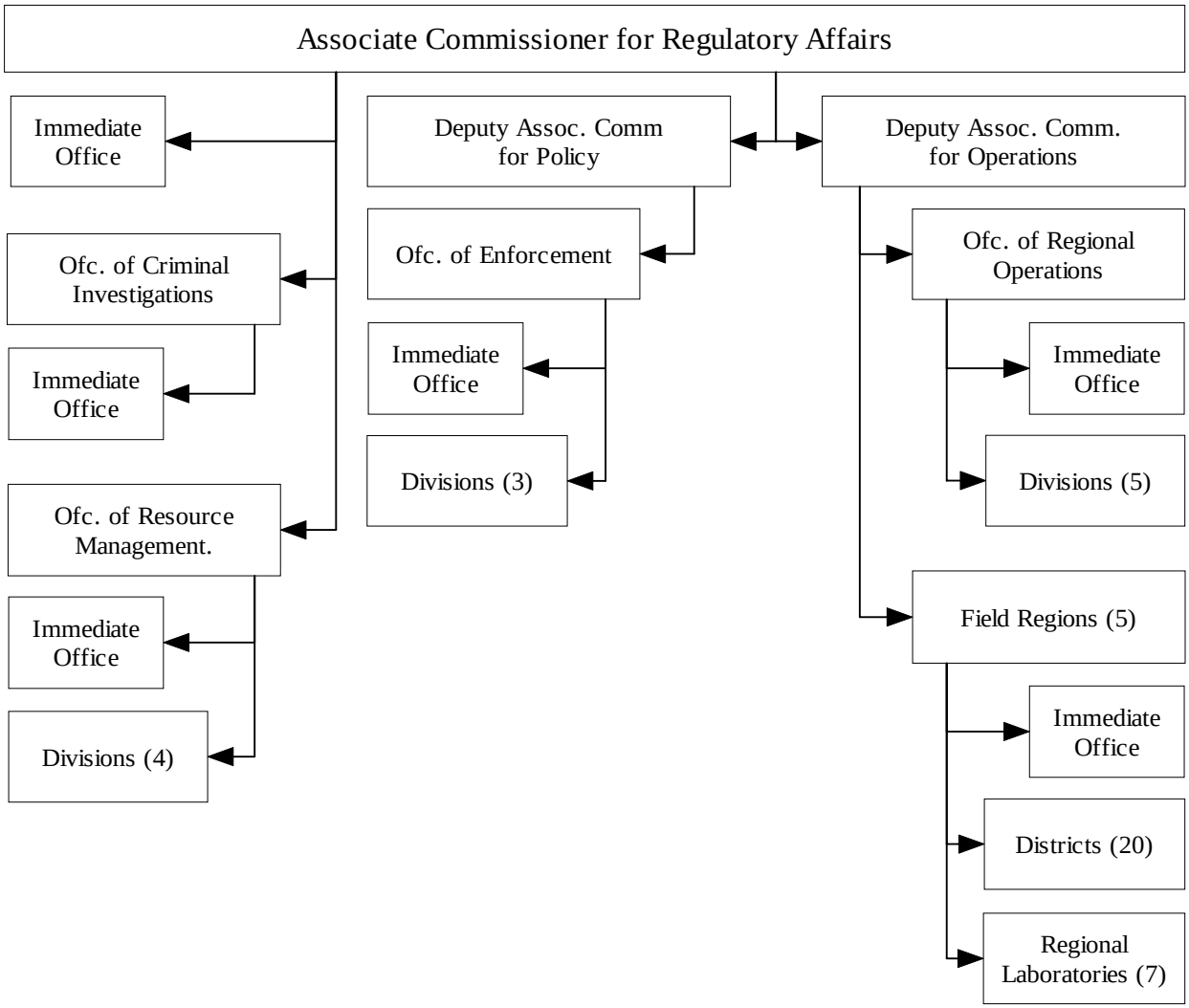
Publicly available FDA organizational charts are maintained by the FDA Office of Management on the Internet at http://www.fda.gov/oc/orgcharts/orgchart.html

A.2. ORA organizational charts

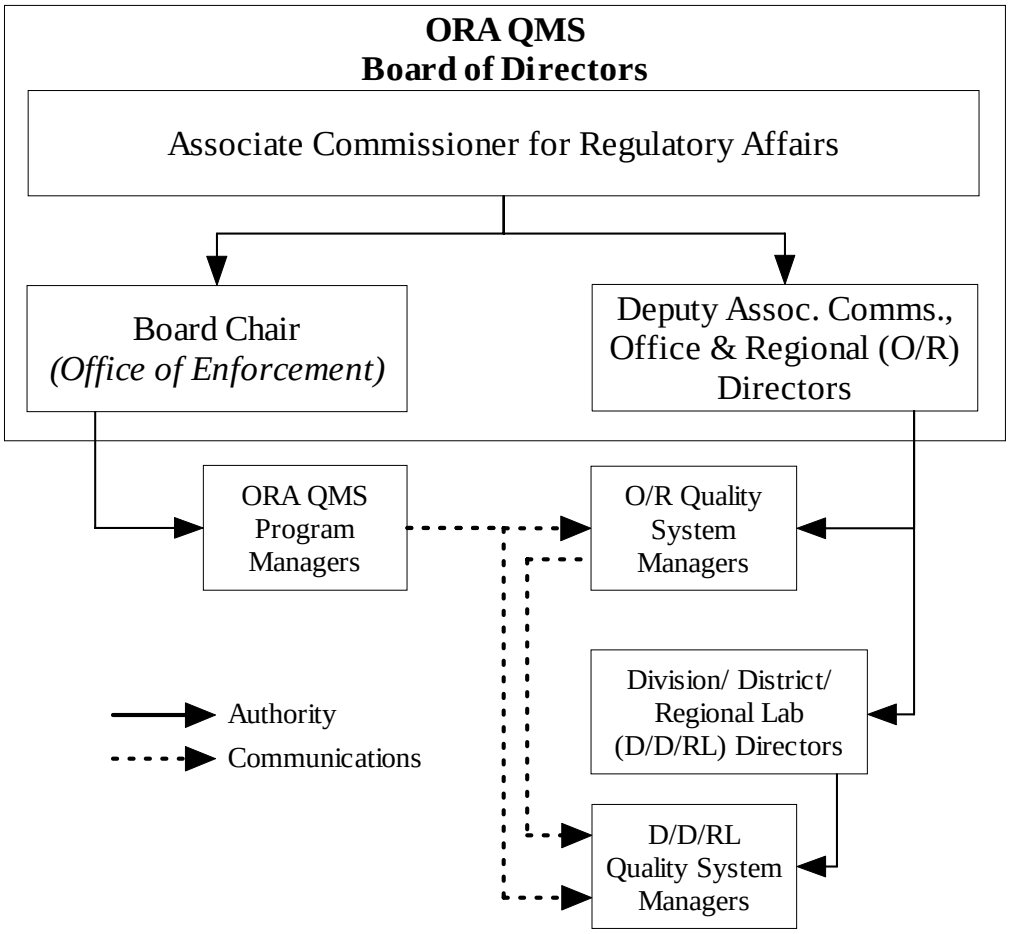
(a) Publicly available ORA organizational charts are maintained by the FDA Office of Management on the Internet at http://www.fda.gov/oc/orgcharts/orgchart.html. Internally available charts are maintained by the Associate Commissioner's staff on the Intranet.

(b) ORA units – Shows chain of command only. Individual regions, divisions, and districts are not listed.

Note: Two regional laboratories are titled as "centers" (engineering and forensics) and five as "regional laboratories"; six other laboratories are district laboratories).



(c) ORA QMS staff



B. Priority work processes

The ORA QMS Board of Directors identified the following work processes as initial priorities for QMS implementation and coverage. Implementation for each of these work processes will be prioritized according to the impact on ORA's mission. Implementation will include both field and headquarters activities in these processes, with input from center customers as well.

NOTE: This is not a complete list of all ORA work processes.

- Domestic Investigations
  - Inspections - consistent use of existing policies and procedures in conducting inspections; accessibility of directives
  - Sample collections - appropriate samples are collected and documented for laboratory analysis

- Imports
  - Field exams - consistent use of existing policies and procedures; appropriate samples are collected and documented for laboratory analysis
  - Filer Evaluations - consistent use of existing policies and procedures; processes withstand scrutiny due to high public visibility

- Laboratory
  - Sample analysis - consistent use of existing policies and procedures in maintaining sample integrity and chain of custody; all necessary scientific analytical requirements are met and recorded
  - Worksheets - analytical records support regulatory action
  - Methods development - appropriate selection, use, and documentation of non-compendium methods

- Compliance
  - Warning letters - consistent use of existing policies and procedures for content and issue; process withstands scrutiny due to high public visibility and frequency of use
  - Seizures - maintain institutional knowledge for effective use of existing policies and procedures (relative to decrease in frequency); consistent use of existing policies and procedures for submissions
  - Freedom of Information - withstand scrutiny due to high public visibility, possible liability, and frequency of use; understanding of overall process