ORA
Quality Manual

March 2012

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 9001" (www.iso.org).

Distribution: FDA employees and the public may access the current version of the *ORA Quality Manual* through the FDA Internet (www.fda.gov/ora). The public may also obtain the manual by making a written Freedom of Information request (www.fda.gov/foi/, see "Freedom of Information").

Comments: ORA welcomes comments as to how this publication may be improved. Please send your comments to the Office of Regulatory Affairs, ATTN: QMS, U.S. Food & Drug Administration, 12420 Parklawn Dr., Room 4100, Rockville, MD 20852.

THIS COPY OF THE *ORA QUALITY MANUAL*
[X] IS CONTROLLED TO BE CURRENT
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Document history

Version #	Status (I, R, C)	Date Approved	Location of Change History	Name, Title & Organization	
				Contact	Approving Official
1.0	initial	10/24/2006	n/a	David K. Elder, Chair, QMS Board of Directors; Director, Office of Enforcement	Margaret O'K. Glavin, Assoc. Commissioner for Regulatory Affairs
1.1	R	09/25/2008	In Document	ORA QMS Staff	Brenda Holman, QMS Executive Lead
1.2	R	12/04/2009	In Document	ORA QMS Staff	Brenda Holman, QMS Executive Lead
2.0	R	03/16/2012	In Document	ORA QMS Staff	RADM Brenda J. Holman, QMS Executive Lead

1. Introduction

1.1 Purpose of this manual

The Office of Regulatory Affairs (ORA), a component of the 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 (ACRA), 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 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.

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: [1, 2]

- to promote public health by promptly and efficiently reviewing clinical 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

[1] U.S. Government. Federal Food Drug and Cosmetic Act. "§903(b) Mission." *U.S. Food and Drug Administration.* 20 Jul. 2006;
[2] "What We Do." *U.S. Food and Drug Administration.* 10 Jan 2012

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[3]. To meet the ambitious goals and achieve a true and lasting paradigm shift in response to the global supply change shift, FDA has developed the Pathway to Global Product Safety and Quality (July 2011). The Pathway to Global Product Safety and Quality engages all stakeholders in a process that will unfold over several years. Success will require boldness, creativity, and patience. It will not be easy, but it is imperative. Global supply chains, international trade, foreign sourcing, and terrorism remind us daily that the rest of the world will not stop and wait for regulators to catch up. It is incumbent upon FDA to engage its international counterparts, industry, and stakeholders worldwide to blaze the Pathway to Global Product Safety and Quality. Additionally, FDA has developed Strategic Priorities which further outline the goals and priority areas that will guide our agency through the next five years and beyond [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.

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

[4] "FDA Strategic Priorities." http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm227527.htm

[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."

The FDA organization alignments reflect the agency's responsibilities, subject matter expertise and mandates in an ever more complex world, where products and services do not fit into a single category. The Agency's programs, in terms of a reporting chain to the Commissioner, are divided into "directorates" that reflect the core functions and responsibilities of the Agency. This management structure enables the Office of the Commissioner to better support the agency's core scientific and regulatory functions, and help tie together programs that share regulatory and scientific foundations.

The Office of the Commissioner is comprised of five Directorates[6,7]. The five Directorates are: 1) Office of Operations; 2) Office of Foods; 3) Office of Medical Products and Tobacco; 4) Office of Global Regulatory Operations and Policy; and 5) Office of the Chief Scientist. The five Directorates which are lead by Deputy Commissioners include:

1. Office of Operations - Provides executive direction, leadership, coordination, and guidance for the overall day-to-day administrative operations of the Agency assuring the timely and effective implementation and high quality delivery of services across the Agency and Centers.
    a. Office of Information Management - Develops the architecture, standards, policies, governance, best practices and technology road map that support the business priorities of the Agency including managing information technology infrastructure, telecommunications, security, strategic planning, capital planning & investment control, enterprise architecture, and applications development and management.
    b. Office of Management - Advises and assists the Commissioner, Deputy Commissioner, Associate Commissioners and other key Agency officials on various management and systems activities.
    c. Office of Equal Employment Opportunity - Advises and assists the Commissioner and other key officials on equal employment opportunity (EEO), diversity, and civil rights activities which impact on policy development and execution of program goals.
    d. Office of Finance, Budget and Acquisitions - Provides executive leadership and management for all FDA financial, budgetary, and acquisitions programs.

[6] "FDA Organization Chart, July 2011."
http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/StaffManualGuides/UCM271426.pdf

[7] "FDA's Staff Manual Guide 1110.1 Overview of the Office of the Commissioner Structure" Jan. 2012
http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/ucm136374.htm

2. Office of Foods - Provides executive leadership and management to all FDA food-related programs. Exercises, on behalf of the Commissioner, direct line authority over the Center for Food Safety and Applied Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM).
    a. Center for Food Safety and Applied Nutrition - human foods (both imported and domestic) and cosmetics;
    b. Center for Veterinary Medicine - food additives, drugs, feeds, and devices used for food animals and pet or companion animals.
3. Office of Medical Products and Tobacco - Provides executive leadership, management and policy direction to all FDA medical-product- and tobacco-related programs. Exercises, on behalf of the Commissioner, direct line authority over the Center for Biologics Evaluation and Research(CBER), the Center for Devices and Radiological Health (CDRH), the Drug Evaluation and Research (CDER), and the Center for Tobacco Products (CTP)
    a. Center for Biologics Evaluation and Research - blood and blood products, vaccines, allergenics, and biological therapeutics;
    b. Center for Devices and Radiological Health - medical devices and radiation-emitting products;
    c. Center for Drug Evaluation and Research - human drug products; and
    d. Center for Tobacco Products - sets performance standard, reviewing premarket applications for new and modified risk tobacco products, requires new warning labels, and establishes and enforces advertising and promotion restrictions.
4. Office of Global Regulatory Operations and Policy - Provides executive oversight, strategic leadership, and policy direction to FDA's domestic and international product quality and safety efforts, including global collaboration, global data-sharing, development and harmonization of standards, field operations, compliance, and enforcement activities.
    a. Office of International Programs - Leads the formation of global alliances and global information sharing among regulators, in order to improve product quality and safety. Serves as the Agency leader and focal point for all international matters
    b. Office of Regulatory Affairs - Advises and assists the Commissioner and other key officials on regulations and compliance-oriented matters that have an impact on policy development and execution and long-range program goal. Coordinates, interprets, and evaluates the Agency's overall compliance efforts; as necessary, establishes compliance policy or recommends policy to the Commissioner

i. Office of Resource Management
ii. Office of Enforcement
iii. Office of Criminal Investigations
iv. Office of Regional Operations

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 Deputy Commissioner for Global Regulatory Operations and Policy. (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.

5. Office of the Chief Scientist – Provides executive oversight to 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.

In addition, the Office of the Commissioner is comprised of:

- Office of Chief Counsel
  Chief Counselor is subject to the professional supervision and control of the General Counsel, Department of Health and Human Services (HHS), and represents FDA in court proceedings and administrative hearings with respect to programs administered by FDA.
- Office of the Executive Secretariat
  Executive Secretariat supports the Commissioner and Principal Deputy Commissioner in the areas of program coordination, correspondence, freedom of information requests, speeches and invitations, agency information dissemination, and reports to Congress.
- Office of the Counselor to the Commissioner
  Office of the Counselor to the Commissioner formulates and renders advice to the Commissioner related to policy development, interpretation and integration that cuts across program lines or which is not well defined. The office provides a leadership role in advocating for and advancing the Commissioner's priorities. Additionally, the office oversees the Office of Crisis Management (OCM) which serves as the FDA's focal point for coordinating emergency and crisis response activities involving FDA regulated products or in situations when FDA regulated products need to be utilized or deployed
- Office of Policy and Planning
  Office of Policy and Planning provides advice to the Commissioner and other key FDA officials on matters relating to strategic direction, policy, development of regulations and guidance, legislative issues, planning and evaluation activities, and counter-terrorism and emerging threats.

- Office of Legislation
  The Office of Legislation directs and manages the Agency's legislative needs and Congressional relations consistent with the mission of the Agency.
- Office of External Affairs
  Office of External Affairs advises the Commissioner, Deputy Commissioners and other key agency officials on FDA's communications to the media, Congress, and the general public on issues that affect agency-wide programs, projects, strategies, partnerships and initiatives. Additionally, the office oversees the Office of Public Affairs, Office of External Relations, and the Office of Special Health Issues.
- Office of Women's Health serves as the principal advisor to the Commissioner and other key Agency officials on scientific, ethical, and policy issues relating to women's health. The office provides leadership and policy direction for the Agency regarding issues of women's health and coordinates efforts to establish and advance a women's health agenda for the Agency.
- Office of Minority Health provides leadership and policy direction for FDA regarding issues of minority health. The office coordinates FDA scientific, policy, and outreach activities to promote minority health.

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;
- monitoring the impact of our activities and work products on the available post-market data of the products we regulate;
- 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 Silver Spring, 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 staff 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[8].

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

Assessment – A process of collecting and analyzing data to determine the current, historical or projected status of an organization. Assessments are performed when there is a major change to a process to assure that the specific change or new requirement has been successfully implemented.

Audits – A systematic, independent and documented process for obtaining evidence and evaluating it objectively to determine the extent to which established criteria are fulfilled.

Component – A constituent part. ORA uses this term interchangeably with the term unit when describing the various offices, districts, etc. within the organization.

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.

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[9].

  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.

Directives – Directions to be followed during standard operations; as per FDA SMG 3280.1, a written communication issued in an organized system to establish policy, organization, procedures, or responsibilities; to require action; or to set forth information needed for the effective operation of a system or program. A directive may be a policy memo, procedure, instruction or form. A directive may also be a guidance documents.

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[8] "FDA Quality System Framework for Internal Activities." *U.S. Food and Drug Administration.* 20 Jul. 2006, specifically Section 6 and Attachment A

[9] "Defining the Customer in a Regulatory Agency." *U.S. Food and Drug Administration.* 20 Jul. 2006

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 positions in ORA responsible for strategic direction: Associate Commissioner and Deputies, Office Directors, Regional Food and Drug Directors, District Directors, and Regional Laboratory Directors.
- 'QUALITY SYSTEM MANAGER' – trained staff member assigned responsibilities for implementing and maintaining a unit's quality system.

Quality Management Information System (QMiS) – A web-based software application that manages QMS documents and processes.

Supporting information – Within the *Quality Manual*, ORA uses this term to designate other procedures used to implement the policy being discussed.

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).

Work – ORA defines this term to encompass the processes, 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
- ISO – International Organization for Standardization
- 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[10]. 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.

[10] 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) ANSI/ISO/ASQ (E) Q9001-2008: 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 Q9004-2009 -Managing for the sustained success of an organization-A quality management approach;
(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 QE19011S-2008: Guidelines for management systems auditing-U.S. Version with supplemental guidance added; and
(6) ANSI/ISO/ASQ E14001-2004: Environmental management systems - Requirements with guidance for use.

Supporting information

- FDA Staff Manual Guides
- "Legislation"
- FDA SMG 2020, *FDA Quality System Framework for Internal Activities*

2.3 Documentation

Organizations use documents 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 • Manuals, guidance, and policies.
3. Local procedures	Local procedures 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 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 document is the "ORA Quality Manual."

(a) 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 document approved by the Associate Commissioner for Regulatory Affairs (ACRA), or designee, and maintained by ORA QMS.

2.3.2
Document control

Work quality depends on access to accurate and timely direction, requiring organizational control of documents, 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 documents, and externally supplied documents[11] 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
- ORA-QMS.001, *Document Control and Management*

[11] 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 defining controls needed for the identification, storage, protection, ability to retrieve, retention and disposition 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, and position descriptions (see *Competency*); and
(4) QMS records such as reports regarding nonconformities, audits, corrective and preventive actions, and management review (see *Measurement*).

(c) As established in the relevant work-related or QMS procedures, ORA managers ensure records contain 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

- ORA-QMS.002, *Control of Records*
- 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 is to demonstrate their support. Management's leadership and participation is necessary for a quality system to be effectively implemented and maintained.

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

establishing and documenting the ORA quality policy, strategic plans, work objectives, and quality objectives; participating in QMS management reviews and follow-up actions; and 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 assuring communication, understanding, and implementation throughout ORA units.

Supporting information

- ORA-QMS-POL.001 ORA Mission, Vision and Quality Policy
- ORA-QMS-POL.002 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 is 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 customer 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 determined and 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 align 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

- "Defining the Customer in a Regulatory Agency"

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 Associate Commissioner for Regulatory Affairs (ACRA) and ORA senior management 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 document approved by the Associate Commissioner for Regulatory Affairs or designee.

(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-QMS-POL.001, ORA Mission, Vision and 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;
(5) continual improvement in fulfilling customer needs as reflected in the work requirements for work products, and,
(6) the integrity of the QMS is maintained when changes are planned and implemented.

Supporting information

- FDA Strategic Priorities

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 Staff Manual Guide (SMGs), Volume I "Organizations and Functions."
(2) Responsibilities and duties 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) Units maintain lists of approved signatories as defined in procedures.
(6) Actors for key management positions are assigned when needed to keep decision-making authorities clear. Acting assignments are communicated to necessary employees.

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

(1) ORA senior managers 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 systems are designed, capable, and implemented in accordance with the principles of the quality system.

(i) The Associate Commissioner for Regulatory Affairs (ACRA) is ORA's top management official.

(ii) The Executive QMS manager in the ACRA's Office is the most responsible official for QMS, reporting directly to the ACRA.

(iii) The senior managers are 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 system 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) Managers, including committee chairs, ensure procedures are established and used to monitor adherence to work and quality system documents.

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

(3) ORA supervisors ensure planned work is accomplished and the quality system is used—they do their work generally within the established systems. They are accountable for ensuring staff is 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 nonconformances 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 assists managers in establishing and maintaining the quality system. Quality system managers are vital members of management. (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

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 managers and staff in quality improvement and attainment of the quality objectives, an organization needs effective communication.

(a) ORA managers ensure procedures and processes 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 documents;
(4) periodic senior management meetings, 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

- FMD 56, *Weekly Management Review*
- ORA-QMS.001, *Document Control and Management*

3.7 Management review

A feedback loop provides stability to a system 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 ORA QMS is reviewed according to documented procedures to ensure continuing suitability, adequacy and effectiveness of the QMS. Unit management representatives ensure reviews are performed.

(b) At a minimum, the QMS management review includes:

(1) policies and procedures;
(2) managerial reports;
(3) review of audits;
(4) review of effectiveness of preventive actions;
(5) status of corrective and preventive actions;
(6) outside assessments;
(7) program results;
(8) complaints and other feedback;
(9) change that could affect the QMS; and,
(10) recommendations for improvement.

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

Supporting information
- ORA-QMS.003, *Management Review*

3.8 Assessment and Audits

Assessment is a check to assure that a specific change or new requirement has been successfully implemented.

(a) At planned intervals, a Quality Management System Assessment is conducted. This assessment is a comprehensive review and evaluation of materials, tools, processes, and strategy of ORA's quality system to determine adequacy and compliance with the Quality Management System established. A properly performed assessment of the Quality Management System identifies weaknesses of quality-related practices. These assessments demonstrate Quality Management system compliance with applicable standards and regulatory requirements, suitability of the Quality Management System for further development and improvement, and recommended corrective/preventive actions with related performance objectives and deadlines.

(b) The ORA-QMS.037 Checklist is used to document this assessment. It is designed to allow for an assessment of an organization or unit to determine how closely existing management practices and procedures correspond to the requirements.

(c) An assessment report is generated based on the results of the checklist.

Supporting information
- ORA Quality Management System Assessment Checklist

4. Resource Management

4.1 Resource provision

Organization managers are responsible for providing and prioritizing resources to accomplish work and quality system activities.

(a) ORA receives resources from FDA through the 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) enhance customer satisfaction by meeting customer requirements,
(2) maintain QMS and continually improve its effectiveness,
(3) monitor the systems through assessments and audits,
(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 managed by supervisors, or senior investigators and analysts, familiar with work and quality procedures and purpose of activity.

(c) ORA managers ensure that employees may initiate action to prevent the occurrence of work nonconformances 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 have an Individual Development Plan (IDP) that outlines their developmental needs and objectives;
(3) employees' specific position descriptions are maintained and available; and,
(4) evaluate effectiveness and maintain records.

(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
- ORA Div. of Human Resource Development training programs
- FMD 101, *ORA System and Criteria for Selection of Employees for Training*

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"
- 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 communicated to 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 Freedom of Information Act"

4.6 Facilities and work environment

An organization's facilities support the work processes needed in achieving the conformity to product requirements 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 Lab Manual*, Volume II, Section 2, ORA-LAB.5.3 *Facilities and Environmental Conditions*
- ORA Laboratory chemical hygiene and hazardous waste 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 ensures the equipment meets ORA's requirements (see *Control of Equipment*).

Supporting information
- FMD 81, *Field Laboratory Equipment Requests*
- ORA Laboratory Manual
- FDA Equipment Inventory & Property Management

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 requirements (including statutory and regulatory) and additional requirements considered necessary by FDA;

(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, FDA Office of Management's "shared services" organization supplies many traditional support services.

(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 Work Planning

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 letter, new compliance programs, denial of entry applications, etc.

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

(b) 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 processes or products 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

- ORA/ORM/DPEM work plan guidance.
- ORA Laboratory Manual ORA-LAB.5.9: *Assuring the Quality of Test Results*

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) After a series of planning activities occur, ORA managers and supervisors accept work and assignments.

(b) The activities include headquarters unit managers and/or designated committee chairs:

(1) collaboration with the FDA Centers and other components to develop work specifications, including through Compliance Programs and Compliance Policy Guides;
(2) development of an annual Work Plan with the FDA centers and the field, and,
(3) review of certain work assignments from the Centers and issue them

to field units.

(b) Field unit managers and supervisors accept plans and specific assignments from headquarters or the centers; and initiate plans and assignments as authorized; and Field unit managers and supervisors assign work that may arise from complaints, recalls, etc., as necessary.

(c) ORA headquarters unit managers and ORA committee chairs ensure that guidance procedures and communication channels for work planning and the review, issuance, and acceptance of certain assignments are followed. The unit director or chair ensures guidance 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 nonconformances, and,
(5) feedback relating to ORA performance.

Supporting information

- ORA/ORM/DPEM work plan guidance
- FMD 17, ORA Field Assignments - *Guidelines for Issuance by Headquarters Offices*

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 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 and notified. i.e., in writing, verbally, electronically, 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
- ORA/ORO/DFSR State Contracts

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 managers and supervisors ensure staff is provided with methods of handling, preservation, and storage to protect equipment and materials from damage or deterioration and to maintain their integrity.

(c) ORA managers and 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 assess the validity of the work previously performed, and appropriate actions are taken if fitness for use is compromised.

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

Supporting information
- Individual unit procedures on equipment and materials
- ORA Laboratory Manual ORA-LAB.5.5, Equipment

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 *Document 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 managers and laboratory supervisors ensure staff uses documented procedures to select analytical 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

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 the use of 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, materials, 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 established procedures are used to maintain the integrity of:

(1) information provided to 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 managers and 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 managers and 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 managers and 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 established 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 of 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);
- to identify system improvement opportunities (e.g., revising work product requirements to better reflect customer needs); and,
- to utilize the Quality Management Information System (QMiS) to analyze, track, and trend complaints and feedback, corrective actions, and to identify system problems.

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 established procedures for obtaining customer feedback and related metrics 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

- ORA-QMS.009, *Complaints and Other 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 managers:

(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 documented and controlled according to established procedures.

Supporting information
- *Quality factors*
- *ORA-LAB.5.9, Assuring the Quality of Test Results*

6.2 Nonconformance 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 managers ensure established procedure is followed and documentation maintained on nonconformances and control non-conforming work.

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

(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
- ORA-QMS.005, *Control of Non-conforming Processes, Products, or Services*

6.3 Data analysis

In addition to working with identified nonconformances, 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.

(b) ORA is in the early stages of implementing the Quality Management Information System (QMiS) which will be utilized to analyze, track, and trend complaints and feedback, corrective actions, and to identify system problems.

Supporting information
- *Quality Factors*
- *ORA-QMS.007, Corrective Action Procedures*

6.4 Risk management

Risk management provides a range of qualitative and quantitative approaches for an organization to make decisions and set priorities. Through the use of risk-based information, an organization can optimize its performance and resource allocation. Risks are viewed and assessed in the context of their impact on the organization's mission and strategic objectives.

(a) When evaluating options for action in work or the QMS, ORA managers and supervisors ensure that the associated risks are considered (e.g., determining the appropriate response to non-conformance with work product requirements). Furthermore, the prioritization of QMS implementation (see *Priority work processes* in appendix) considers risk-based inputs from appropriate parties, including customers and/or other stakeholders

(b) To use risk-based information in its programs, ORA considers problem context and definition, costs and benefits, options for action, and ex post evaluation of outcomes. This is supplemented by seeking new data, models, and tools that may improve risk management.

Supporting information
- *Quality Factors*

6.5 Audits and assessments

An organization undergoes audits and/or assessments to determine if their quality system conforms to planned requirements and is effectively implemented and maintained: audits measure the robustness or conformity of 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 the process for facilitating audits from sources external to ORA;

(2) that a national audit program for conducting audits of ORA units covered by the ORA QMS is conducted; and,

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

Supporting information

- ORA-QMS.004, *Audits*
- FDA SMG 2830.2, *Internal Guidance for Site Audits of Agency Components Relative to International Agreements or Other Circumstances*

6.6 Corrective actions

When quality-related problems and issues are identified, the organization resolves them and prevents them from recurring. Problems may be identified through data analysis, nonconformance 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 managers ensure ORA units follow established procedures to investigate nonconformances and complaints, to implement effective corrective actions 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

- ORA-QMS.007, *Corrective Action Procedure*

6.7 Preventive actions

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 follow established procedures to identify potential quality problems, to select the necessary actions 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
- ORA-QMS.008, *Preventive Action Procedure*

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.

Supporting information
- ORA-QMS.006, *Continual Improvement Procedure*

7. Change History

Version 1.1

Foreword – Distribution section revised; Comments section revised; deleted Initial Release Note
Table of Contents – 2.3.2 changed to Document Control; Appendix B changed to Work Processes and Products; Added 7. Change History
Footer – website changed to *www.fda.gov/ora/*

Section 1.3 (a) – added seventh bullet
Section 1.4. (b) – added term “component”
Section 1.4 (b) (3) – revised definition of Document/Directives
Section 1.4 (b) (4) – deleted third, fourth, and sixth bullet
Section 1.4 (b) (5) – changed directives to documents and deleted last sentence

Section 2.2 Supporting information – deleted FDA Intranet from first bullet and deleted last bullet

Section 2.3 (a) – revised 2. and 3.
Section 2.3. (b) – deleted directives
Section 2.3.1 (a) – revised and (b) revised and changed directive to document
Section 2.3.2 – changed to Document Control and changed Supporting Information
Section 2.3.3 Supporting information – revised first bullet

Section 3.3. (a) & (b) – revised

Section 3.4. Supporting information – revised to FDA Strategic Plan

Section 3.5 (b) (1) and (i) and (ii) – revised
Section 3.5 (b) (2) (ii) – changed directives to documents
Section 3.5 (b) (4) (iv) – revised
Section 3.5 Supporting information – deleted last two bullets

Section 3.6 (b) (3) – changed directives to documents
Section 3.6 Supporting Information – deleted first bullet and revised third bullet

Section 3.7 - (a) revised and (b) added (4) and revised (2)
Section 3.7 Supporting information – changed first bullet; deleted second bullet

Section 4.3 Supporting information – deleted third bullet

Section 4.6 Supporting information – deleted second and third bullet; revised fifth bullet

Section 5.1 Supporting information – deleted first, third, and fifth bullet
Section 5.2. (a) - added (5)
Section 5.2 Supporting information – deleted first and last bullet; revised second bullet

Section 5.3 and 5.4 Supporting information – revised

Section 5.5.1 (a) – changed Directive control to Document control

Section 6.1.1., 6.1.2, 6.2, 6.3, 6.4, 6.5, 6.6, 6.7, and 6.8 Supporting Information – revised
Section 6.5 (b) (1) & (2) – revised

Appendices: A.2 (c) – deleted; B. re-titled and revised

Version 1.2

Footnotes: 1, 4, and 6 – date and/or websites updated
Supporting Information: 2.2, 3.2, 3.6. 4.3, 4.4, 4.7, 5.2 - websites
Section 3.8 - added

Appendix C & Index of Terms (ISO 9001:2005) - added

Version 1.3

Headers- Fixed to reflect correct page numbers, sections and document control number.

Foreword- Change of address for written comments regarding ORA Quality Manual

Section 1.2(b) – Additional components within the Office of the Commissioner included (Office of the Counselor to the Commissioner, Office of the Chief of Staff, Office of Special Medical Programs, Office of Foods, Office of the Chief Scientist, Office of Administration, Office of Women's Health, and Office of Equal Employment Opportunity and Diversity Management)

Section 1.2(b) - Center for Tobacco (CTP) added

Section 1.4 – Definitions for "Documents" and "Directives" removed

Attachment A.2 – Updated ORA organizational charts

Note: Minor grammatical and typographical corrections were made within the document

Version 2.0

Headers- Fixed to reflect correct page numbers, sections and document control number.

Foreword- Update reference for ISO 9000 to ISO 9001

Section 1.2(b) – Addition of the five directorates: Office of Operations, Office of Foods, Office of Medical Products and Tobacco, Office of Global Regulatory Operations and

Policy, and Office of the Chief Scientist.

Section 1.4b – Definition for "Senior Manager" updated to remove reference to SES and add DD, Regional Lab Directors. Definitions for "Assessment", "Audits", "Directives" and "QMiS" added.

Section 1.4c – Abbreviation for ISO added.

Section 3.8 – Section title changed to "Assessment and Audits"

Section 4.3 – Bullet item added: "(4) evaluate effectiveness and maintain records."

Section 6.1 – Add bullet to describe QMiS implementation.

Section 6.3 – Add bullet to describe QMiS as part of data analysis.

Section 6.5 – Change title to "Audits and Assessments"

Section 6.6 – Change title to "Corrective Actions"

Section 6.7 – Change title to "Preventive Actions"

Attachment A.2 – Updated ORA organizational charts

Attachment D – Added a definition of complaint.

Note: Minor grammatical and typographical corrections were made within the document

A.1. FDA organizational chart

Publicly available FDA organizational charts are maintained by the FDA Office of Management.

A.2. ORA organizational charts

(a) Publicly available ORA organizational charts are maintained by the FDA Office of Management on the Internet.
(b) Internally available charts are maintained by the Associate Commissioner's staff on the Intranet.

B. Work processes and products

A list of examples of work processes and products are provided.

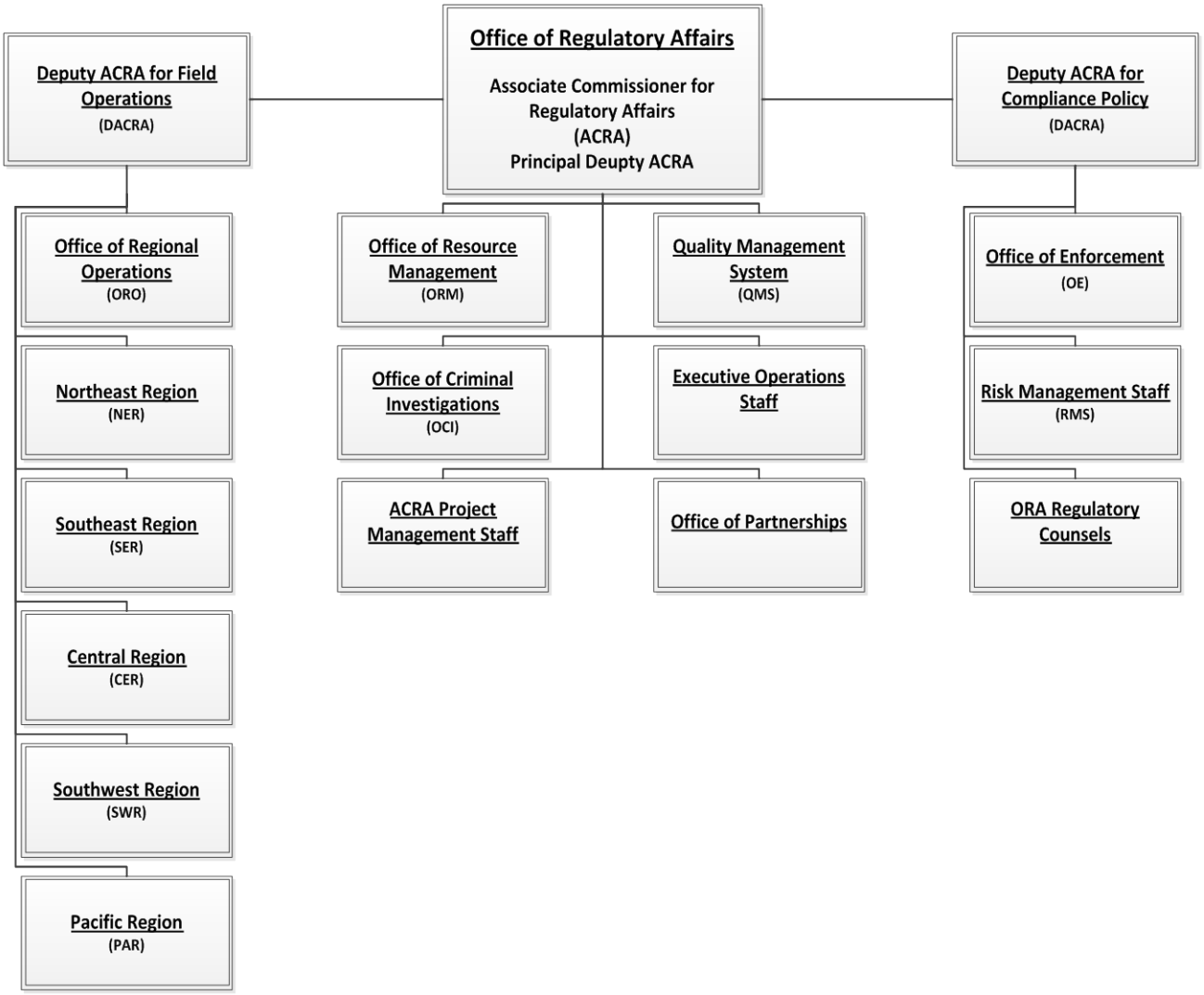
C.1. Cross-reference list ORA QMS, SMG 2020 and ISO 9001:2008

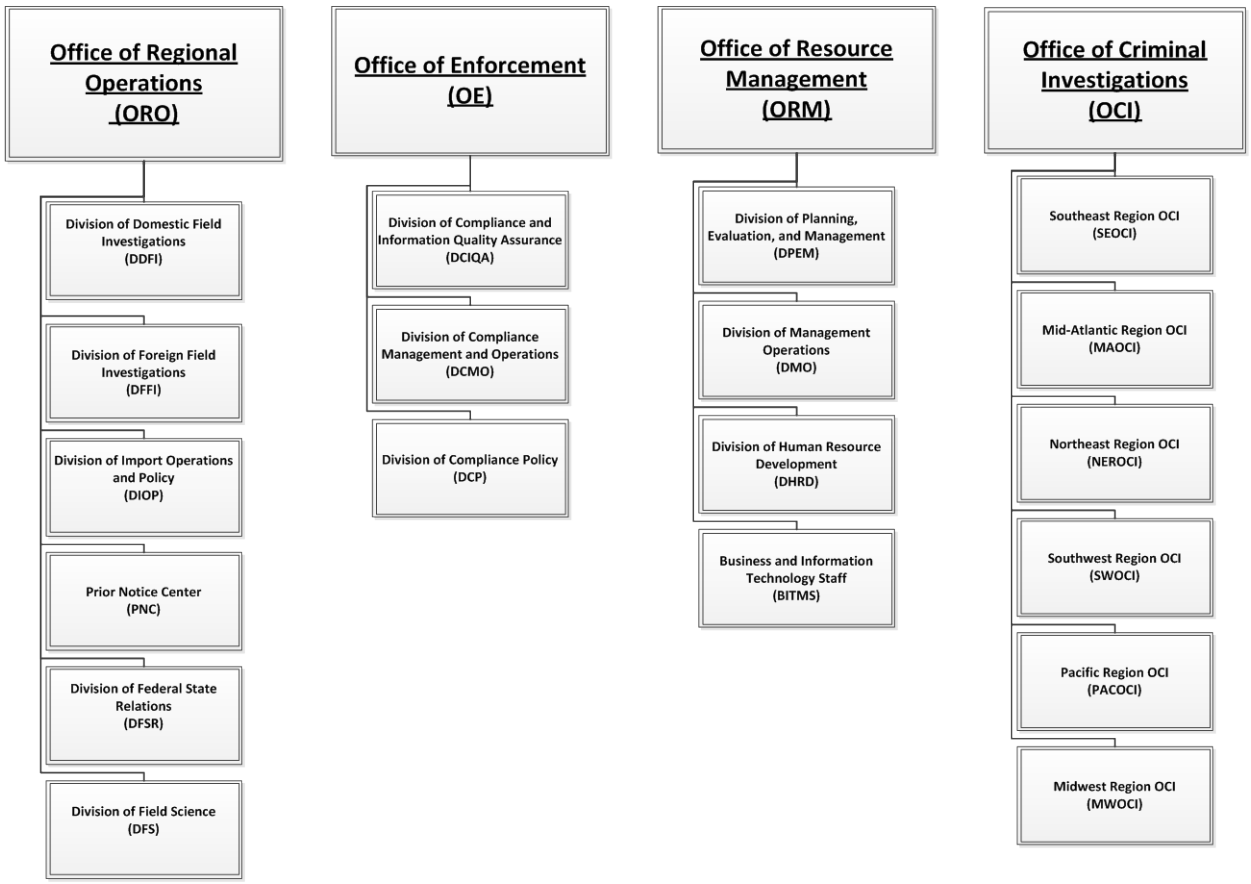
Cross-reference between elements of the ORA Quality Manual and, where relevant, SMG 2020 and ISO/IEC 9001:2008.

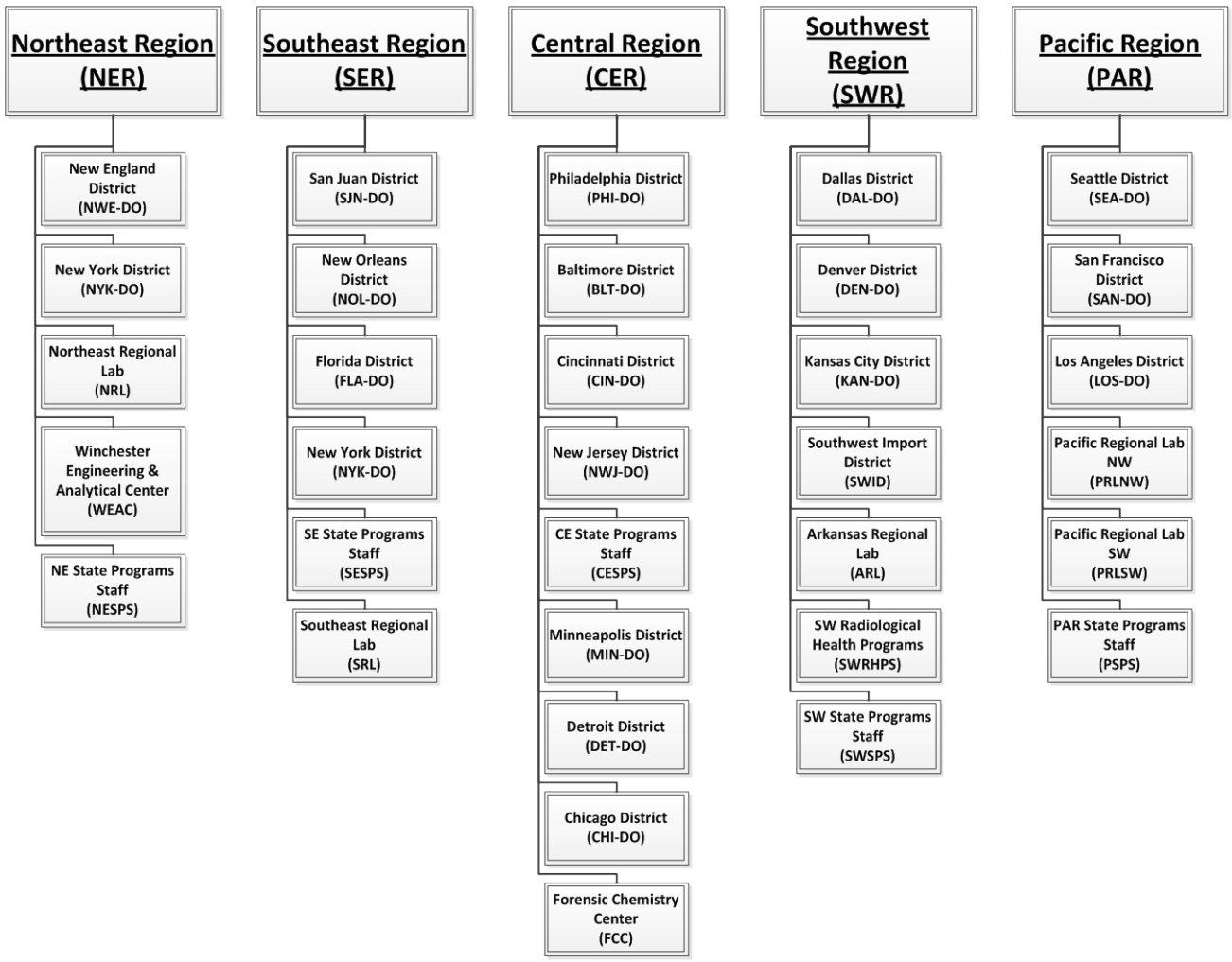
D. 8

Cross-reference between elements of the ORA Quality Manual and, where relevant, SMG 2020 and ISO/IEC 9001:2008.

A. ORA Organizational Charts




Office of Regional Operations (ORO)
Division of Domestic Field Investigations (DDFI)
Division of Foreign Field Investigations (DFFI)
Division of Import Operations and Policy (DIOP)
Prior Notice Center (PNC)
Division of Federal State Relations (DFSR)
Division of Field Science (DFS)
Office of Enforcement (OE)
Division of Compliance and Information Quality Assurance (DCIQA)
Division of Compliance Management and Operations (DCMO)
Division of Compliance Policy (DCP)
Office of Resource Management (ORM)
Division of Planning, Evaluation, and Management (DPEM)
Division of Management Operations (DMO)
Division of Human Resource Development (DHRD)
Business and Information Technology Staff (BITMS)
Office of Criminal Investigations (OCI)
Southeast Region OCI (SEOCI)
Mid-Atlantic Region OCI (MAOCI)
Northeast Region OCI (NEROCI)
Southwest Region OCI (SWOCI)
Pacific Region OCI (PACOCI)
Midwest Region OCI (MWOCI)


Northeast Region (NER)
New England District (NWE-DO)
New York District (NYK-DO)
Northeast Regional Lab (NRL)
Winchester Engineering & Analytical Center (WEAC)
NE State Programs Staff (NESPS)
Southeast Region (SER)
San Juan District (SJN-DO)
New Orleans District (NOL-DO)
Florida District (FLA-DO)
New York District (NYK-DO)
SE State Programs Staff (SESPS)
Southeast Regional Lab (SRL)
Central Region (CER)
Philadelphia District (PHI-DO)
Baltimore District (BLT-DO)
Cincinnati District (CIN-DO)
New Jersey District (NWJ-DO)
CE State Programs Staff (CESPS)
Minneapolis District (MIN-DO)
Detroit District (DET-DO)
Chicago District (CHI-DO)
Forensic Chemistry Center (FCC)
Southwest Region (SWR)
Dallas District (DAL-DO)
Denver District (DEN-DO)
Kansas City District (KAN-DO)
Southwest Import District (SWID)
Arkansas Regional Lab (ARL)
SW Radiological Health Programs (SWRHPS)
SW State Programs Staff (SWSPS)
Pacific Region (PAR)
Seattle District (SEA-DO)
San Francisco District (SAN-DO)
Los Angeles District (LOS-DO)
Pacific Regional Lab NW (PRLNW)
Pacific Regional Lab SW (PRLSW)
PAR State Programs Staff (PSPS)

B. Work processes and products

The following work processes and products are examples for QMS implementation and coverage. Implementation will include both field and headquarters activities in work processes and products, with input from center customers as well.

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

- Domestic Investigations
  - Inspections - consistent use of existing policies and procedures in conducting inspections
  - Establishment Inspection Report – inspection reports support regulatory action
  - 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

C. Cross-References to SMG 2020 and ISO/IEC 9001

o Cross-reference between elements of the ORA Quality Manual and, where relevant, SMG 2020 and ISO/IEC 9001:2008.

ORA Quality Manual	*FDA SMG 2020*	*ISO.IEC 9001:2008*
1.3 ORA Organization Appendix A.2	**0. Quality System Infrastructure**	**4.1 General Requirements**
2. Quality Management System 2.1 Scope 2.2 Applicable Requirements 2.3 Documentation 2.3.2 Document Control 2.3.3 Record Control	**0.1 Define Quality System Scope** 0.2 Build Quality System to Meet Requirements 0.3 Document the Quality System	**4. Quality Management System** 4.1 General Requirements 4.2 Documentation Requirements 4.2.3 Control of Documents 4.2.4 control of Records
3. Management Responsibility 3.1 Management commitment 3.2 Customer focus 3.3 Quality policy 3.4 Strategic and quality planning 3.5 Responsibility and authority 3.6 Internal Communication 3.7 Management Review 3.8 Assessment	**1. Strategic Management** 1.1 Provide Leadership 1.3 Identify Customers and Products/Services 1.4 Establish Policies, Objectives, and Plans 1.5 Structure the Organization 1.2 Review System Effectiveness	**5. Management Responsibility** 5.1 Management Commitment 5.2 customer Focus 5.3 Quality Policy 5.4 Planning 5.5 Responsibility, Authority, and Communication 5.6 Management Review
4. Resource Management 4.1 Resource provision 4.2 Personnel assignment 4.3 Competency and training 4.4 Ethics 4.5 Confidentiality 4.6 Facilities and work environment 4.7 Equipment 4.8 Purchase of supplies and services 4.9 Support services	**2. Resource Management** 2.1 Develop Personnel 2.4 Supply and Maintain Equipment 2.2 Purchase Materials and Services 2.5 Provide Support Services	**6. Resource Management** 6.1 Provision of Resources 6.2 Human Resources 6.3 Infrastructure 6.4 Work Environment 7.4 Purchasing
5. Work Process 5.1 Planning work processes 5.2 Work plans and assignments 5.3 Contracting work 5.4 Control of equipment and materials 5.5 Operations 5.6 Reporting results	**3. Lifecycle Management** 3.1 Plan Work 3.2 Design New Products, Services, Processes 3.3 Accept Work 2.3 Control of Outsourced Work 3.4 Perform Work under Controlled Conditions 3.5 Detect Problems before Product/Service Release	**7. Product Realization** 7.1 Planning of Product Realization 7.3 Design and Development 7.2 Customer-Related Processes 7.6 Control of Measuring and Monitoring Equipment 7.5 Production and Service Provision
6. Quality Measurement, Acceptance, And Improvement 6.1 Measurement planning and Implementation 6.2 Nonconformance control 6.3 Data Analysis 6.4 Risk Assessment 6.5 Audits 6.6 Corrective action 6.7 Preventive action 6.8 Continual Improvement	4. Quality System Evaluation 4.1 Monitor and Measure Selected Metrics 4.2 Work through Problems 4.3 Analyze Data for Trends 4.4 Assess Consequences 4.5 conduct Audits 4.6 Address Recurring Problems 4.7 Anticipate Problems 4.8 Promote Improvement	**8. Measurement, Analysis, and Improvement** 8.1 General 8.2 Monitoring and Measurement 8.3 Control of Nonconforming Product 8.4 Analysis of Data (8.2 Monitoring and Measurement) 8.5 Improvement 8.5 Improvement 8.5 Improvement

D.

1. Purpose

This document is designed to reconcile common quality system terms in reference to the ORA Quality System. It also integrates new terms and definitions related to the ORA Quality Management System.

2. Scope/Policy

This glossary contains definitions of terms used in the ORA Quality Management System. It does not include terms related to ORA's technical operations unless those terms are also in common use in quality systems.

- This document is a reference, not a directive: these definitions do not supersede specific definitions given in a directive's glossary section.

3. Responsibilities

(a) ORA Quality System Managers and Management are responsible for maintaining the Quality System in accordance with the definitions below.
(b) The Executive Director of ORA Strategic Initiatives is the approving official for any changes to this index of terms.

4. Procedure for Use

The definitions are arranged in alphabetical order. Each term is followed by a definition, reference to related terms and any QMS procedural reference.

5. Supporting documents

American National Standard: Quality Management Systems Fundamentals and Vocabulary, ISO 9000: 2005 Terms and Definitions. American Society for Quality Press: Milwaukee, WI.

6. Glossary

Audit: Systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.
Audit Conclusion: Outcome of an audit provided by an audit team after consideration of the audit objectives and all audit findings.
Audit Criteria: Set of policies, procedures or requirements.
Audit Evidence: Records, statements of fact or other information, which are relevant to the audit criteria and verifiable.
Audit Findings: Results of the evaluation of the collected audit evidence against audit criteria.
Audit Plan: Description of the activities and arrangement for an audit.
Audit Program: Set of one or more audits planned for a specific time frame and directed towards a specific purpose.
Audit Scope: Extent and boundaries of an audit.
Audit Team: One or more auditors conducting an audit, supported if needed by technical experts.
Auditor: Person with the demonstrated personal attributes and competence to conduct an audit

Capability: Ability of an organization, system or process to realize a product that will fulfill the requirements for that product.
Characteristic: Distinguishing feature
Competence: Demonstrated ability to apply knowledge and skills.
Complaint: Complaints are negative reactions usually in written form made to the organization related to a specific product or service produced or provided by the organization after the product has been released or service completed (*ISO 10002*).
Conformity: Fulfillment of a requirement
Continual Improvement: Recurring activity to increase the ability to fulfill requirements.
Corrective Action: Action to eliminate a detected nonconformances or other undesirable situation. (Similar to a correction).
Customer Organization: Receives a product (can also be a person)
Customer Satisfaction: Customer's perception of the degree to which the customer's requirements have been fulfilled.
Contract: Binding agreement
Defect: Non-fulfillment of a requirement.
Dependability: Collective term used to describe the availability performance and its influencing factors: reliability performance, maintainability performance and maintenance support performance.
Design and Development: Set of processes that transform requirements into specified characteristics or into the specification of a product, process or system.
Document: Information and its supporting medium
Effectiveness: Extent to which planned activities are realized and planned results achieved.
Efficiency: Relationship between the result achieved and the resources used
Information: meaningful data
Infrastructure: System of facilities, equipment and services needed for the operation of an organization.
Inspection: Conformity evaluation by observation and judgment accompanied as appropriate by measurement, testing or gauging.
Interested party: Person and/or group having an interest in the performance or success of an organization.
Management: Coordinated activities to direct and control an organization.
Management System: to establish policy and objectives and to achieve those objectives
Measuring Equipment: Measuring instrument, software, measurement standard, reference material or combination thereof necessary to realize a measurement process.
Non-Conformances: Non-fulfillment of a requirement
Objective evidence: Data supporting the existence or verity of something.
Organization: Group of people and facilities with an arrangement of responsibilities, authorities and relationships.
Organizational Structure: Arrangement of responsibilities, authorities and

relationships between people.
Preventive Action: Action to eliminate the cause of a potential nonconformances or other undesirable potential situation.
Process: Set of interrelated or interacting activities, which transforms inputs into outputs.
Procedure: Specified way to carry out an activity or a process.
Product: Result of a Process
Project: Unique process consisting of a set of coordinated and controlled activities with start and finish dates, undertaken to achieve an objective conforming to specific requirements, including the constraints of time, cost and resources.
Qualification process: Process to demonstrate the ability to fulfill specified requirements.
Quality: Degree to which a set of inherent characteristics fulfills requirements.
Quality Assurance: Part of quality management focused on providing confidence that quality requirements will be fulfilled.
Quality Control: Part of quality management focused on fulfilling quality requirements.
Quality Improvement: Part of quality management focused on increasing the ability to fulfill quality requirements
Quality Management: Coordinated activities to direct and control an organization with regard to quality.
Quality Manual: Document specifying the quality management system of an organization.
Quality Objective: Something sought, or aimed for, related to quality.
Quality Plan: Document specifying which procedures and associated resources shall be applied by whom
Quality Planning: Part of quality management focused on setting quality objectives and specifying necessary operational processes and related resources to fulfill the quality objectives.
Quality Policy: Overall intentions and direction of an organization related to quality as formally expressed by top management.
Record: Document stating results achieved or providing evidence of activities performed.
Release: Permission to proceed to the next stage of a process.
Requirements: need or expectation that is stated, generally implied or obligatory.
Review: Activity undertaken to determine the suitability, adequacy and effectiveness of the subject matter to achieve established objectives.
Rework: Action on a nonconforming product to make it conform to the requirements.
Self-Assessment: A comprehensive and systematic review of the organization's activities and results referenced against the quality management system or a model of excellence.
Specification: Document stating requirements
System: Set of interrelated or interacting elements

Test: Determination of one or more characteristics according to a procedure.
Top Management: Person or group of people who directs and controls an organization at the highest level.
Traceability: Ability to trace the history, application or location of that which is under consideration.
Validation: Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled.
Verification: Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled.
Work environment: Set of conditions under which work is performed.