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4.1 Organization

I. Principal Responsibilities

The Office of Regulatory Affairs Associate Commissioner is responsible for establishing the organization's commitment to the management system, implementing it, and delegating responsibility for its accomplishment.

The Director of the Office of Regulatory Science is responsible for issuing policy and procedures for the ORA laboratories and monitoring their implementation.

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

II. Policies

4.1.1 The Food and Drug Administration (FDA) is a government agency under the Department of Health and Human Services (DHHS). The agency is required to follow the federal regulations in 21 CFR, 29 CFR, 40 CFR, 49 CFR, the FD&C Act and PHS Act.

4.1.2 The intent of ORA is to operate testing laboratories according to the following requirements:

- FDA policies and procedures,
- ISO/IEC 17025,
- customer contracts (workplan),
- ORA compliance programs and assignments,
- Federal and State laws and regulations, and
- American Association for Laboratory Accreditation (A2LA) Accreditation Criteria.

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- 4.1.3** ORA laboratories operate permanent facilities in five regions across the United States and Puerto Rico at the locations identified in the Staff Manual Guide (SMG), Volume I, Section 1300. ORA may operate mobile laboratories as extensions to specified fixed laboratory sites.
- 4.1.4** The regulatory laboratories are a part of the Office of Regulatory Affairs, FDA and are identified in the SMG, Volume I, Section 1300. The organizational charts are found at www.fda.gov, About FDA. Each laboratory also maintains an organizational chart or charts. Key personnel are identified in these charts.
- 4.1.5** a. The laboratory has managerial staff with the authority to discharge their duties as reflected in the prepared job descriptions by the laboratory. This authority includes the implementation, maintenance, and improvement of the management system. Management authorities are defined in government classification standards found on the U.S. Office of Personnel Management website, www.opm.gov. The resources needed to discharge these duties are identified in Volume I, Section 5.2 to Section 5.6. The identification of departures from the management system and testing requirements is documented according to the laboratory's corrective action procedure.
- 4.1.5** b. A Financial Disclosure form OGE 450 is completed annually by employees to prevent participation in any financial matter that might adversely affect the integrity of their work. Form HHS 520, Approval of Outside Activity, is completed and approved for employees seeking outside employment.
- 4.1.5** c. Reports of information and data are transmitted and filed in accordance with official policies, directives, and notices of the department and the agency. Reports and data are not released until reviewed and verified. The majority of reports are sent to internal customers only, except as required by law or regulation. Information is released only to the customer or designated representative. Field Management Directive (FMD) No. 147, Procedure for Release of Analytical Results Pursuant to Section 704 (d), provides guidance for reporting analytical results to an external customer. Additionally, FDA facilities are controlled-access buildings to further ensure protection of data.

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- 4.1.5 d.** To avoid conflicts of interest, pressures, and influences, FDA employees are familiar with and observe the Standards of Ethical Conduct. These principles of ethics can be found at <http://inside.fda.gov:9003/EmployeeResources/Ethics/FDAEthicsProgram/default.htm>. Executive Order 12674, issued in 1989 and modified in 1990 by Executive Order 12731, states fourteen general principles that broadly define the obligations of public service. Two core concepts are embodied in these principles: (a) Employees shall not use public office for private gain, (b) and employees shall act impartially and not give preferential treatment to any private organization or individual. The Office of Government Ethics (OGE) requires one hour of ethics training annually. Training is provided on ethics rules, regulations and integrity in order to help employees avoid placing themselves in a conflict of interest situation. An employee who performs laboratory testing performs and documents a demonstration of competence as prescribed in Volume I, Subsection 5.2
- 4.1.5 e.** The regulatory laboratories are a part of the Office of Regulatory Affairs, FDA and are identified in SMG, Volume I, Section 1300. The organization and the relationship among the laboratory staff is reflected in the laboratory's organizational chart maintained by the laboratory Quality Management System (QMS) Manager.
- 4.1.5 f.** Job responsibilities for laboratory employees are documented in the management system procedures and operating instructions. Position descriptions are maintained by the Rockville Human Resources Center (RHRC).
- 4.1.5 g.** The laboratory employees performing testing have access to consensus standards, instrument manufacturers' manuals, and laboratory procedures for reference. Demonstration of competence for technical personnel is documented and used as evidence of desired familiarity with laboratory methods. Supervisors are designated and trainees do not perform regulatory work until competent as per the laboratory training program.
- 4.1.5 h.** The Supervisor is responsible for the technical operations of the laboratory. Resources for training, laboratory methods, measurement traceability, and purchasing are described in sections of this Volume, and in procedures.

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Demonstration of competence for technical personnel is documented and used as evidence of desired familiarity with laboratory methods. Supervisors are designated and trainees do not perform regulatory work until competent as per the laboratory training program.

- 4.1.5** h. The Supervisor is responsible for the technical operations of the laboratory. Resources for training, laboratory methods, measurement traceability, and purchasing are described in sections of this Volume, and in procedures.
- 4.1.5** i. The laboratory Quality System Manager (QSM) is responsible for the laboratory's management system and its implementation. The QSM has direct access to the Laboratory Director, who is responsible for decisions concerning policy and resources.
- 4.1.5** j. Qualified laboratory personnel are assigned to serve in the absence of key managerial personnel, such as Laboratory Director, Quality System Manager, and Supervisor. For example, the Supervisor or Deputy Director may serve in the absence of the Laboratory Director; either the Laboratory Director, Deputy Director or Supervisor may serve in the absence of the QSM; and senior technical personnel may serve in the absence of Supervisors.
- 4.1.5** k. Laboratory personnel are aware of their function and contribution in the management system and of its objectives.
- 4.1.6** Effective communication from management occurs through the use of but not limited to memos, newsletters, electronic presentations, emails, or verbally to laboratory personnel regarding the effectiveness of the management system.

Related Procedures

- Each ORA laboratory has its own corrective action procedure. A template is provided in Volume II, Section 1, ORA-LAB.4.11 Corrective Action Procedure.
- Each ORA laboratory has its own training procedure. A template is provided in Volume II, Section 1, ORA-LAB.5.2 Personnel: Training Procedure.
- ORA-QMS.007, Corrective Action Procedure.