# QSE 1 – Organization

## Key Concepts

This quality system essential (QSE) describes the responsibilities of executive management, the nature of the quality system, and the need for ongoing attention to operational and quality issues through demonstrated management commitment.

## Key Terms

**Customer:** The recipient of a product or service. A customer may be internal (eg, another organizational unit within the same organization) or external (eg, a patient, client, donor, or another organization).

**Emergency Management:** Strategies and specific activities designed to manage situations in which there is a significant disruption to organization operations or a significantly increased demand for the organization's products or services.

**Executive Management:** The highest-level personnel within an organization, including employees, clinical leaders, and independent contractors, who have responsibility for the operations of the organization and who have the authority to establish or change the organization's quality policy. Executive management may be an individual or a group of individuals.

**Organization:** An institution, or a location or operational area within that organization; the entity assessed by the AABB and receiving AABB accreditation for specific activities.

**Policy:** A set of basic principles or guidelines that direct or restrict the organization's plans, actions, and decisions.

**Procedure:** A defined series of tasks and instructions that specify how an activity is to be performed.

**Process:** A set of related activities that transform inputs into outputs.

**Quality Management System:** The organizational structure, responsibilities, policies, processes, procedures, and resources established by executive management to achieve quality.

## Examples of Objective Evidence

- Policies, processes, and procedures related to this chapter.
- Organizational charts or documents describing roles, responsibilities, and decision-making authority.
- Evidence of executive management review of a quality system.
- Applicable federal, national, state, and local laws and regulations, as well as copies of any required certificates.
- Defined quality system.
- Process for approving exceptions to policies, processes, and procedures, as well as documented examples, if applicable.
- Risk assessments and mitigation strategies.
- Emergency operation and disaster continuity plan(s).
- Executive management review of customer feedback.

# 1. Organization

## 1.0 Organization

The organization shall define the parties responsible for the provision of products or services.

### 1.1 Executive Management

The organization shall have a defined executive management. Executive management shall have:

1) Responsibility and authority for the quality system and operations.
2) Responsibility for compliance with these *MT Standards* and applicable laws and regulations, including all applicable current good manufacturing practice (cGMP) requirements.
3) Authority to establish or make changes to the quality system.

#### 1.1.1 Laboratory Director Responsibilities

The laboratory shall have a director who has a doctoral degree in medical, biological, clinical laboratory sciences, or genetics and has at least 2 years of relevant training or experience in molecular testing. The laboratory director shall have responsibility and authority for all policies, processes, and procedures. The laboratory director may delegate these responsibilities to another qualified individual; however, the laboratory director shall retain ultimate responsibility for laboratory director duties.*

*42 CFR 493.1405, 42 CFR 493.1407, 42 CFR 493.1443, and 42 CFR 493.1445.

### 1.1.2 Laboratory Supervisor Responsibilities

The laboratory shall have a supervisor who is qualified by training or experience. The supervisor shall have responsibility for technical aspects of molecular testing.

**1.1.2.1** The supervisor shall have at least 2 years of relevant experience in molecular testing and one of the following qualifications*:

1) Medical license and certification in blood banking/transfusion medicine or molecular genetic pathology by the American Board of Pathology or non-US equivalent organization or agency.
2) Certification as Technologist in Molecular Biology (MB) by the American Society for Clinical Pathology (ASCP), certification as Technologist in Blood Banking (BB) from ASCP, certification as Specialist in Blood Banking (SBB) from ASCP, certification as Certified Histocompatibility Specialist (CHS) from the American College of Histocompatibility and Immunogenetics (ACHI), or certification from an organization or agency issuing an equivalent credential.
3) Advanced science degree in a relevant field.

**1.1.2.1.1** When the individual does not meet the requirements stated in Standard 1.1.2.1, exceptions shall be considered on a case-by-case basis by the Molecular Testing Accreditation Committee.

*42 CFR 493.1411.