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## 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.

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**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, 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.

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# 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 *IRL 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 Medical Director Qualifications and Responsibilities

The laboratory shall have a medical director who is a licensed physician and qualified by education, training, and/or experience. The medical director shall have responsibility and authority for all medical and technical policies, processes, and procedures,\* including those that pertain to laboratory personnel, test performance, and services. The medical director may delegate these responsibilities to another qualified physician; however, the medical director shall retain ultimate responsibility for medical director duties.

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\*42 CFR 493.1251(d).

**1.1.1.1** The medical director shall:

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- 1) Be available to the supervisor, designee, and/or technical staff.
  - 2) Approve services that are not routinely performed by the facility. Standard 7.1 applies.
  - 3) Serve as a consultant for the community on transfusion medicine issues.

**1.1.2 Supervisor Qualifications and Responsibilities**

The laboratory shall have an individual (hereinafter referred to as a supervisor) who is responsible for all aspects of immunohematology testing and services and who is qualified by education, training, and/or experience.

**1.1.2.1** The supervisor shall have one of the following qualifications:

- 1) Certification as a Specialist in Blood Banking (SBB) or international equivalent credential.
- 2) Doctorate in an immunohematology-related field.
- 3) Medical license and certification in blood banking/transfusion medicine by the American Board of Pathology or equivalent agency outside the United States.

**1.1.2.1.1** When the individual does not possess one of these qualifications,\* exceptions shall be considered on a case-by-case basis by the Immunohematology Reference Laboratory Accreditation Committee.

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\*42 CFR 493.1449(q).