
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.

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- 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 *BB/TS 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.
- 4) A participatory role in management review of the quality system.

1.1.1 Medical Director Qualifications and Responsibilities

The blood bank or transfusion service (hereinafter referred to as the BB/TS) shall have a medical director who is a licensed physician, qualified by training, experience, and facility-defined relevant continuing education in activities required by these *BB/TS Standards* for which the facility is accredited. The medical director shall have responsibility and authority for all medical and technical policies, processes, and procedures—including those that pertain to laboratory personnel, operations, quality, and test performance—and for the consultative and support services that relate to the care and safety of donors and/or transfusion recipients. The medical director may delegate these responsibilities to another qualified physician; however, the medical director shall retain ultimate responsibility for medical director duties.*

1.2 Quality System

The organization shall have a quality system. The organization's executive management shall ensure that this quality system is implemented and followed at all levels of the organization.

1.2.1 Quality Representative

The quality system shall be under the supervision of a designated person who reports to executive management.

*21 CFR 630.3(i), 42 CFR 493.1251, 42 CFR 493.1407, and 42 CFR 493.1445.


 **1.2.2 Management Reviews**

Management shall assess the effectiveness of the quality system at defined intervals.

 **1.3 Policies, Processes, and Procedures**

Policies, processes, and procedures shall be implemented and maintained to satisfy the applicable requirements of these *BB/TS Standards*. All such policies, processes, and procedures shall be in writing or captured electronically and shall be followed.

1.3.1 The medical director and/or laboratory director (as applicable) shall approve all medical and technical policies, processes, and procedures. Standard 1.1.1 applies.*

 **1.3.2** Any exceptions to medical and technical policies, processes, and procedures shall require justification and preapproval by the medical director and/or laboratory director, as applicable. Standard 1.1.1 applies.*

 **1.4 Risk Assessment**

The facility shall have a process in place to perform risk assessments for activities at defined intervals.

1.4.1 Mitigation strategies shall identify, assess, and address the level of risk associated with quality and safety.


1.5 Operational Continuity

The organization shall address continuity in the event that operations are at risk.

1.5.1 The BB/TS shall have a policy to address product inventory shortages.

1.6 Emergency Preparedness

The organization shall have an emergency operation plan(s) to respond to the effects of internal and external disasters.

 **1.6.1** The emergency management plan, including emergency communication systems, shall be tested at defined intervals.

*42 CFR 493.1251(d), 42 CFR 493.1407, and 42 CFR 493.1445.