
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 *RT 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) Responsibility to conduct scheduled management reviews to assess the effectiveness of the quality system.
- 5) Responsibility to obtain official transcripts for laboratory directors, laboratory director designees, and laboratory supervisors.



1.1.1 Laboratory Director Qualifications and Responsibilities

The laboratory shall have a laboratory director who has a doctoral degree in medicine, biology, chemistry, genetics, or clinical laboratory science.



- 1.1.1.1** The laboratory director shall have at least 2 years of training or experience in relationship testing in an AABB-accredited (or equivalent) laboratory or under the guidance of a laboratory director currently or previously employed in an accredited

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laboratory. Participation in proficiency testing shall be part of the training/experience. Where indicated, the laboratory director may delegate responsibilities to another qualified individual; however, the laboratory director shall retain ultimate responsibility for laboratory director duties.

1.1.1.1.1 In cases where the director candidate's 2 or more years of experience is not in a laboratory accredited by AABB, exceptions shall be evaluated on a case-by-case basis by the Relationship Testing Accreditation Committee. Standard 1.1.6 applies.

1.1.2 The laboratory director shall be a part of executive management.



1.1.2.1 The laboratory director shall have responsibility and authority for all policies, processes, and procedures and to stop or suspend laboratory operations.

1.1.3 Laboratory Director Designee

Any laboratory director designee shall have a doctoral degree in medicine, biology, chemistry, genetics, or clinical laboratory science and shall be qualified by training or experience.



1.1.4 Technical Leader Serving as Laboratory Director

For forensic DNA laboratories accredited to the current Federal Bureau of Investigation (FBI) Quality Assurance Standards, the technical leader serving as a laboratory director for relationship testing purposes shall be further qualified by training or experience to serve in the role of laboratory director for the purposes of these *RT Standards*. The technical leader shall have

3 years of training/experience in relationship testing in an AABB-accredited (or equivalent) relationship testing laboratory or under the guidance of a laboratory director currently or previously employed in an accredited laboratory. Participation in proficiency testing shall be part of the training/experience.

1.1.4.1 In cases where the experience of the director candidate is not in a laboratory accredited by AABB (or equivalent), exceptions shall be evaluated on a case-by-case basis by the Relationship Testing Accreditation Committee. Standard 1.1.6 applies.



1.1.5 Laboratory Supervisor Qualifications and Responsibilities

The laboratory shall have one or more supervisor(s) with responsibility for the day-to-day supervision of laboratory processes and procedures. The laboratory supervisor(s) shall have, at a minimum, a bachelor's degree in biology, chemistry, genetics, clinical laboratory science, or a related field, and at least 2 years of training or experience in relationship testing.



1.1.6 Staffing Changes

The laboratory shall communicate to AABB all initial appointments or staffing changes for the laboratory director, laboratory director designee(s), laboratory supervisor(s), and/or quality representative within 30 days of appointment.

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. All such policies, processes, and procedures

shall be in writing or captured electronically and shall be followed.

1.2.1 Quality Representative

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



1.2.1.1 The quality representative shall have relevant training and experience.



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 *RT 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.



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.



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.