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, 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.

Guidance

The primary purpose of this chapter is to ensure that a laboratory has statements of quality goals or objectives and that all parties involved in activities that affect quality understand these goals and objectives of the organization and their responsibility in fulfilling them. Another purpose is to ensure that management at the highest level of the laboratory is ultimately responsible and accountable for quality in the activities covered by the *IRL Standards*. Standard 1.0 requires that there be a structure that clearly identifies the parties who are responsible for providing immunohematology reports and testing services covered by the *IRL Standards.* It also requires that the relationship of individuals who are responsible for key quality functions be defined. Each laboratory must evaluate and identify key quality functions within its own organization. An organizational chart would be one example of meeting this standard.

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.

Guidance

Although others in the laboratory may be more involved in carrying out the quality system, executive management is ultimately responsible and accountable for the quality of the activities covered by these *IRL Standards.* Executive management of the laboratory should play a visible role in supporting and implementing the quality system throughout the laboratory. Executive management is defined as the highest level of personnel within an organization, including employees who have responsibility for the operations of the organization and who have the authority to establish or change the organization's quality policy. Depending on the size and complexity of the laboratory, executive management may consist of only the laboratory supervisor, or a group including the laboratory supervisor, an operations executive(s), customer service representatives, risk assessment managers, and representatives from other areas deemed appropriate by the laboratory. The laboratory must define the structure of executive management in its policies.

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,* includ-

*42 CFR 493.1251(d).

For accredited facilities that are assessed by AABB for conformance with CLIA, refer to the Verification of CLIA Compliance Form before on-site assessment.

ing 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.

1.1.1.1 The medical director shall:

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.

Guidance

The medical director is required to participate in the development of policies, processes, and procedures related to the laboratory. The responsibilities for the immunohematology reference laboratory (IRL) should be defined. The medical director should have direct responsibility for medically related issues such as consultation with hospital physicians, management of rare-unit issue and transfusion, transfusion recommendations for unusual antibody identification, and transfusion recommendations for patients for whom compatible units are unavailable. The guidance for Standard 6.1.5.1 contains more information regarding the review of all documents.

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 equivalent international 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 Laboratories Accreditation Committee.

Guidance

International credentials considered to be equivalent to a Specialist in Blood Banking (SBB) are listed in the AABB Accreditation Committee procedures [see Process for Evaluating Exceptions to Immunohematology Reference Laboratory (IRL) Supervisor Qualifications]. This document is available on the AABB website under the Accredited Member Tools tab.

*42 CFR 493.1449(d).

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