
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.

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 *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,* including those that pertain to laboratory personnel, test performance, and services. The med-

*42 CFR 493.1251(d).

ical 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.

G u i d a n c e

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 recommendation 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 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.

G u i d a n c e

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.

1.1.3

Staffing Changes

The laboratory shall communicate initial appointments and staffing changes for the medical director, medical director designee, and immunohematology reference laboratory supervisor within 30 days to AABB's Accreditation and Quality Department.

*42 CFR 493.1449(q).

Guidance

When changes occur in the managerial structure of the laboratory, the changes are required to be reported to the AABB National Office. This notification must include a curriculum vitae and documentation for appropriate experience and training. This notification can be sent to the Accreditation Department at the AABB National Office by mail (4550 Montgomery Avenue, Suite 700, North Tower, Bethesda, MD, 20814), fax (301-657-0957), or email (accreditation@aabb.org, with attached files). Documentation must be approved by AABB before the person assumes the position. New staff members must meet the requirements of Standards 1.1.1, 1.1.2, or 1.2.1.

During periods of interim leadership within an IRL, the facility has the following options:

1. In the case of management of multiple IRLs, the supervisor may sit in another location until a qualified supervisor is hired.
2. If Standard 1.1.2.1 is not met, the change should be reported to the AABB National Office within 30 days.
3. The Immunohematology Reference Laboratory Accreditation Committee may be petitioned to grant a temporary exception for SBB equivalency when the designated interim individual does not possess one of the qualifications listed.
4. Interim management should not exceed 1 year without notifying the Immunohematology Reference Laboratory Accreditation Committee.

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.

Guidance

Standard 1.2 requires that each IRL have a quality system. Implicit in this requirement are development, documentation, ongoing maintenance, and training in regard to the quality system. The quality system must, at a minimum, address the elements identified in Chapters 1 through 10 of the *IRL Standards*. A quality system is composed of the policies, processes, and procedures that affect the quality of products, services, or reports. All requirements contained in *IRL Standards* can be assumed to affect quality. If the laboratory is a stand-alone laboratory (ie, functions independently from a hospital), it would be expected to have its own quality system. If the laboratory is one of several operating departments or divisions in an AABB-accredited organization, such as a blood center, there is often a quality system that applies to all services, which would include the laboratory. Facilities currently implementing a quality system that satisfies AABB requirements can be assured that the requirements of this section are met.

1.2.1 Quality Representative

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

Guidance

Standard 1.2.1 requires that there be a designated individual within the organization who oversees quality system implementation. The designated individual may have other responsibilities, and ideally will not assess activities for which he or she is responsible. The individual designated to oversee the quality function must report to executive management; exercise control in all matters relating to compliance with

these *IRL Standards* and federal, state, and local regulations; and have authority to recommend corrective action when it is appropriate.



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 *IRL Standards*. All such policies, processes, and procedures shall be in writing or captured electronically and shall be followed.

Guidance

Standard 1.3 requires that the laboratory develop and implement written quality and operational policies, processes, and procedures.

A **policy** is a documented general principle that guides present and future decisions. Policies are often generated as a result of standards, regulations, or a company's "rules." A mission statement is generally understood to be at the level of a policy. A policy might also be a generally articulated "rule," such as a no-smoking policy.

A **process** is a description of a specific work goal and defines what is done and who does it. Processes are larger and more complicated activities than procedures. Processes usually involve more than one person, and often more than one department or work area within a laboratory. The responsibility of a particular person within a process may or may not involve performing a specific procedure. Although most facilities have documented their procedures, documentation of processes is less prevalent. A common way to describe a process in writing is by using a flow diagram with interconnected steps and branch points. Processes may also be described in tables or a narrative format. Documentation of all processes is required by Standard 1.3.

A **procedure** is a series of simple tasks that complete one piece of work. When written down, the procedure serves as a set of work instructions. Procedures are usually performed by one person, from beginning to end. Instructions for ABO/RhD typing, an adsorption, Donath-Landsteiner testing, and antibody titer are examples of procedures. There may be policies that relate to some of the steps in a procedure—for example, determining the strength of anti-D with the patient's cells before assigning Rh type or performing elutions only if the patient was transfused in the previous X number of days.

A way to think about the distinction among a policy, a process, and a procedure is that:

- Policies are rules.
- Processes are what we do.
- Procedures are how we do things.

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.

Chapter 7, Deviations, Nonconformances, and Adverse Events, applies.