1. ORGANIZATION

1.0 Organization

The immunohematology reference laboratory (hereinafter "the laboratory") shall have a structure that clearly defines and documents the parties responsible for the provision of immunohematology reports and testing services and the relationship of individuals responsible for key quality functions.

G u i d a n c e

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 laboratory shall have a defined executive management. Executive management shall have:

1) Responsibility and authority for the laboratory's operations.
2) The authority to establish or make changes to the laboratory's quality system.
3) The responsibility for compliance with these *IRL Standards,* applicable laws, and regulations.
4) Participation in management review of the quality system.
5) A process to identify the laboratory's customers and their needs and expectations for products and services.

G u i d a n c e

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, 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 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 7.0 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 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 6.1.3 contains more information regarding the review of all documents.

1.1.2 Supervisor Qualifications and Responsibilities

The laboratory shall have a supervisor who has responsibility 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. Standard 1.4 applies.

G u i d a n c e

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.

*42 CFR 493.1251(d).

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.

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 Technical Supervisor Qualifications). This document is available on the AABB website under the Accreditation Member Tools tab.

1.2 Quality System

A quality system shall be defined, documented, implemented, and maintained. All personnel shall be trained in its application.

Guidance

Standard 1.2 requires that each immunohematology reference laboratory have a quality system. Implicit in this requirement are development, documentation, ongoing maintenance, and training of 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 through scheduled management reviews.