

---

# 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.

### 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. Standard 4.2 applies.

#### 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

---

\*42 CFR 493.1251(d).

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.

**1.1.2 Supervisor Qualifications and Responsibilities**

The laboratory shall have 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. Standard 1.4 applies.

---

## 1.2 Quality System

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

### 1.2.1 Quality Representative

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



### 1.2.2 Management Reviews

Management shall assess the effectiveness of the quality system through scheduled management reviews.

## 1.3 Policies, Processes, and Procedures

Quality and operational policies, processes, and procedures shall be developed and implemented to ensure that the requirements of these *IRL Standards* are satisfied. All such policies, processes, and procedures shall be in writing or captured electronically and shall be followed.



**1.3.1** Any exceptions to policies, processes, and procedures warranted by clinical situations shall require justification and preapproval by the medical director. Chapter 7, Deviations, Nonconformances, and Adverse Events, applies.



## 1.4 Staffing Changes

The laboratory shall communicate initial appointments and staffing changes for the medical director, medical director designee, and immunohematology reference laboratory supervisor (if Standard 1.1.2.1 is not met) within 30 days to AABB.