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 management at the highest level of the facility is ultimately responsible and accountable for quality in the activities covered by the *MT Standards*. Standard 1.0 requires that there be a structure that clearly identifies the parties who are responsible for providing the molecular testing activities covered by the *MT Standards*. It also requires that the relationship of individuals who are responsible for key quality functions be defined. Each facility must evaluate and identify key quality functions within its own organization, incorporating quality goals or objectives that everyone in the organization understands. 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 *MT 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 *MT 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 director, or a group including the laboratory supervisor, quality representative, 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 Laboratory Director Responsibilities

The laboratory shall have a director with all of the following*:

1) An earned doctoral degree in medical, biological, or clinical laboratory sciences, or genetics.
2) At least 2 years of relevant training or experience in molecular testing.
3) Responsibility and authority for all policies, processes, and procedures.

*42 CFR 493.1405, 42 CFR 493.1407, 42 CFR 493.1443, and 42 CFR 493.1445.

Guidance

The laboratory director is required to have adequate experience to detect possible errors in test performance or in the interpretation of test results. Adequate experience is best demonstrated by the manner in which the person directs the laboratory, through accuracy of review (for example, signoffs on validations, procedures, or audit findings), through the processes and procedures established for the performance of testing, through interactions with the staff, and through demonstration of adequate knowledge of molecular testing for the prediction of red cell, platelet, or neutrophil antigens.

At a minimum, on a continuing basis, the laboratory director should demonstrate the direct review of:

- Validation of new test procedures.
- Proficiency test summaries.
- Standard operating procedures.
- Results of internal and external assessments.
- Reports, templates, forms, and processes.

Some laboratories may find it necessary or practical to have multiple people with the training needed to perform delegated functions of the laboratory director. This division of responsibility is acceptable; however, it is required that one individual, the laboratory director, have overall responsibility for the laboratory. If there is a laboratory director and duties are delegated to others, their relationship and responsibilities must be clarified in the laboratory's policies and processes.

Although the laboratory director may delegate some responsibilities in the United States under the statutes of the Clinical Laboratory Improvement Amendments (CLIA), some duties are not delegable, such as periodic review of operating procedures. A discussion of laboratory director responsibilities can be found in Brochure #7 of the Centers for Medicare and Medicaid Services (CMS), which can be found at https://www.cms.gov/CLIA/downloads/brochure7.pdf.

Under CLIA, the laboratory director may not delegate responsibility and must ensure that:

1. Testing systems in the laboratory provide quality services in all aspects of test performance (including the preanalytic, analytic, and postanalytic phases of testing) and are appropriate for the patient population.
2. Physical and environmental conditions of the laboratory are adequate and appropriate for the testing performed.
3. The environment for employees is safe from physical, chemical, and biological hazards, and safety and biohazard requirements are followed.
4. A general supervisor (high-complexity testing) is available to provide day-to-day supervision of all testing personnel and reporting of test results, as well as provide on-site supervision for specific minimally qualified testing personnel when they are performing high-complexity testing.
5. Sufficient numbers of appropriately educated, experienced, and/or trained personnel who provide appropriate consultation, properly supervise, and accurately perform tests and report test results in accordance with the written duties and responsibilities specified by the director are employed by the laboratory.
6. New test procedures are reviewed, included in the procedure manual, and followed by personnel.
7, Each employee's responsibilities and duties are specified in writing.

To demonstrate that a laboratory director has sufficient advanced training and/or practical experience in those methods the laboratory employs for the molecular testing of red cell, platelet, or neutrophil antigens, the potential laboratory director can:

- Document at least 2 years of experience using the method(s) in question and reviewing results.

- Document training in the use of the method(s) for the testing used during postgraduate training, training in another laboratory, or training under the guidance of the director of an accredited laboratory.
- Attend relevant continuing education opportunities on a regular basis. Participation in relevant continuing education alone may not constitute specific training but is considered in conjunction with other documentation to demonstrate specific expertise in this field.
- Demonstrate authorship or co-authorship in a peer-reviewed published work concerned with the use of the method(s) for molecular testing of red cell, platelet, or neutrophil antigens, as it may also be considered in conjunction with other documentation to demonstrate specific expertise in this field.

Standard 1.1.1 requires that the laboratory director have a doctoral degree, as indicated. Individuals educated outside the United States who are requesting clarification for equivalency to a doctorate degree from a US school must provide documentation from a member of the National Association of Credential Evaluation Services (NACES) that the foreign degree is equivalent to the required degree. For the position of laboratory director, equivalency must be shown.

Organizations with current NACES membership may be found at http://www.naces.org/ or by contacting the organization at:

International Education Research Foundation, Inc
P.O. Box 366
Culver City, CA 90231-3665
Phone: (310) 258-9451
Fax: (310) 342-7086

1.1.1.1 Laboratory Director Designee

The laboratory director may delegate the responsibilities, as permitted, to another qualified individual; however, the laboratory director shall retain ultimate responsibility for laboratory director duties.

G u i d a n c e

Any division of responsibility is acceptable; however, the laboratory director retains the overall responsibility for laboratory activities.

1.1.2 Laboratory Supervisor Responsibilities

The laboratory shall have a supervisor who is qualified by training or experience. The supervisor shall have responsibility for technical aspects of molecular testing.

1.1.2.1 The supervisor shall have at least 2 years of relevant experience in molecular testing and one of the following qualifications*:

1) Medical license and certification in blood banking/transfusion medicine or molecular genetic pathology by the American Board of Pathology or non-US equivalent organization or agency.

*42 CFR 493.1411.

2) Certification as Technologist in Molecular Biology (MB) by the American Society for Clinical Pathology (ASCP), certification as Specialist in Blood Banking (SBB) from ASCP, certification as Certified Histocompatibility Specialist (CHS) from the American College of Histocompatibility and Immunogenetics (ACHI), or certification from an organization or agency issuing an equivalent credential.
3) Advanced science degree in a relevant field.

1.1.2.1.1 When the individual does not meet the requirements stated in Standard 1.1.2.1, exceptions shall be considered on a case-by-case basis by the Molecular Testing Accreditation Committee.

Guidance

The requirement for 2 years of experience is a minimum requirement; some states may require more than 2 years of experience in molecular testing for supervisors.

If equivalency is not determined by documentation from NACES (see Standard 1.1.1), then the following suggested items can be submitted to the Molecular Testing Accreditation Committee for review:

1. The proposed supervisor's curriculum vitae (CV).
2. Documentation of degrees and other certification. (Note: Criteria for assessment of degrees and certification are listed below.)
3. A description of the proposed supervisor's pertinent on-the-job experience. (A detailed CV may meet this requirement.)
4. A description of the proposed supervisor's duties, particularly how the person functions as the technical expert. (For example, this individual is consulted when a technical problem is not resolved by the "bench" staff.)
5. A list of the proposed technical supervisor's publications and presentations in the field of immunohematology (if not already provided in the CV).
6. A description of what the proposed supervisor would do if a case could not be resolved, and identification of the person to whom the case would normally be referred.

Criteria for the assessment of acceptable degrees and certification might include the following:

1. Bachelor's degree in a science-related field and successful completion of a Specialist in Blood Bank Technology program accredited by the Commission on Accreditation of Allied Health Education Programs.
2. National certification, or a bachelor's degree and 2 years of full-time relevant clinical laboratory experience within the last 10 years. Laboratory experience is defined as including:
    a. DNA procedures including, but not limited to, DNA extractions, various analysis techniques [eg, polymerase chain reaction (PCR), restriction fragment length polymorphism (RFLP)], and interpretation of molecular test results.
    b. Quality control/quality assurance.
    c. Laboratory operations.
3. Master's or doctorate degree in a science-related field and 2 years of full-time laboratory experience in molecular testing within the last 10 years. Science-related fields include medical, biological, or clinical laboratory sciences, or genetics fields.

National Certification	Education	Certification	US Equivalent
United States: American Society for Clinical Pathology (www.ascp.org)	4-year university + bachelor of science degree with appropriate science hours + internship + exam	MT(ASCP)	
	4-year university + experience + exam	BB(ASCP)	
	4-year university + internship or experience + exam	SBB(ASCP)	
Canada: Canadian Society for Medical Laboratory Science (www.csmls.org)	3-year technical college (old) + exam	RT – CSMLS (old)	MT(ASCP)
	4-year university (new) + exam	MT-CSMLS (new)	MT(ASCP)
	5 years' experience/ education + exam	ART-CSMLS in Immunohematology	SBB(ASCP)
United Kingdom: Institute of Biomedical Science (www.ibms.org)	3-year technical college (old) + exam	AIBMS	MT(ASCP)
	4-year university (new) + exam	AIBMS	MT(ASCP)
	2 years' training + 5 years' experience + exam (old)	FIBMS in Immunohematology	SBB(ASCP)
Australia: Australian Institute of Medical and Clinical Scientists (www.aims.org.au)	3-year bachelor of applied science university degree + 2 years' experience	AIMS-Corporate Member MLS	SBB
	5 years' experience + examination or thesis	FAIMS in Blood Transfusion	MT(ASCP)
New Zealand: New Zealand Institute of Medical Laboratory Science (www.nzimls.org.nz)	University: bachelor of science in medical laboratory science	MLS licensed by Medical Sciences Council of New Zealand	MT(ASCP)
	2 years' experience + certification exam and dissertation	FNZIMLS in Transfusion Science	SBB

Note: Other nations might have different requirements.