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 The organization shall define the parties responsible for the provision of products or services.

G u i d a n c e

The primary purpose of this chapter is to ensure that a relationship testing laboratory (hereinafter "the laboratory") has statements of quality goals or objectives. All individuals involved in activities that are related to the provision of relationship testing services or relationship testing results should understand the quality goals and objectives of the laboratory and their responsibility for fulfilling those goals and objectives. 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 standards.

The relationship testing laboratory provides a service (relationship testing) and a product (a relationship test report). *RT Standards* require that there be a structure that clearly identifies the parties who are responsible for providing relationship testing services and relationship test results covered by these *RT Standards*. Therefore, the laboratory has to identify the key quality functions that affect the quality of the product or service provided. While the laboratory director is ultimately responsible, the laboratory should define which individuals are responsible for key quality functions; each laboratory is expected to evaluate its operations and identify positions that affect quality. Peripheral support functions within the laboratory, such as accounting, would not be considered key quality functions because they would not directly affect the quality of the relationship testing result. An organizational chart clearly indicating the different positions, managerial or otherwise, and associated specific responsibilities, is one example of how to meet this standard. It is important to note that designating responsibility of a key quality criterion to more than one position or individual typically serves to dilute or otherwise render ambiguous the sense of accountability to that specific item.

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 *RT Standards* and applicable laws and regulations, including all applicable current good manufacturing practice (cGMP) requirements.

G u i d a n c e

While 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 *RT Standards*. Executive management of the laboratory should take a visible role in supporting and implementing the quality system throughout the laboratory.

Executive management is defined as the highest-level personnel within an organization, including employees and independent contractors, who have responsibility for the operations of the organization and may include the laboratory director, 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.

Because many laboratories perform both accredited and nonaccredited activities in the same facility, executive management must define the individual(s) responsible for specific adherence to these *RT Standards* for all accredited activities. This individual must have sufficient authority to establish a clear separation between accredited and nonaccredited activities. Policies should be drafted to ensure that any work product or advertising materials for nonaccredited activities contain no inappropriate or misleading claims of accreditation. Standards 1.1.1.1 and 6.5.1 through 6.5.5 apply.

3) Authority to establish or make changes to the quality system.
4) Responsibility to conduct scheduled management reviews to assess the effectiveness of the quality system.

Guidance

Nonscheduled reviews may be necessary in the event of reported nonconformances. Executive management is required to participate in these reviews (per Standard 1.1); however, this review should not necessarily be limited to that individual or group. Other individuals who may provide important input include senior technologists, department/laboratory managers, quality assurance managers, and risk assessment managers.

Each laboratory should determine how frequently management reviews will occur. For a laboratory with a new quality system, it is recommended that reviews take place three or four times a year. Once management is satisfied that the quality system is working as intended, fewer management review meetings need to be scheduled. For example, if a laboratory has had a quality system in place for 10 years and it operates smoothly, an annual review may suffice.

Management reviews should include discussion of the status of implementation of the quality system for the relationship testing laboratory. In addition, particular attention should be focused on results of internal and external assessments and resulting follow-up on issues requiring corrective or preventive action. This management review also presents an opportunity to discuss risk assessments, the cost of implementing the quality system, marketing efforts to customers, and customer response.

An example of management review of the quality system includes performing periodic (quarterly, biannual, or annual) reviews and sending reports to the laboratory's executive management regarding the effectiveness of the quality system.

5) Responsibility to obtain official transcripts for laboratory directors, laboratory director designees, and laboratory supervisors.

Guidance

To obtain an official transcript, an individual needs to contact their university and request that it be sent to the facility. A small fee may be incurred.

1.1.1 Laboratory Director Qualifications and Responsibilities
The laboratory shall have a laboratory director who has a doctoral degree in medicine, biology, chemistry, genetics, or clinical laboratory science.

1.1.1.1 The laboratory director shall have at least 2 years of training or experience in relationship testing in an AABB-accredited (or equivalent) laboratory or under the guidance

of a laboratory director currently or previously employed in an accredited laboratory. Participation in proficiency testing shall be part of the training/experience. Where indicated, the laboratory director may delegate responsibilities to another qualified individual; however, the laboratory director shall retain ultimate responsibility for laboratory director duties.

Guidance

The laboratory director is required to have ample experience to detect possible errors in test performance or in the interpretation of test results. The ample experience is best demonstrated by the training the individual has received and their activity with the laboratory. That training should cover all areas of the laboratory, from specimen collection through reporting of relationship results. This training and experience should be received prior to appointment to the position of laboratory director. The ample experience is also reflected in the manner in which the person directs the laboratory, case review, the processes and procedures established for the performance of testing, interactions with the staff, and demonstration of adequate knowledge of the operations of genetics and the calculations that form the foundation of the science of relationship testing.

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

1) Validation of new test procedures.
2) Proficiency test summaries.
3) Standard operating procedures.
4) Results of internal and external assessments.
5) Case reports to clients.

New laboratory directors should submit a current CV, evidence of training and experience, letter of qualification from the director performing the training, and a portfolio of a minimum of 20-50 cases representative of the testing performed.

To demonstrate that a laboratory director has sufficient advanced training and/or practical experience in those methods the laboratory employs for relationship testing, the potential laboratory director can:

1) Document at least 2 years of experience reviewing relationship test results using the method(s) in question. Documentation can include the submission to the AABB of a portfolio of reviews of 20-50 cases representing the testing to be performed by the laboratory.
2) Document training in the use of the method(s) for relationship testing during postgraduate training, training in another laboratory, or training under the guidance of the director of an accredited laboratory.
3) Document regular attendance at relevant continuing education opportunities. It should be noted that participation in relevant continuing education alone does not constitute specific training in relationship testing but is considered in conjunction with other documentation to demonstrate specific expertise in this field.
4) Document authorship or co-authorship in peer-reviewed published work concerned with the use of the method(s) for relationship testing.

Individuals who are in a designee position but who have completed training and wish to move into a director position must provide documentation of their training experience that is signed by the director who has performed the training.

Documentation of training and experience should be submitted to AABB's Accreditation and Quality Department prior to assuming responsibility for an AABB-accredited facility.

If the laboratory director candidate has experience that might be considered comparable but was gained in a laboratory that has not been accredited by AABB, or seeks exception to this requirement, they may submit evidence for consideration to the Relationship Testing Accreditation Committee. Such evidence may include items 1-4 above, along with an explanation of how this experience might be considered equivalent to training and experience at an AABB-accredited facility as well as other accreditations. The individual candidate should not take up laboratory director responsibilities until and unless the committee deems the experience equivalent or grants an exception.

Standard 1.1.1 requires that the laboratory director have a doctoral degree, as indicated in the standard. Foreign individuals requesting clarification for equivalency to a doctorate degree from a US school must provide documentation from a member of the National Association of Credentials Evaluation Services (NACES) that the foreign degree is equivalent to the required degree. Current NACES membership may be found at http://www.naces.org/. For the position of laboratory director, equivalency must be shown.

Some laboratories may find it necessary or practical to have multiple persons with the training needed to perform delegable functions of the laboratory director. In some laboratories, a laboratory director designee may provide expertise in a given area (see Standard 1.1.3). This division of responsibility is acceptable. However, it is required that one individual, the laboratory director, has the overall responsibility for the laboratory. If there is a laboratory director and multiple laboratory director designees, their relationship and responsibilities must be clarified in the laboratory's policies and processes.

1.1.1.1.1 In cases where the director candidate's 2 or more years of experience is not in a laboratory accredited by AABB, exceptions shall be evaluated on a case-by-case basis by the Relationship Testing Accreditation Committee. Standard 1.1.6 applies.

Guidance

Evidence of training and experience as described in the guidance for Standard 1.1.1.1 may be submitted to accreditation@aabb.org for evaluation to determine equivalence. For forensic laboratories where the technical leader functions as a relationship testing laboratory director, see Standard 1.1.4.

1.1.2 The laboratory director shall be a part of executive management.

1.1.2.1 The laboratory director shall have responsibility and authority for all policies, processes, and procedures and to stop or suspend laboratory operations.

Guidance

Short tandem repeat (STR) typing is an example of a process. Within the process of STR typing, you would find several procedures, eg, DNA extraction, polymerase chain reaction (PCR) amplification, and electrophoresis.

Accessioning a sample is also an example of a process, which is composed of several procedures such as examination of the sample, review of chain of custody/identification records, and determination of sample acceptability for testing.

While many laboratories 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 6.1.5.

A procedure is a series of tasks that complete one piece of work. When written down, the procedure serves as a set of work instructions. There may be policies that relate to some of the steps in a procedure, for example, the handling of biohazardous waste or the acceptance of samples that do not meet the laboratory's criteria might be policies that are connected with accessioning a sample.

The laboratory director retains ultimate responsibility for the provision of relationship test results and relationship testing services, including decisions on technical matters and staff competence. It is important that the laboratory director has sufficient training in relationship testing to direct a relationship testing laboratory. The laboratory director should be able to demonstrate general training and/or experience and expertise in those methods the laboratory employs for relationship testing (eg, STR, SNP, and NGS methods). As stated above, it is important that the laboratory director be an integral part of the executive management team and that the executive management team functions in such a manner as to facilitate the establishment, review, and implementation of lab policies, processes, and procedures for which the laboratory director is responsible.

1.1.3 Laboratory Director Designee

Any laboratory director designee shall have a doctoral degree in medicine, biology, chemistry, genetics, or clinical laboratory science and shall be qualified by training or experience.

Guidance

The laboratory director may delegate responsibility to another qualified individual; however, the laboratory director is required to retain ultimate responsibility for laboratory director duties. This standard recognizes that laboratories may need to employ individuals who have doctorate degrees to assist in testing and reviewing of case reports, but who lack the qualifications to be a laboratory director. These individuals can be viewed as laboratory directors in training. These individuals may review and sign cases. The laboratory director designee is required to have adequate experience to detect possible errors in test performance or in the interpretation of test results. The laboratory director determines when the designee begins signing cases. In these situations, the laboratory director is responsible for the training and monitoring of the work of these individuals. Documentation of training is required; the laboratory director should provide signed approval that the designee is qualified to perform the delegated task.

See the guidance that accompanies Standard 1.1.1 concerning the roles and responsibilities of the director designee.

1.1.4 Technical Leader Serving as Laboratory Director

For forensic DNA laboratories accredited to the current Federal Bureau of Investigation (FBI) Quality Assurance Standards, the technical leader serving as a laboratory director for relationship testing purposes shall be further qualified by training or experience to serve in the role of laboratory director for the purposes of these *RT Standards*. The technical leader shall have 3 years of training/experience in relationship testing in an AABB-accredited (or equivalent) relationship testing laboratory or under the guidance of a laboratory director currently or previously employed in an accredited laboratory. Participation in proficiency testing shall be part of the training/experience.