



1.2.2.1

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

G u i d a n c e

Standard 1.2.2.1 requires that the relationship testing laboratory director approve and ensure that the laboratory adheres to a written quality manual and operational policies, processes, and procedures.

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

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

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.

Short tandem repeat (STR) typing is an example of a process. Within the process of STR typing you would find several procedures, ie, 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 6.1.4.

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.

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.

1.2.3 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. Standard 1.2.4 applies.

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 1.2 concerning the roles and responsibilities of the director designee.



1.2.4 Technical Leader Serving as Laboratory Director

For forensic DNA laboratories accredited to the current Federal Bureau of Investigation (FBI) quality assurance standards laboratories, the technical leader serving as a laboratory director shall be qualified by education, 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 or experience in relationship testing in an AABB-accredited relationship testing laboratory (or equivalent) 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.

Guidance

A technical leader qualified to the current FBI quality assurance standards (QAS) for Forensic DNA testing laboratories and currently employed in a forensic lab accredited to those standards may serve as the AABB laboratory director in that lab under these *RT Standards*. The FBI QAS educational qualifications for a technical leader include a Master's degree in biology, chemistry, or forensic-science-related area and 12 semesters or equivalent credit hours from a combination of undergraduate and graduate coursework covering biochemistry, genetics, molecular biology, and statistics or population genetics. The minimum experience requirements for a technical leader include three years of forensic DNA laboratory experience obtained at a laboratory where forensic DNA testing was conducted for the identification and evaluation of biological evidence in criminal matters. This is a departure from the long standing requirement in parentage, and clinical laboratories in general, that the laboratory director has a doctorate degree. In addition to meeting the QAS requirements, 3 years of documented training or experience in relationship testing is required for a technical leader to ensure a thorough understanding of relationship testing and these *RT Standards* to serve in this role. The concern here is that forensic laboratories have no substantive standards in this area and anecdotal reports received by the committee of incorrect relationship calculations by forensic laboratories. By allowing forensic laboratories to obtain AABB relationship testing accreditation under their forensic accreditation standard of not having a laboratory director

with a doctoral degree, forensic laboratories are given the opportunity to improve the quality of relationship reports from their laboratories. AABB will monitor the effectiveness of this change.

 **1.3 Laboratory Supervisor Qualifications and Responsibilities**

The laboratory shall have one or more supervisor(s) with responsibility for the day-to-day supervision of laboratory processes and procedures. The laboratory supervisor(s) shall have, at a minimum, a bachelor's degree in biology, chemistry, genetics, clinical laboratory science, or a related field, and at least 2 years of training or experience in relationship testing.

G u i d a n c e

The laboratory is required to have laboratory supervisors who are responsible for the day-to-day activities. In addition, the laboratory supervisors are expected to be on site or accessible to the laboratory during regular hours of operation. Examples of a general supervisor's qualifications may include, but are not limited to:

- BS/BA in biology, chemistry, or related science.
- Two years of experience in a field related to the area he or she supervises.
- Experience in technique, interpretation of test results, and resolving problems in relationship analysis.

Examples of a laboratory supervisor's responsibilities may include:

- Review of identification and sample collection records.
- Review of calculations and preparation of reports.
- Review of interpretation of results.

The laboratory director may also fulfill the role of laboratory supervisor. If a laboratory has multiple laboratory supervisors, their relationship and respective responsibilities should be defined in the laboratory's policies and processes.

 **1.4 Staffing Changes**

The laboratory shall communicate to the AABB all initial appointments or staffing changes for the laboratory director, laboratory director designee(s), laboratory supervisor(s), and/or quality representative within 30 days of appointment.

G u i d a n c e

When changes occur in the managerial structure of the laboratory, the changes must be reported to the AABB National Office. This notification must include a curriculum vitae and documentation of appropriate experience and training. 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 50 cases representative of the testing performed. This notification can be sent to the Accreditation Department at the AABB National Office by mail (4550 Montgomery Avenue, North Tower, Suite 700, Bethesda, MD, 20814), fax (301-657-0957), or email (with attached files) (accreditation@aabb.org). Documentation must be approved by AABB prior to assuming the position. New staff members must meet the requirements of standards 1.2, 1.2.2, or 1.3.

 **1.5 Laboratory Status Changes**

The laboratory shall communicate, in writing, status changes to AABB within 30 days from when the laboratory ceases or resumes on-site testing.